

Subject Case Report Forms

1181 (Prod: Covance Clinical Development Services, Daytona Beach, Florida)

Generated On: 20 Jul 2016 16:51:47

All time stamps listed in this document are displayed in GMT

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Form: Subject

Data signed: (hfarmer1) 27 Mar 2015 14:29:37

Generated On: 20 Jul 2016 16:51:47

Screening number	1181
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Site number	DAY
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Subject Status

Form: Subject Status

Data signed: (hfarmer1) 27 Mar 2015 14:29:43

Generated On: 20 Jul 2016 16:51:47

Date of 'Screen Failed' Event

Date of 'Discontinued From
Enrollment' Event

Randomization Date

28 FEB 2014
DD/MMM/YYYY

Randomization Time

13:56
hour:min 24-hour clock

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Screening

Form: Date of Visit

Data signed: (hfarmer1) 27 Mar 2015 14:29:51

Generated On: 20 Jul 2016 16:51:47

Date of Visit

17 FEB 2014
DD/MMM/YYYY

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Screening

Form: Additional Informed Consent

Data signed: (hfarmer1) 27 Mar 2015 14:29:43

Generated On: 20 Jul 2016 16:51:47

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

No ☒

Consent Date _____

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

No ☒

Consent Date _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Screening

Form: Inclusion Criteria

Data signed: (hfarmer1) 27 Mar 2015 14:29:44

Generated On: 20 Jul 2016 16:51:47

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Screening

Form: Inclusion Criteria (1)

Data signed: (hfarmer1) 27 Mar 2015 14:29:44

Generated On: 20 Jul 2016 16:51:47

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

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: 1181**

Folder: Screening

Form: Inclusion Criteria (2)

Data signed: (hfarmer1) 27 Mar 2015 14:29:44

Generated On: 20 Jul 2016 16:51:47

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"/>
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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: 1181

Folder: Screening

Form: Inclusion Criteria (3)

Data signed: (hfarmer1) 27 Mar 2015 14:29:44

Generated On: 20 Jul 2016 16:51:47

Inclusion Criterion Number

3

Inclusion Criterion

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

Result

Yes

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

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Screening

Form: Inclusion Criteria (4)

Data signed: (hfarmer1) 27 Mar 2015 14:29:44

Generated On: 20 Jul 2016 16:51:47

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: 1181**

Folder: Screening

Form: Inclusion Criteria (5)

Data signed: (hfarmer1) 27 Mar 2015 14:29:44

Generated On: 20 Jul 2016 16:51:47

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: 1181**

Folder: Screening

Form: Inclusion Criteria (6)

Data signed: (hfarmer1) 27 Mar 2015 14:29:44

Generated On: 20 Jul 2016 16:51:47

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: 1181**

Folder: Screening

Form: Exclusion Criteria

Data signed: (hfarmer1) 27 Mar 2015 14:29:43

Generated On: 20 Jul 2016 16:51:47

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Screening

Form: Exclusion Criteria (1)

Data signed: (hfarmer1) 27 Mar 2015 14:29:43

Generated On: 20 Jul 2016 16:51:47

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

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

Result	No
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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: 1181

Folder: Screening

Form: Exclusion Criteria (2)

Data signed: (hfarmer1) 27 Mar 2015 14:29:43

Generated On: 20 Jul 2016 16:51:47

Exclusion Criterion Number	2
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Exclusion Criterion	A subject who is legally incompetent, physically or mentally incapable of giving consent (e.g., emergency situation, under guardianship, subject in a social or sanitary establishment, prisoners or subjects who are involuntarily incarcerated).
---------------------	--

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: 1181

Folder: Screening

Form: Exclusion Criteria (3)

Data signed: (hfarmer1) 27 Mar 2015 14:29:43

Generated On: 20 Jul 2016 16:51:47

Exclusion Criterion Number

3

Exclusion Criterion

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

Result

No

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

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Screening

Form: Exclusion Criteria (4)

Data signed: (hfarmer1) 27 Mar 2015 14:29:43

Generated On: 20 Jul 2016 16:51:47

Exclusion Criterion Number	4
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Exclusion Criterion	Subject who has forced expiratory volume in 1 second/forced vital capacity (FEV1/FVC) <0.7 and FEV1 <80% predicted value at postbronchodilator spirometry (GOLD, 2013).
---------------------	---

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: 1181**

Folder: Screening

Form: Exclusion Criteria (5)

Data signed: (hfarmer1) 27 Mar 2015 14:29:43

Generated On: 20 Jul 2016 16:51:47

Exclusion Criterion Number	5
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Exclusion Criterion	Subject with asthma condition (FEV1/FVC < 0.75 and reversibility in FEV1 > 12% (or > 200 mL) from pre to post-bronchodilator values).
---------------------	---

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: 1181

Folder: Screening

Form: Exclusion Criteria (6)

Data signed: (hfarmer1) 27 Mar 2015 14:29:43

Generated On: 20 Jul 2016 16:51:47

Exclusion Criterion Number	6
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Exclusion Criterion	Subjects with renal insufficiency as defined by serum creatinine levels of >1.3 mg/dL for females and >1.5 mg/dL for males.
---------------------	---

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: 1181**

Folder: Screening

Form: Exclusion Criteria (7)

Data signed: (hfarmer1) 27 Mar 2015 14:29:43

Generated On: 20 Jul 2016 16:51:47

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

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: 1181

Folder: Screening

Form: Exclusion Criteria (8)

Data signed: (hfarmer1) 27 Mar 2015 14:29:43

Generated On: 20 Jul 2016 16:51:47

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

Exclusion Criterion	As per Investigator judgment, the subject has medical conditions which require or will require in the course of the study, a medical intervention (e.g., start of treatment, surgery, hospitalization) which may interfere with the study participation and/or study results.
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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: 1181**

Folder: Screening

Form: Exclusion Criteria (9)

Data signed: (hfarmer1) 27 Mar 2015 14:29:43

Generated On: 20 Jul 2016 16:51:47

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: 1181

Folder: Screening

Form: Exclusion Criteria (10)

Data signed: (hfarmer1) 27 Mar 2015 14:29:43

Generated On: 20 Jul 2016 16:51:47

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Screening

Form: Exclusion Criteria (11)

Data signed: (hfarmer1) 27 Mar 2015 14:29:43

Generated On: 20 Jul 2016 16:51:47

Exclusion Criterion Number	12
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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>
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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: 1181**

Folder: Screening

Form: Exclusion Criteria (12)

Data signed: (hfarmer1) 27 Mar 2015 14:29:43

Generated On: 20 Jul 2016 16:51:47

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: 1181

Folder: Screening

Form: Exclusion Criteria (13)

Data signed: (hfarmer1) 27 Mar 2015 14:29:43

Generated On: 20 Jul 2016 16:51:47

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: 1181**

Folder: Screening

Form: Exclusion Criteria (14)

Data signed: (hfarmer1) 27 Mar 2015 14:29:43

Generated On: 20 Jul 2016 16:51:47

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: 1181**

Folder: Screening

Form: Exclusion Criteria (15)

Data signed: (hfarmer1) 27 Mar 2015 14:29:43

Generated On: 20 Jul 2016 16:51:47

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

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: 1181**

Folder: Screening

Form: Exclusion Criteria (16)

Data signed: (hfarmer1) 27 Mar 2015 14:29:43

Generated On: 20 Jul 2016 16:51:47

Exclusion Criterion Number	17
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Exclusion Criterion	Donation or receipt of whole blood or blood products within 3 months prior to Admission.	<input checked="" type="radio"/>
---------------------	--	----------------------------------

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: 1181**

Folder: Screening

Form: Exclusion Criteria (17)

Data signed: (hfarmer1) 27 Mar 2015 14:29:43

Generated On: 20 Jul 2016 16:51:47

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

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

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

*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: 1181**

Folder: Screening

Form: Exclusion Criteria (18)

Data signed: (hfarmer1) 27 Mar 2015 14:29:43

Generated On: 20 Jul 2016 16:51:47

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

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

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

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Screening

Form: Exclusion Criteria (19)

Data signed: (hfarmer1) 27 Mar 2015 14:29:43

Generated On: 20 Jul 2016 16:51:47

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

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

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

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Screening

Form: Exclusion Criteria (20)

Data signed: (hfarmer1) 27 Mar 2015 14:29:43

Generated On: 20 Jul 2016 16:51:47

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

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: 1181**

Folder: Screening

Form: Exclusion Criteria (21)

Data signed: (hfarmer1) 27 Mar 2015 14:29:43

Generated On: 20 Jul 2016 16:51:47

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

Exclusion Criterion	For women only : Subject does not agree to use an acceptable method of effective contraception	<input type="radio"/>
---------------------	---	-----------------------

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

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Screening

Form: Demographics

Data signed: (hfarmer1) 27 Mar 2015 14:29:43

Generated On: 20 Jul 2016 16:51:47

Date of Birth

(b) (6)

Sex

Male ☒

Race

White ☒

Other, specify _____

Ethnicity

Not Hispanic ☒

Date the Subject signed the Informed Consent

17 FEB 2014
DD/MMM/YYYY

Time the Subject signed the Informed Consent

10:17
hour:min 24-hour clock

Age(Derived)

24

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Screening

Form: Medical History/Concomitant Disease

Data signed: (hfarmer1) 27 Mar 2015 14:29:45

Generated On: 20 Jul 2016 16:51:47

Date of collection

17 FEB 2014
DD/MMM/YYYY

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

Yes ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Screening

Form: Medical History/Concomitant Disease (1)

Data signed: (hfarmer1) 27 Mar 2015 14:29:45

Generated On: 20 Jul 2016 16:51:47

Date of collection	17 FEB 2014 DD/MMM/YYYY
--------------------	----------------------------

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

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

Diagnosis Description	SEASONAL ALLERGIES
-----------------------	--------------------

Onset Date DD/MMM/YYYY	UN UNK 2008
---------------------------	-------------

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

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Screening

Form: Medical History/Concomitant Disease (2)

Data signed: (hfarmer1) 27 Mar 2015 14:29:45

Generated On: 20 Jul 2016 16:51:47

Date of collection	17 FEB 2014 DD/MMM/YYYY
--------------------	----------------------------

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

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

Diagnosis Description	NEARSIGHTED, WEARS CONTACTS BILATERALLY
-----------------------	--

Onset Date DD/MMM/YYYY	UN UNK 1992
---------------------------	-------------

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

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Screening

Form: Vital Signs<Screening/<

Data signed: (hfarmer1) 27 Mar 2015 14:29:51

Generated On: 20 Jul 2016 16:51:47

Were Vitals Signs assessed?

Yes ☒

If No, please specify the reason: _____

Has the subject smoked within 15 minutes prior to
assessment

No ☒

Date of assessment

17 FEB 2014
DD/MMM/YYYY

Time of assessment

11:11
hour:min 24-hour clock

Pulse rate

65
beats per minute

Respiratory rate

14
breaths per minute

Blood Pressure (systolic)

136
mmHg

Blood Pressure (diastolic)

91
mmHg

Vital Signs Position of Subject

Supine ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Screening

Form: Physical Examination

Data signed: (hfarmer1) 27 Mar 2015 14:29:45

Generated On: 20 Jul 2016 16:51:47

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

17 FEB 2014
DD/MMM/YYYY

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Screening

Form: Physical Examination (1)

Data signed: (hfarmer1) 27 Mar 2015 14:29:45

Generated On: 20 Jul 2016 16:51:47

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of assessment 17 FEB 2014
DD/MMM/YYYY

System General Appearance ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Screening

Form: Physical Examination (2)

Data signed: (hfarmer1) 27 Mar 2015 14:29:45

Generated On: 20 Jul 2016 16:51:47

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

17 FEB 2014
DD/MMM/YYYY

System

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

Outcome

Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done

False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Screening

Form: Physical Examination (3)

Data signed: (hfarmer1) 27 Mar 2015 14:29:45

Generated On: 20 Jul 2016 16:51:47

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of assessment 17 FEB 2014
DD/MMM/YYYY

System Thyroid Gland ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Screening

Form: Physical Examination (4)

Data signed: (hfarmer1) 27 Mar 2015 14:29:45

Generated On: 20 Jul 2016 16:51:47

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of assessment 17 FEB 2014
DD/MMM/YYYY

System Heart ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Screening

Form: Physical Examination (5)

Data signed: (hfarmer1) 27 Mar 2015 14:29:45

Generated On: 20 Jul 2016 16:51:47

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of assessment 17 FEB 2014
DD/MMM/YYYY

System Chest ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Screening

Form: Physical Examination (6)

Data signed: (hfarmer1) 27 Mar 2015 14:29:45

Generated On: 20 Jul 2016 16:51:47

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of assessment 17 FEB 2014
DD/MMM/YYYY

System Lungs ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Screening

Form: Physical Examination (7)

Data signed: (hfarmer1) 27 Mar 2015 14:29:45

Generated On: 20 Jul 2016 16:51:47

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of assessment 17 FEB 2014
DD/MMM/YYYY

System Gastrointestinal ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Screening

Form: Physical Examination (8)

Data signed: (hfarmer1) 27 Mar 2015 14:29:45

Generated On: 20 Jul 2016 16:51:47

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of assessment 17 FEB 2014
DD/MMM/YYYY

System Cardiovascular System ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Screening

Form: Physical Examination (9)

Data signed: (hfarmer1) 27 Mar 2015 14:29:45

Generated On: 20 Jul 2016 16:51:47

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of assessment 17 FEB 2014
DD/MMM/YYYY

System Neurologic ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Screening

Form: Physical Examination (10)

Data signed: (hfarmer1) 27 Mar 2015 14:29:45

Generated On: 20 Jul 2016 16:51:47

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of assessment 17 FEB 2014
DD/MMM/YYYY

System Skin ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Screening

Form: Physical Examination (11)

Data signed: (hfarmer1) 27 Mar 2015 14:29:45

Generated On: 20 Jul 2016 16:51:47

Was the physical examination performed? Yes ☐

If No, please specify the reason: _____

Date of assessment 17 FEB 2014
DD/MMM/YYYY

System Back ☐

Outcome Normal ☐

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Screening

Form: Physical Examination (12)

Data signed: (hfarmer1) 27 Mar 2015 14:29:45

Generated On: 20 Jul 2016 16:51:47

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of assessment 17 FEB 2014
DD/MMM/YYYY

System Musculoskeletal ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Screening

Form: Physical Examination (13)

Data signed: (hfarmer1) 27 Mar 2015 14:29:45

Generated On: 20 Jul 2016 16:51:47

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of assessment 17 FEB 2014
DD/MMM/YYYY

System Abdomen ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Screening

Form: Physical Examination (14)

Data signed: (hfarmer1) 27 Mar 2015 14:29:45

Generated On: 20 Jul 2016 16:51:47

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of assessment 17 FEB 2014
DD/MMM/YYYY

System Dentition ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Screening

Form: Physical Examination (15)

Data signed: (hfarmer1) 27 Mar 2015 14:29:45

Generated On: 20 Jul 2016 16:51:47

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

17 FEB 2014
DD/MMM/YYYY

System

Other ☒

Other, Specify _____

Outcome _____

Abnormal, please specify _____

Clinically significant _____

Not Done

True

Not Done; please specify the reason: _____

NOT EXAMINED

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Screening

Form: Physical Examination (16)

Data signed: (hfarmer1) 27 Mar 2015 14:29:45

Generated On: 20 Jul 2016 16:51:47

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

17 FEB 2014
DD/MMM/YYYY

System

Other ☒

Other, Specify _____

Outcome _____

Abnormal, please specify _____

Clinically significant _____

Not Done

True

Not Done; please specify the reason: _____

NOT EXAMINED

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Screening

Form: Physical Examination (17)

Data signed: (hfarmer1) 27 Mar 2015 14:29:45

Generated On: 20 Jul 2016 16:51:47

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

17 FEB 2014
DD/MMM/YYYY

System

Other ☒

Other, Specify _____

Outcome _____

Abnormal, please specify _____

Clinically significant _____

Not Done

True

Not Done; please specify the reason: _____

NOT EXAMINED

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Screening

Form: Physical Examination (18)

Data signed: (hfarmer1) 27 Mar 2015 14:29:45

Generated On: 20 Jul 2016 16:51:47

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

17 FEB 2014
DD/MMM/YYYY

System

Other ☒

Other, Specify _____

Outcome _____

Abnormal, please specify _____

Clinically significant _____

Not Done

True

Not Done; please specify the reason: _____

NOT EXAMINED

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Screening

Form: Physical Examination (19)

Data signed: (hfarmer1) 27 Mar 2015 14:29:45

Generated On: 20 Jul 2016 16:51:47

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

17 FEB 2014
DD/MMM/YYYY

System

Other ☒

Other, Specify _____

Outcome _____

Abnormal, please specify _____

Clinically significant _____

Not Done

True

Not Done; please specify the reason: _____

NOT EXAMINED

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Screening

Form: Advice on the risk of smoking and debriefing

Data signed: (hfarmer1) 27 Mar 2015 14:29:51

Generated On: 20 Jul 2016 16:51:47

Has the subject received advices on the risks of
smoking?

Yes ☒

Has a debriefing been performed about THS 2.2?

Yes ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Screening

Form: Identification of Current Cigarette Brand

Data signed: (hcoleman1) 18 Jun 2015 21:06:54

Generated On: 20 Jul 2016 16:51:47

Date

17 FEB 2014
DD/MMM/YYYY

Brand name

MARLBORO RICH BLUE
MENTHOL

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Screening

Form: THS 2.2 menthol product demonstration

Data signed: (hfarmer1) 27 Mar 2015 14:29:51

Generated On: 20 Jul 2016 16:51:47

Has the subject seen a THS 2.2 menthol product
demonstration?

Yes ☒

If the subject did not see the demonstration please
explain

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Screening

Form: Smoking History

Data signed: (hfarmer1) 27 Mar 2015 14:29:51

Generated On: 20 Jul 2016 16:51:47

Date of Assessment

17 FEB 2014
DD/MMM/YYYY

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

No ☐

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

Yes ☐

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

10 to 19 ☐

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

Yes ☐

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

No ☐

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Screening

Form: Weight and Height

Data signed: (hfarmer1) 27 Mar 2015 14:29:51

Generated On: 20 Jul 2016 16:51:47

Measurement(s) assessed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

17 FEB 2014
DD/MMM/YYYY

Weight

61.6
kg

Height

161.0
cm

BMI (Derived)

23.8
kg/m2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Screening

Form: ECG (12-Lead Standard)

Data signed: (hfarmer1) 27 Mar 2015 14:29:43

Generated On: 20 Jul 2016 16:51:47

Was the ECG performed? Yes ☒

If No, please specify the reason: _____

Date of assessment: 17 FEB 2014
DD/MMM/YYYY

Position Supine ☒

Heart Rate 65
beats per minute

QRS Interval 109
msec

QT Interval 417
msec

QTcB Interval 435
msec

QTcF Interval 429
msec

PR Interval 134
msec

Interpretation Normal ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Screening

Form: ECG (12-Lead Standard)

Data signed: (hfarmer1) 27 Mar 2015 14:29:43

Generated On: 20 Jul 2016 16:51:47

If Abnormal, Clinical Significance _____

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Screening

Form: Spirometry (1)

Data signed: (hfarmer1) 27 Mar 2015 14:29:48

Generated On: 20 Jul 2016 16:51:47

Was the spirometry performed? Yes ☒

If No, please specify the reason: _____

Category Without short-acting ☒
bronchodilator

Position SITTING

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

Date of assessment 17 FEB 2014
DD/MMM/YYYY

Time of assessment 11:53

Predicted FVC value 4.50
L

Best measured FVC value 4.39
L

Percent of predicted FVC value 98
%

Best measured FEV1 value 3.38
L

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Screening

Form: Spirometry (1)

Data signed: (hfarmer1) 27 Mar 2015 14:29:48

Generated On: 20 Jul 2016 16:51:47

Predicted FEV1 value	3.80 L
----------------------	-----------

Percent of predicted FEV1 value	89 %
---------------------------------	---------

Calculated ratio between FEV1/FVC	0.77
-----------------------------------	------

MEF 25/75 value	2.85 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: 1181**

Folder: Screening

Form: Spirometry (2)

Data signed: (hfarmer1) 27 Mar 2015 14:29:48

Generated On: 20 Jul 2016 16:51:47

Was the spirometry performed? Yes ☒

If No, please specify the reason: _____

Category With short-acting ☒
bronchodilator

Position SITTING

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

Date of assessment 17 FEB 2014
DD/MMM/YYYY

Time of assessment 12:22

Name of bronchodilator ALBUTEROL SULFATE

Dose 180 MCG

Predicted FVC value 4.50
L

Best measured FVC value 4.46
L

Percent of predicted FVC value 99
%

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Screening

Form: Spirometry (2)

Data signed: (hfarmer1) 27 Mar 2015 14:29:48

Generated On: 20 Jul 2016 16:51:47

Best measured FEV1 value	3.64 L
Predicted FEV1 value	3.80 L
Percent of predicted FEV1 value	96 %
Calculated ratio between FEV1/FVC	0.82
MEF 25/75 value	3.48 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: 1181**

Folder: Screening

Form: Chest X-Ray

Data signed: (hfarmer1) 27 Mar 2015 14:29:51

Generated On: 20 Jul 2016 16:51:47

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

Yes ☒

If No, please specify the reason: _____

Date of assessment

24 FEB 2014
DD/MMM/YYYY

System

Chest ☒

Interpretation

Normal ☒

Clinically significant _____

Abnormal, please specify: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Screening

Form: Haematology

Data signed: (hfarmer1) 27 Mar 2015 14:29:44

Generated On: 20 Jul 2016 16:51:47

Were samples collected?

Yes ☒

If No, please specify the reason: _____

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

Yes ☒

Please document clinically relevant abnormalities in the AE form

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Screening

Form: Clinical Chemistry

Data signed: (hfarmer1) 27 Mar 2015 14:29:44

Generated On: 20 Jul 2016 16:51:47

Were samples collected?

Yes ☒

If No, please specify the reason: _____

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

Yes ☒

Please document clinically relevant abnormalities in the AE form

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Screening

Form: Urine analysis

Data signed: (hfarmer1) 27 Mar 2015 14:29:44

Generated On: 20 Jul 2016 16:51:47

Were samples collected?

Yes ☒

If No, please specify the reason: _____

Please document clinically relevant abnormalities in the AE form

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Screening

Form: Serology for HIV and Hepatitis B and C

Data signed: (hfarmer1) 27 Mar 2015 14:29:44

Generated On: 20 Jul 2016 16:51:47

Category

Serology ☒

Not Done

False

If Not Done, please specify the reason:

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Screening

Form: Urine Drug Screen

Data signed: (hfarmer1) 27 Mar 2015 14:29:44

Generated On: 20 Jul 2016 16:51:47

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

If Not Done, please specify the reason: _____

Date of sample collection	17 FEB 2014 DD/MMM/YYYY
---------------------------	----------------------------

Time of sample collection	10:58 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: 1181

Folder: Screening

Form: Urine Drug Screen (4)

Data signed: (hfarmer1) 27 Mar 2015 14:29:44

Generated On: 20 Jul 2016 16:51:47

Drug type	Result
Cannabinoids	Negative
Cocaine	Negative
Opiates	Negative

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Screening

Form: Alcohol Test

Data signed: (hfarmer1) 27 Mar 2015 14:29:44

Generated On: 20 Jul 2016 16:51:47

Was the alcohol test performed? Yes ☒

If No, please specify the reason: _____

Method used Breath test ☒

Date of assessment 17 FEB 2014
DD/MMM/YYYY

Time of assessment 11:02
hour:min 24-hour clock

Result Negative ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Screening

Form: Urine Cotinine Test

Data signed: (hfarmer1) 27 Mar 2015 14:29:44

Generated On: 20 Jul 2016 16:51:47

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

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

If Not Done, please specify the reason: _____

Date of Sample Collection	25 FEB 2014 DD/MMM/YYYY
---------------------------	----------------------------

Time of Sample Collection	10:04 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: 1181**

Folder: Screening

Form: Lab-BU-LabCorp CHEMISTRY(17 FEB 2014)

Data signed: (hfarmer1) 27 Mar 2015 14:29:51

Generated On: 20 Jul 2016 16:51:47

Experiment Type

CHEMISTRY

Date of Sample Collection
YYYY/MM/DD

17 FEB 2014

Please document clinically relevant abnormalities in the AE form

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Screening

Form: Lab-BU-LabCorp CHEMISTRY(17 FEB 2014)

Data signed: (hfarmer1) 27 Mar 2015 14:29:51

Generated On: 20 Jul 2016 16:51:47

Experiment Type	CHEMISTRY
Date of Sample Collection YYYY/MM/DD	17 FEB 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Male <input checked="" type="radio"/>
Time of Sample Collection	11:40
Analyte Name	GLUCOSE, SERUM
Code	001032
Result	86
Unit	MG/DL
Lower limit	65
Upper limit	99
Flag	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Screening

Form: Lab-BU-LabCorp CHEMISTRY(17 FEB 2014)

Data signed: (hfarmer1) 27 Mar 2015 14:29:51

Generated On: 20 Jul 2016 16:51:47

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

04857100030

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Screening

Form: Lab-BU-LabCorp (2)

Data signed: (hfarmer1) 27 Mar 2015 14:29:51

Generated On: 20 Jul 2016 16:51:47

Experiment Type

CHEMISTRY

Date of Sample Collection
YYYY/MM/DD

17 FEB 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male ☒

Time of Sample Collection

11:40

Analyte Name

BUN

Code

001040

Result

10

Unit

MG/DL

Lower limit

6

Upper limit

20

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Screening

Form: Lab-BU-LabCorp (2)

Data signed: (hfarmer1) 27 Mar 2015 14:29:51

Generated On: 20 Jul 2016 16:51:47

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

04857100030

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Screening

Form: Lab-BU-LabCorp (3)

Data signed: (hfarmer1) 27 Mar 2015 14:29:51

Generated On: 20 Jul 2016 16:51:47

Experiment Type

CHEMISTRY

Date of Sample Collection
YYYY/MM/DD

17 FEB 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male ☒

Time of Sample Collection

11:40

Analyte Name

CHOLESTEROL, TOTAL

Code

001065

Result

185

Unit

MG/DL

Lower limit

100

Upper limit

189

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Screening

Form: Lab-BU-LabCorp (3)

Data signed: (hfarmer1) 27 Mar 2015 14:29:51

Generated On: 20 Jul 2016 16:51:47

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

04857100030

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Screening

Form: Lab-BU-LabCorp (4)

Data signed: (hfarmer1) 27 Mar 2015 14:29:51

Generated On: 20 Jul 2016 16:51:47

Experiment Type

CHEMISTRY

Date of Sample Collection
YYYY/MM/DD

17 FEB 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male ☒

Time of Sample Collection

11:40

Analyte Name

PROTEIN, TOTAL, SERUM

Code

001073

Result

7.5

Unit

G/DL

Lower limit

6.0

Upper limit

8.5

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Screening

Form: Lab-BU-LabCorp (4)

Data signed: (hfarmer1) 27 Mar 2015 14:29:51

Generated On: 20 Jul 2016 16:51:47

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

04857100030

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Screening

Form: Lab-BU-LabCorp (5)

Data signed: (hfarmer1) 27 Mar 2015 14:29:51

Generated On: 20 Jul 2016 16:51:47

Experiment Type

CHEMISTRY

Date of Sample Collection
YYYY/MM/DD

17 FEB 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male ☒

Time of Sample Collection

11:40

Analyte Name

ALBUMIN, SERUM

Code

001081

Result

5.0

Unit

G/DL

Lower limit

3.5

Upper limit

5.5

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Screening

Form: Lab-BU-LabCorp (5)

Data signed: (hfarmer1) 27 Mar 2015 14:29:51

Generated On: 20 Jul 2016 16:51:47

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

04857100030

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Screening

Form: Lab-BU-LabCorp (6)

Data signed: (hfarmer1) 27 Mar 2015 14:29:51

Generated On: 20 Jul 2016 16:51:47

Experiment Type	CHEMISTRY
Date of Sample Collection YYYY/MM/DD	17 FEB 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Male <input checked="" type="radio"/>
Time of Sample Collection	11:40
Analyte Name	BILIRUBIN, TOTAL
Code	001099
Result	0.6
Unit	MG/DL
Lower limit	0.0
Upper limit	1.2
Flag	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Screening

Form: Lab-BU-LabCorp (6)

Data signed: (hfarmer1) 27 Mar 2015 14:29:51

Generated On: 20 Jul 2016 16:51:47

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

04857100030

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Screening

Form: Lab-BU-LabCorp (7)

Data signed: (hfarmer1) 27 Mar 2015 14:29:51

Generated On: 20 Jul 2016 16:51:47

Experiment Type

CHEMISTRY

Date of Sample Collection
YYYY/MM/DD

17 FEB 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male ☒

Time of Sample Collection

11:40

Analyte Name

ALKALINE PHOSPHATASE, S

Code

001107

Result

47

Unit

IU/L

Lower limit

39

Upper limit

117

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Screening

Form: Lab-BU-LabCorp (7)

Data signed: (hfarmer1) 27 Mar 2015 14:29:51

Generated On: 20 Jul 2016 16:51:47

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

04857100030

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Screening

Form: Lab-BU-LabCorp (8)

Data signed: (hfarmer1) 27 Mar 2015 14:29:51

Generated On: 20 Jul 2016 16:51:47

Experiment Type	CHEMISTRY
Date of Sample Collection YYYY/MM/DD	17 FEB 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Male <input checked="" type="radio"/>
Time of Sample Collection	11:40
Analyte Name	LDH
Code	001115
Result	151
Unit	IU/L
Lower limit	0
Upper limit	225
Flag	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Screening

Form: Lab-BU-LabCorp (8)

Data signed: (hfarmer1) 27 Mar 2015 14:29:51

Generated On: 20 Jul 2016 16:51:47

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

04857100030

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Screening

Form: Lab-BU-LabCorp (9)

Data signed: (hfarmer1) 27 Mar 2015 14:29:51

Generated On: 20 Jul 2016 16:51:47

Experiment Type

CHEMISTRY

Date of Sample Collection
YYYY/MM/DD

17 FEB 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male ☒

Time of Sample Collection

11:40

Analyte Name

AST (SGOT)

Code

001123

Result

18

Unit

IU/L

Lower limit

0

Upper limit

40

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Screening

Form: Lab-BU-LabCorp (9)

Data signed: (hfarmer1) 27 Mar 2015 14:29:51

Generated On: 20 Jul 2016 16:51:47

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

04857100030

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Screening

Form: Lab-BU-LabCorp (10)

Data signed: (hfarmer1) 27 Mar 2015 14:29:51

Generated On: 20 Jul 2016 16:51:47

Experiment Type	CHEMISTRY
Date of Sample Collection YYYY/MM/DD	17 FEB 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Male <input checked="" type="radio"/>
Time of Sample Collection	11:40
Analyte Name	TRIGLYCERIDES
Code	001172
Result	87
Unit	MG/DL
Lower limit	0
Upper limit	114
Flag	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Screening

Form: Lab-BU-LabCorp (10)

Data signed: (hfarmer1) 27 Mar 2015 14:29:51

Generated On: 20 Jul 2016 16:51:47

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

04857100030

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Screening

Form: Lab-BU-LabCorp (11)

Data signed: (hfarmer1) 27 Mar 2015 14:29:51

Generated On: 20 Jul 2016 16:51:47

Experiment Type

CHEMISTRY

Date of Sample Collection
YYYY/MM/DD

17 FEB 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male ☒

Time of Sample Collection

11:40

Analyte Name

POTASSIUM, SERUM

Code

001180

Result

3.9

Unit

MMOL/L

Lower limit

3.5

Upper limit

5.2

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Screening

Form: Lab-BU-LabCorp (11)

Data signed: (hfarmer1) 27 Mar 2015 14:29:51

Generated On: 20 Jul 2016 16:51:47

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

04857100030

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Screening

Form: Lab-BU-LabCorp (12)

Data signed: (hfarmer1) 27 Mar 2015 14:29:51

Generated On: 20 Jul 2016 16:51:47

Experiment Type

CHEMISTRY

Date of Sample Collection
YYYY/MM/DD

17 FEB 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male ☒

Time of Sample Collection

11:40

Analyte Name

SODIUM, SERUM

Code

001198

Result

137

Unit

MMOL/L

Lower limit

134

Upper limit

144

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Screening

Form: Lab-BU-LabCorp (12)

Data signed: (hfarmer1) 27 Mar 2015 14:29:51

Generated On: 20 Jul 2016 16:51:47

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

04857100030

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Screening

Form: Lab-BU-LabCorp (13)

Data signed: (hfarmer1) 27 Mar 2015 14:29:51

Generated On: 20 Jul 2016 16:51:47

Experiment Type	CHEMISTRY
Date of Sample Collection YYYY/MM/DD	17 FEB 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Male <input checked="" type="radio"/>
Time of Sample Collection	11:40
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: 1181**

Folder: Screening

Form: Lab-BU-LabCorp (13)

Data signed: (hfarmer1) 27 Mar 2015 14:29:51

Generated On: 20 Jul 2016 16:51:47

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

04857100030

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Screening

Form: Lab-BU-LabCorp (14)

Data signed: (hfarmer1) 27 Mar 2015 14:29:51

Generated On: 20 Jul 2016 16:51:47

Experiment Type	CHEMISTRY
Date of Sample Collection YYYY/MM/DD	17 FEB 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Male <input checked="" type="radio"/>
Time of Sample Collection	11:40
Analyte Name	CREATININE, SERUM
Code	001370
Result	0.74
Unit	MG/DL
Lower limit	0.76
Upper limit	1.27
Flag	Low <input checked="" type="radio"/>

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Screening

Form: Lab-BU-LabCorp (14)

Data signed: (hfarmer1) 27 Mar 2015 14:29:51

Generated On: 20 Jul 2016 16:51:47

Clinically Significant?

No ☒

Comment

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

04857100030

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Screening

Form: Lab-BU-LabCorp (15)

Data signed: (hfarmer1) 27 Mar 2015 14:29:51

Generated On: 20 Jul 2016 16:51:47

Experiment Type	CHEMISTRY
Date of Sample Collection YYYY/MM/DD	17 FEB 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Male <input checked="" type="radio"/>
Time of Sample Collection	11:40
Analyte Name	ALT (SGPT)
Code	001545
Result	12
Unit	IU/L
Lower limit	0
Upper limit	44
Flag	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Screening

Form: Lab-BU-LabCorp (15)

Data signed: (hfarmer1) 27 Mar 2015 14:29:51

Generated On: 20 Jul 2016 16:51:47

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

04857100030

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Screening

Form: Lab-BU-LabCorp (16)

Data signed: (hfarmer1) 27 Mar 2015 14:29:51

Generated On: 20 Jul 2016 16:51:47

Experiment Type

CHEMISTRY

Date of Sample Collection
YYYY/MM/DD

17 FEB 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male ☒

Time of Sample Collection

11:40

Analyte Name

GGT

Code

001958

Result

9

Unit

IU/L

Lower limit

0

Upper limit

65

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Screening

Form: Lab-BU-LabCorp (16)

Data signed: (hfarmer1) 27 Mar 2015 14:29:51

Generated On: 20 Jul 2016 16:51:47

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

04857100030

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Screening

Form: Lab-BU-LabCorp (17)

Data signed: (hfarmer1) 27 Mar 2015 14:29:51

Generated On: 20 Jul 2016 16:51:47

Experiment Type

CHEMISTRY

Date of Sample Collection
YYYY/MM/DD

17 FEB 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male ☒

Time of Sample Collection

11:40

Analyte Name

HEP C VIRUS AB

Code

140683

Result

0.2

Unit

S/CO RATIO

Lower limit

0.0

Upper limit

0.9

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Screening

Form: Lab-BU-LabCorp (17)

Data signed: (hfarmer1) 27 Mar 2015 14:29:51

Generated On: 20 Jul 2016 16:51:47

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

04857100030

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Screening

Form: Lab-BU-LabCorp SEROLOGY(17 FEB 2014)

Data signed: (hfarmer1) 27 Mar 2015 14:29:53

Generated On: 20 Jul 2016 16:51:47

Experiment Type

SEROLOGY

Date of Sample Collection
YYYY/MM/DD

17 FEB 2014

Please document clinically relevant abnormalities in the AE form

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Screening

Form: Lab-BU-LabCorp SEROLOGY(17 FEB 2014)

Data signed: (hfarmer1) 27 Mar 2015 14:29:53

Generated On: 20 Jul 2016 16:51:47

Experiment Type

SEROLOGY

Date of Sample Collection
YYYY/MM/DD

17 FEB 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male ☒

Time of Sample Collection

11:40

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: 1181**

Folder: Screening

Form: Lab-BU-LabCorp SEROLOGY(17 FEB 2014)

Data signed: (hfarmer1) 27 Mar 2015 14:29:53

Generated On: 20 Jul 2016 16:51:47

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

04857100030

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Screening

Form: Lab-BU-LabCorp (2)

Data signed: (hfarmer1) 27 Mar 2015 14:29:53

Generated On: 20 Jul 2016 16:51:47

Experiment Type

SEROLOGY

Date of Sample Collection
YYYY/MM/DD

17 FEB 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male ☒

Time of Sample Collection

11:40

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: 1181**

Folder: Screening

Form: Lab-BU-LabCorp (2)

Data signed: (hfarmer1) 27 Mar 2015 14:29:53

Generated On: 20 Jul 2016 16:51:47

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

04857100030

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Screening

Form: Lab-BU-LabCorp (3)

Data signed: (hfarmer1) 27 Mar 2015 14:29:53

Generated On: 20 Jul 2016 16:51:47

Experiment Type

SEROLOGY

Date of Sample Collection
YYYY/MM/DD

17 FEB 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male ☒

Time of Sample Collection

11:40

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: 1181**

Folder: Screening

Form: Lab-BU-LabCorp (3)

Data signed: (hfarmer1) 27 Mar 2015 14:29:53

Generated On: 20 Jul 2016 16:51:47

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

04857100030

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Screening

Form: Lab-BU-LabCorp HEMATOLOGY(17 FEB 2014)

Data signed: (hfarmer1) 27 Mar 2015 14:29:54

Generated On: 20 Jul 2016 16:51:47

Experiment Type

HEMATOLOGY

Date of Sample Collection
YYYY/MM/DD

17 FEB 2014

Please document clinically relevant abnormalities in the AE form

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Screening

Form: Lab-BU-LabCorp HEMATOLOGY(17 FEB 2014)

Data signed: (hfarmer1) 27 Mar 2015 14:29:54

Generated On: 20 Jul 2016 16:51:47

Experiment Type	HEMATOLOGY
Date of Sample Collection YYYY/MM/DD	17 FEB 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Male <input checked="" type="radio"/>
Time of Sample Collection	11:40
Analyte Name	WBC
Code	005025
Result	5.2
Unit	X10E3/UL
Lower limit	3.4
Upper limit	10.8
Flag	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Screening

Form: Lab-BU-LabCorp HEMATOLOGY(17 FEB 2014)

Data signed: (hfarmer1) 27 Mar 2015 14:29:54

Generated On: 20 Jul 2016 16:51:47

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

04857100030

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Screening

Form: Lab-BU-LabCorp (2)

Data signed: (hfarmer1) 27 Mar 2015 14:29:54

Generated On: 20 Jul 2016 16:51:47

Experiment Type	HEMATOLOGY
Date of Sample Collection YYYY/MM/DD	17 FEB 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Male <input checked="" type="radio"/>
Time of Sample Collection	11:40
Analyte Name	RBC
Code	005033
Result	5.25
Unit	X10E6/UL
Lower limit	4.14
Upper limit	5.80
Flag	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Screening

Form: Lab-BU-LabCorp (2)

Data signed: (hfarmer1) 27 Mar 2015 14:29:54

Generated On: 20 Jul 2016 16:51:47

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

04857100030

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Screening

Form: Lab-BU-LabCorp (3)

Data signed: (hfarmer1) 27 Mar 2015 14:29:54

Generated On: 20 Jul 2016 16:51:47

Experiment Type

HEMATOLOGY

Date of Sample Collection
YYYY/MM/DD

17 FEB 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male ☒

Time of Sample Collection

11:40

Analyte Name

HEMOGLOBIN

Code

005041

Result

15.3

Unit

G/DL

Lower limit

12.6

Upper limit

17.7

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Screening

Form: Lab-BU-LabCorp (3)

Data signed: (hfarmer1) 27 Mar 2015 14:29:54

Generated On: 20 Jul 2016 16:51:47

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

04857100030

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Screening

Form: Lab-BU-LabCorp (4)

Data signed: (hfarmer1) 27 Mar 2015 14:29:54

Generated On: 20 Jul 2016 16:51:47

Experiment Type

HEMATOLOGY

Date of Sample Collection
YYYY/MM/DD

17 FEB 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male ☒

Time of Sample Collection

11:40

Analyte Name

HEMATOCRIT

Code

005058

Result

43.8

Unit

%

Lower limit

37.5

Upper limit

51.0

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Screening

Form: Lab-BU-LabCorp (4)

Data signed: (hfarmer1) 27 Mar 2015 14:29:54

Generated On: 20 Jul 2016 16:51:47

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

04857100030

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Screening

Form: Lab-BU-LabCorp (5)

Data signed: (hfarmer1) 27 Mar 2015 14:29:54

Generated On: 20 Jul 2016 16:51:47

Experiment Type	HEMATOLOGY
Date of Sample Collection YYYY/MM/DD	17 FEB 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Male <input checked="" type="radio"/>
Time of Sample Collection	11:40
Analyte Name	MCV
Code	015065
Result	83
Unit	FL
Lower limit	79
Upper limit	97
Flag	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Screening

Form: Lab-BU-LabCorp (5)

Data signed: (hfarmer1) 27 Mar 2015 14:29:54

Generated On: 20 Jul 2016 16:51:47

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

04857100030

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Screening

Form: Lab-BU-LabCorp (6)

Data signed: (hfarmer1) 27 Mar 2015 14:29:54

Generated On: 20 Jul 2016 16:51:47

Experiment Type	HEMATOLOGY
Date of Sample Collection YYYY/MM/DD	17 FEB 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Male <input checked="" type="radio"/>
Time of Sample Collection	11:40
Analyte Name	MCH
Code	015073
Result	29.1
Unit	PG
Lower limit	26.6
Upper limit	33.0
Flag	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Screening

Form: Lab-BU-LabCorp (6)

Data signed: (hfarmer1) 27 Mar 2015 14:29:54

Generated On: 20 Jul 2016 16:51:47

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

04857100030

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Screening

Form: Lab-BU-LabCorp (7)

Data signed: (hfarmer1) 27 Mar 2015 14:29:54

Generated On: 20 Jul 2016 16:51:47

Experiment Type	HEMATOLOGY
Date of Sample Collection YYYY/MM/DD	17 FEB 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Male <input checked="" type="radio"/>
Time of Sample Collection	11:40
Analyte Name	MCHC
Code	015081
Result	34.9
Unit	G/DL
Lower limit	31.5
Upper limit	35.7
Flag	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Screening

Form: Lab-BU-LabCorp (7)

Data signed: (hfarmer1) 27 Mar 2015 14:29:54

Generated On: 20 Jul 2016 16:51:47

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

04857100030

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Screening

Form: Lab-BU-LabCorp (8)

Data signed: (hfarmer1) 27 Mar 2015 14:29:54

Generated On: 20 Jul 2016 16:51:47

Experiment Type	HEMATOLOGY
Date of Sample Collection YYYY/MM/DD	17 FEB 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Male <input checked="" type="radio"/>
Time of Sample Collection	11:40
Analyte Name	NEUTROPHILS
Code	015107
Result	66
Unit	%
Lower limit	40
Upper limit	74
Flag	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Screening

Form: Lab-BU-LabCorp (8)

Data signed: (hfarmer1) 27 Mar 2015 14:29:54

Generated On: 20 Jul 2016 16:51:47

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

04857100030

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Screening

Form: Lab-BU-LabCorp (9)

Data signed: (hfarmer1) 27 Mar 2015 14:29:54

Generated On: 20 Jul 2016 16:51:47

Experiment Type

HEMATOLOGY

Date of Sample Collection
YYYY/MM/DD

17 FEB 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male ☒

Time of Sample Collection

11:40

Analyte Name

LYMPHS

Code

015123

Result

28

Unit

%

Lower limit

14

Upper limit

46

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Screening

Form: Lab-BU-LabCorp (9)

Data signed: (hfarmer1) 27 Mar 2015 14:29:54

Generated On: 20 Jul 2016 16:51:47

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

04857100030

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Screening

Form: Lab-BU-LabCorp (10)

Data signed: (hfarmer1) 27 Mar 2015 14:29:54

Generated On: 20 Jul 2016 16:51:47

Experiment Type

HEMATOLOGY

Date of Sample Collection
YYYY/MM/DD

17 FEB 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male ☒

Time of Sample Collection

11:40

Analyte Name

MONOCYTES

Code

015131

Result

5

Unit

%

Lower limit

4

Upper limit

12

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Screening

Form: Lab-BU-LabCorp (10)

Data signed: (hfarmer1) 27 Mar 2015 14:29:54

Generated On: 20 Jul 2016 16:51:47

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

04857100030

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Screening

Form: Lab-BU-LabCorp (11)

Data signed: (hfarmer1) 27 Mar 2015 14:29:54

Generated On: 20 Jul 2016 16:51:47

Experiment Type

HEMATOLOGY

Date of Sample Collection
YYYY/MM/DD

17 FEB 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male

Time of Sample Collection

11:40

Analyte Name

EOS

Code

015149

Result

1

Unit

%

Lower limit

0

Upper limit

5

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Screening

Form: Lab-BU-LabCorp (11)

Data signed: (hfarmer1) 27 Mar 2015 14:29:54

Generated On: 20 Jul 2016 16:51:47

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

04857100030

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Screening

Form: Lab-BU-LabCorp (12)

Data signed: (hfarmer1) 27 Mar 2015 14:29:54

Generated On: 20 Jul 2016 16:51:47

Experiment Type

HEMATOLOGY

Date of Sample Collection
YYYY/MM/DD

17 FEB 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male ☒

Time of Sample Collection

11:40

Analyte Name

BASOS

Code

015156

Result

0

Unit

%

Lower limit

0

Upper limit

3

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Screening

Form: Lab-BU-LabCorp (12)

Data signed: (hfarmer1) 27 Mar 2015 14:29:54

Generated On: 20 Jul 2016 16:51:47

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

04857100030

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Screening

Form: Lab-BU-LabCorp (13)

Data signed: (hfarmer1) 27 Mar 2015 14:29:54

Generated On: 20 Jul 2016 16:51:47

Experiment Type

HEMATOLOGY

Date of Sample Collection
YYYY/MM/DD

17 FEB 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male ☒

Time of Sample Collection

11:40

Analyte Name

PLATELETS

Code

015172

Result

179

Unit

X10E3/UL

Lower limit

155

Upper limit

379

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Screening

Form: Lab-BU-LabCorp (13)

Data signed: (hfarmer1) 27 Mar 2015 14:29:54

Generated On: 20 Jul 2016 16:51:47

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

04857100030

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Screening

Form: Lab-BU-LabCorp (14)

Data signed: (hfarmer1) 27 Mar 2015 14:29:54

Generated On: 20 Jul 2016 16:51:47

Experiment Type	HEMATOLOGY
Date of Sample Collection YYYY/MM/DD	17 FEB 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Male <input checked="" type="radio"/>
Time of Sample Collection	11:40
Analyte Name	NEUTROPHILS (ABSOLUTE)
Code	015909
Result	3.4
Unit	X10E3/UL
Lower limit	1.4
Upper limit	7.0
Flag	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Screening

Form: Lab-BU-LabCorp (14)

Data signed: (hfarmer1) 27 Mar 2015 14:29:54

Generated On: 20 Jul 2016 16:51:47

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

04857100030

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Screening

Form: Lab-BU-LabCorp (15)

Data signed: (hfarmer1) 27 Mar 2015 14:29:54

Generated On: 20 Jul 2016 16:51:47

Experiment Type	HEMATOLOGY
Date of Sample Collection YYYY/MM/DD	17 FEB 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Male <input checked="" type="radio"/>
Time of Sample Collection	11:40
Analyte Name	LYMPHS (ABSOLUTE)
Code	015917
Result	1.5
Unit	X10E3/UL
Lower limit	0.7
Upper limit	3.1
Flag	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Screening

Form: Lab-BU-LabCorp (15)

Data signed: (hfarmer1) 27 Mar 2015 14:29:54

Generated On: 20 Jul 2016 16:51:47

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

04857100030

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Screening

Form: Lab-BU-LabCorp (16)

Data signed: (hfarmer1) 27 Mar 2015 14:29:54

Generated On: 20 Jul 2016 16:51:47

Experiment Type	HEMATOLOGY
Date of Sample Collection YYYY/MM/DD	17 FEB 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Male <input checked="" type="radio"/>
Time of Sample Collection	11:40
Analyte Name	MONOCYTES(ABSOLUTE)
Code	015925
Result	0.3
Unit	X10E3/UL
Lower limit	0.1
Upper limit	0.9
Flag	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Screening

Form: Lab-BU-LabCorp (16)

Data signed: (hfarmer1) 27 Mar 2015 14:29:54

Generated On: 20 Jul 2016 16:51:47

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

04857100030

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Screening

Form: Lab-BU-LabCorp (17)

Data signed: (hfarmer1) 27 Mar 2015 14:29:54

Generated On: 20 Jul 2016 16:51:47

Experiment Type

HEMATOLOGY

Date of Sample Collection
YYYY/MM/DD

17 FEB 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male ☒

Time of Sample Collection

11:40

Analyte Name

EOS (ABSOLUTE)

Code

015933

Result

0.1

Unit

X10E3/UL

Lower limit

0.0

Upper limit

0.4

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Screening

Form: Lab-BU-LabCorp (17)

Data signed: (hfarmer1) 27 Mar 2015 14:29:54

Generated On: 20 Jul 2016 16:51:47

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

04857100030

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Screening

Form: Lab-BU-LabCorp (18)

Data signed: (hfarmer1) 27 Mar 2015 14:29:54

Generated On: 20 Jul 2016 16:51:47

Experiment Type

HEMATOLOGY

Date of Sample Collection
YYYY/MM/DD

17 FEB 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male ☒

Time of Sample Collection

11:40

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: 1181**

Folder: Screening

Form: Lab-BU-LabCorp (18)

Data signed: (hfarmer1) 27 Mar 2015 14:29:54

Generated On: 20 Jul 2016 16:51:47

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

04857100030

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Screening

Form: Lab-BU-LabCorp URINALYSIS(17 FEB 2014)

Data signed: (hfarmer1) 27 Mar 2015 14:29:56

Generated On: 20 Jul 2016 16:51:47

Experiment Type

URINALYSIS

Date of Sample Collection
YYYY/MM/DD

17 FEB 2014

Please document clinically relevant abnormalities in the AE form

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Screening

Form: Lab-BU-LabCorp URINALYSIS(17 FEB 2014)

Data signed: (hfarmer1) 27 Mar 2015 14:29:56

Generated On: 20 Jul 2016 16:51:47

Experiment Type

URINALYSIS

Date of Sample Collection
YYYY/MM/DD

17 FEB 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male ☒

Time of Sample Collection

11:06

Analyte Name

SPECIFIC GRAVITY

Code

13060

Result

1.005

Unit

Lower limit

1.001

Upper limit

1.035

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Screening

Form: Lab-BU-LabCorp URINALYSIS(17 FEB 2014)

Data signed: (hfarmer1) 27 Mar 2015 14:29:56

Generated On: 20 Jul 2016 16:51:47

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Screening

Form: Lab-BU-LabCorp (2)

Data signed: (hfarmer1) 27 Mar 2015 14:29:56

Generated On: 20 Jul 2016 16:51:47

Experiment Type

URINALYSIS

Date of Sample Collection
YYYY/MM/DD

17 FEB 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male

Time of Sample Collection

11:06

Analyte Name

PH

Code

13078

Result

7

Unit

Lower limit

5

Upper limit

8

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Screening

Form: Lab-BU-LabCorp (2)

Data signed: (hfarmer1) 27 Mar 2015 14:29:56

Generated On: 20 Jul 2016 16:51:47

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Screening

Form: Lab-BU-LabCorp (3)

Data signed: (hfarmer1) 27 Mar 2015 14:29:56

Generated On: 20 Jul 2016 16:51:47

Experiment Type	URINALYSIS
Date of Sample Collection YYYY/MM/DD	17 FEB 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Male <input checked="" type="radio"/>
Time of Sample Collection	11:06
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: 1181**

Folder: Screening

Form: Lab-BU-LabCorp (3)

Data signed: (hfarmer1) 27 Mar 2015 14:29:56

Generated On: 20 Jul 2016 16:51:47

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Screening

Form: Lab-BU-LabCorp (4)

Data signed: (hfarmer1) 27 Mar 2015 14:29:56

Generated On: 20 Jul 2016 16:51:47

Experiment Type

URINALYSIS

Date of Sample Collection
YYYY/MM/DD

17 FEB 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male ☒

Time of Sample Collection

11:06

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: 1181**

Folder: Screening

Form: Lab-BU-LabCorp (4)

Data signed: (hfarmer1) 27 Mar 2015 14:29:56

Generated On: 20 Jul 2016 16:51:47

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Screening

Form: Lab-BU-LabCorp (5)

Data signed: (hfarmer1) 27 Mar 2015 14:29:56

Generated On: 20 Jul 2016 16:51:47

Experiment Type

URINALYSIS

Date of Sample Collection
YYYY/MM/DD

17 FEB 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male ☒

Time of Sample Collection

11:06

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: 1181**

Folder: Screening

Form: Lab-BU-LabCorp (5)

Data signed: (hfarmer1) 27 Mar 2015 14:29:56

Generated On: 20 Jul 2016 16:51:47

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Screening

Form: Lab-BU-LabCorp (6)

Data signed: (hfarmer1) 27 Mar 2015 14:29:56

Generated On: 20 Jul 2016 16:51:47

Experiment Type

URINALYSIS

Date of Sample Collection
YYYY/MM/DD

17 FEB 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male ☒

Time of Sample Collection

11:06

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: 1181**

Folder: Screening

Form: Lab-BU-LabCorp (6)

Data signed: (hfarmer1) 27 Mar 2015 14:29:56

Generated On: 20 Jul 2016 16:51:47

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Screening

Form: Lab-BU-LabCorp (7)

Data signed: (hfarmer1) 27 Mar 2015 14:29:56

Generated On: 20 Jul 2016 16:51:47

Experiment Type

URINALYSIS

Date of Sample Collection
YYYY/MM/DD

17 FEB 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male ☒

Time of Sample Collection

11:06

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: 1181**

Folder: Screening

Form: Lab-BU-LabCorp (7)

Data signed: (hfarmer1) 27 Mar 2015 14:29:56

Generated On: 20 Jul 2016 16:51:47

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Screening

Form: FTND Questionnaire

Generated On: 20 Jul 2016 16:51:47

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

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

Date of assessment	2014 FEB 17
DD/MMM/YYYY	DD/MMM/YYYY

Time of assessment	12:31
	hour:min 24-hour clock

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

1. How soon after you wake up do you smoke your first cigarette?	6-30 minutes <input checked="" type="radio"/>
--	---

2. Do you find it difficult to refrain from smoking in places where it is forbidden?	Yes <input checked="" type="radio"/>
--	--------------------------------------

3. Which cigarette would you hate most to give up?	Any other <input checked="" type="radio"/>
--	--

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

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

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Screening

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

Data signed: (hfarmer1) 27 Mar 2015 14:29:50

Generated On: 20 Jul 2016 16:51:47

Was paper questionnaire used? Yes ☒

Reason not done _____

Type PROCHASKA STAGE OF
CHANGE QUESTIONNAIRE:
INTENTION TO QUIT
SMOKING

Date of assessment 17 FEB 2014
DD/MMM/YYYY

Time of assessment 10:25
hour:min 24-hour clock

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

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

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Admission (Day -2)

Form: Date of Visit

Data signed: (hfarmer1) 27 Mar 2015 14:29:59

Generated On: 20 Jul 2016 16:51:47

Date of Visit

26 FEB 2014
DD/MMM/YYYY

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Admission (Day -2)

Form: Inclusion Criteria

Data signed: (hfarmer1) 27 Mar 2015 14:29:57

Generated On: 20 Jul 2016 16:51:47

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

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Admission (Day -2)

Form: Inclusion Criteria (1)

Data signed: (hfarmer1) 27 Mar 2015 14:29:57

Generated On: 20 Jul 2016 16:51:47

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

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

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

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

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Admission (Day -2)

Form: Inclusion Criteria (2)

Data signed: (hfarmer1) 27 Mar 2015 14:29:57

Generated On: 20 Jul 2016 16:51:47

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

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

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

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

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Admission (Day -2)

Form: Inclusion Criteria (3)

Data signed: (hfarmer1) 27 Mar 2015 14:29:57

Generated On: 20 Jul 2016 16:51:47

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

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

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

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

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Admission (Day -2)

Form: Inclusion Criteria (4)

Data signed: (hfarmer1) 27 Mar 2015 14:29:57

Generated On: 20 Jul 2016 16:51:47

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

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

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

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Admission (Day -2)

Form: Exclusion Criteria

Data signed: (hfarmer1) 27 Mar 2015 14:29:57

Generated On: 20 Jul 2016 16:51:47

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

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Admission (Day -2)

Form: Exclusion Criteria (1)

Data signed: (hfarmer1) 27 Mar 2015 14:29:57

Generated On: 20 Jul 2016 16:51:47

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

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

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

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

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Admission (Day -2)

Form: Exclusion Criteria (2)

Data signed: (hfarmer1) 27 Mar 2015 14:29:57

Generated On: 20 Jul 2016 16:51:47

Exclusion Criterion Number

3

Exclusion Criterion

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

Result

No

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Admission (Day -2)

Form: Exclusion Criteria (3)

Data signed: (hfarmer1) 27 Mar 2015 14:29:57

Generated On: 20 Jul 2016 16:51:47

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

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

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

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

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Admission (Day -2)

Form: Exclusion Criteria (4)

Data signed: (hfarmer1) 27 Mar 2015 14:29:57

Generated On: 20 Jul 2016 16:51:47

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

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

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

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

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Admission (Day -2)

Form: Exclusion Criteria (5)

Data signed: (hfarmer1) 27 Mar 2015 14:29:57

Generated On: 20 Jul 2016 16:51:47

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

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

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

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

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Admission (Day -2)

Form: Exclusion Criteria (6)

Data signed: (hfarmer1) 27 Mar 2015 14:29:57

Generated On: 20 Jul 2016 16:51:47

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

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

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

*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: 1181

Folder: Admission (Day -2)

Form: Exclusion Criteria (7)

Data signed: (hfarmer1) 27 Mar 2015 14:29:57

Generated On: 20 Jul 2016 16:51:47

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

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

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

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

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Admission (Day -2)

Form: Exclusion Criteria (8)

Data signed: (hfarmer1) 27 Mar 2015 14:29:57

Generated On: 20 Jul 2016 16:51:47

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

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

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

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

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Admission (Day -2)

Form: Exclusion Criteria (9)

Data signed: (hfarmer1) 27 Mar 2015 14:29:57

Generated On: 20 Jul 2016 16:51:47

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

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

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

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

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Admission (Day -2)

Form: Exclusion Criteria (10)

Data signed: (hfarmer1) 27 Mar 2015 14:29:57

Generated On: 20 Jul 2016 16:51:47

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

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

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

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Admission (Day -2)

Form: Exclusion Criteria (11)

Data signed: (hfarmer1) 27 Mar 2015 14:29:57

Generated On: 20 Jul 2016 16:51:47

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

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

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

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Admission (Day -2)

Form: Exclusion Criteria (12)

Data signed: (hfarmer1) 27 Mar 2015 14:29:57

Generated On: 20 Jul 2016 16:51:47

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

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

Result	No	<input 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: 1181

Folder: Admission (Day -2)

Form: Exclusion Criteria (13)

Data signed: (hfarmer1) 27 Mar 2015 14:29:57

Generated On: 20 Jul 2016 16:51:47

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

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

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

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

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Admission (Day -2)

Form: Exclusion Criteria (14)

Data signed: (hfarmer1) 27 Mar 2015 14:29:57

Generated On: 20 Jul 2016 16:51:47

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

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

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

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Admission (Day -2)

Form: Vital Signs

Data signed: (hfarmer1) 27 Mar 2015 14:29:59

Generated On: 20 Jul 2016 16:51:47

Were Vitals Signs assessed? Yes ☒

If No, please specify the reason: _____

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

Time of assessment 11:54
hour:min 24-hour clock

Pulse rate 61
beats per minute

Respiratory rate 16
breaths per minute

Blood Pressure (systolic) 139
mmHg

Blood Pressure (diastolic) 82
mmHg

Vital Signs Position of Subject Supine ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Admission (Day -2)

Form: Product preference

Data signed: (hfarmer1) 27 Mar 2015 14:29:59

Generated On: 20 Jul 2016 16:51:47

Which Product Arm would you prefer to be randomized
to:

No preference ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Admission (Day -2)

Form: Advice on the risk of smoking and debriefing

Data signed: (hfarmer1) 27 Mar 2015 14:29:59

Generated On: 20 Jul 2016 16:51:47

Has the subject received advices on the risks of
smoking?

Yes ☒

Has a debriefing been performed about THS 2.2?

Yes ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Admission (Day -2)

Form: Physical Examination

Data signed: (hfarmer1) 27 Mar 2015 14:29:57

Generated On: 20 Jul 2016 16:51:47

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Admission (Day -2)

Form: Physical Examination (1)

Data signed: (hfarmer1) 27 Mar 2015 14:29:57

Generated On: 20 Jul 2016 16:51:47

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

System General Appearance ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Admission (Day -2)

Form: Physical Examination (2)

Data signed: (hfarmer1) 27 Mar 2015 14:29:57

Generated On: 20 Jul 2016 16:51:47

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

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

Outcome ☒ Normal

Abnormal, please specify _____

Clinically significant _____

Not Done ☐ False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Admission (Day -2)

Form: Physical Examination (3)

Data signed: (hfarmer1) 27 Mar 2015 14:29:57

Generated On: 20 Jul 2016 16:51:47

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

System Thyroid Gland ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Admission (Day -2)

Form: Physical Examination (4)

Data signed: (hfarmer1) 27 Mar 2015 14:29:57

Generated On: 20 Jul 2016 16:51:47

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

System Heart ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Admission (Day -2)

Form: Physical Examination (5)

Data signed: (hfarmer1) 27 Mar 2015 14:29:57

Generated On: 20 Jul 2016 16:51:47

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

System Chest ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Admission (Day -2)

Form: Physical Examination (6)

Data signed: (hfarmer1) 27 Mar 2015 14:29:57

Generated On: 20 Jul 2016 16:51:47

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

System Lungs ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Admission (Day -2)

Form: Physical Examination (7)

Data signed: (hfarmer1) 27 Mar 2015 14:29:57

Generated On: 20 Jul 2016 16:51:47

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

System Gastrointestinal ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Admission (Day -2)

Form: Physical Examination (8)

Data signed: (hfarmer1) 27 Mar 2015 14:29:57

Generated On: 20 Jul 2016 16:51:47

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

System Cardiovascular System ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Admission (Day -2)

Form: Physical Examination (9)

Data signed: (hfarmer1) 27 Mar 2015 14:29:57

Generated On: 20 Jul 2016 16:51:47

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

System Neurologic ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Admission (Day -2)

Form: Physical Examination (10)

Data signed: (hfarmer1) 27 Mar 2015 14:29:57

Generated On: 20 Jul 2016 16:51:47

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

System Skin ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Admission (Day -2)

Form: Physical Examination (11)

Data signed: (hfarmer1) 27 Mar 2015 14:29:57

Generated On: 20 Jul 2016 16:51:47

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

System Back ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Admission (Day -2)

Form: Physical Examination (12)

Data signed: (hfarmer1) 27 Mar 2015 14:29:57

Generated On: 20 Jul 2016 16:51:47

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

System Musculoskeletal ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Admission (Day -2)

Form: Physical Examination (13)

Data signed: (hfarmer1) 27 Mar 2015 14:29:57

Generated On: 20 Jul 2016 16:51:47

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

System Abdomen ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Admission (Day -2)

Form: Physical Examination (14)

Data signed: (hfarmer1) 27 Mar 2015 14:29:57

Generated On: 20 Jul 2016 16:51:47

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: 1181**

Folder: Admission (Day -2)

Form: Physical Examination (15)

Data signed: (hfarmer1) 27 Mar 2015 14:29:57

Generated On: 20 Jul 2016 16:51:47

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

System

Other ☒

Other, Specify _____

Outcome _____

Abnormal, please specify _____

Clinically significant _____

Not Done

True

Not Done; please specify the reason: _____

NOT EXAMINED

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Admission (Day -2)

Form: Physical Examination (16)

Data signed: (hfarmer1) 27 Mar 2015 14:29:57

Generated On: 20 Jul 2016 16:51:47

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

System

Other ☒

Other, Specify _____

Outcome _____

Abnormal, please specify _____

Clinically significant _____

Not Done

True

Not Done; please specify the reason: _____

NOT EXAMINED

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Admission (Day -2)

Form: Physical Examination (17)

Data signed: (hfarmer1) 27 Mar 2015 14:29:57

Generated On: 20 Jul 2016 16:51:47

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

System

Other ☒

Other, Specify _____

Outcome _____

Abnormal, please specify _____

Clinically significant _____

Not Done

True

Not Done; please specify the reason: _____

NOT EXAMINED

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Admission (Day -2)

Form: Physical Examination (18)

Data signed: (hfarmer1) 27 Mar 2015 14:29:57

Generated On: 20 Jul 2016 16:51:47

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

System

Other ☒

Other, Specify _____

Outcome _____

Abnormal, please specify _____

Clinically significant _____

Not Done

True

Not Done; please specify the reason: _____

NOT EXAMINED

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Admission (Day -2)

Form: Physical Examination (19)

Data signed: (hfarmer1) 27 Mar 2015 14:29:57

Generated On: 20 Jul 2016 16:51:47

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

System

Other ☒

Other, Specify _____

Outcome _____

Abnormal, please specify _____

Clinically significant _____

Not Done

True

Not Done; please specify the reason: _____

NOT EXAMINED

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Admission (Day -2)

Form: Identification of Current Cigarette Brand

Data signed: (hcoleman1) 18 Jun 2015 21:06:54

Generated On: 20 Jul 2016 16:51:47

Brand name

MARLBORO RICH BLUE
MENTHOL

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Admission (Day -2)

Form: THS 2.2 menthol product test

Data signed: (hfarmer1) 27 Mar 2015 14:29:59

Generated On: 20 Jul 2016 16:51:47

Was the THS 2.2 menthol product trial performed?

Yes ☒

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

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

1

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

Yes ☒

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Admission (Day -2)

Form: Smoking History

Data signed: (hfarmer1) 27 Mar 2015 14:29:59

Generated On: 20 Jul 2016 16:51:47

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

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

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

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Admission (Day -2)

Form: Weight

Data signed: (hfarmer1) 27 Mar 2015 14:29:59

Generated On: 20 Jul 2016 16:51:47

Measurement(s) assessed?

Yes ☒

If No, please specify the reason: _____

Time of assessment

11:27
hour:min 24-hour clock

Weight

60.9
kg

Waist circumference

91
cm

BMI

23.5

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Admission (Day -2)

Form: Urine Drug Screen

Data signed: (hfarmer1) 27 Mar 2015 14:29:57

Generated On: 20 Jul 2016 16:51:47

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

If Not Done, please specify the reason: _____

Time of sample collection	11:25 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: 1181

Folder: Admission (Day -2)

Form: Urine Drug Screen (6)

Data signed: (hfarmer1) 27 Mar 2015 14:29:57

Generated On: 20 Jul 2016 16:51:47

Drug type	Result
Opiates	Negative

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Admission (Day -2)

Form: Alcohol Test

Data signed: (hfarmer1) 27 Mar 2015 14:29:57

Generated On: 20 Jul 2016 16:51:47

Was the alcohol test performed? Yes ☒

If No, please specify the reason: _____

Method used Breath test ☒

Time of assessment 11:43
hour:min 24-hour clock

Result Negative ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Admission (Day -2)

Form: CO Breath Test

Data signed: (hfarmer1) 27 Mar 2015 14:29:57

Generated On: 20 Jul 2016 16:51:47

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

If Not Done, please specify the reason: _____

Actual Time of Assessment	11:45
	hour:min 24-hour clock

Result	6
	ppm

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Admission (Day -2)

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

Data signed: (hfarmer1) 27 Mar 2015 14:29:59

Generated On: 20 Jul 2016 16:51:47

Was paper questionnaire used? Yes ☒

Reason not done _____

Type PROCHASKA STAGE OF
CHANGE QUESTIONNAIRE:
INTENTION TO QUIT
SMOKING

Date of assessment 26 FEB 2014
DD/MMM/YYYY

Time of assessment 12:03
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: 1181**

Folder: Baseline (Day -1)

Form: Date of Visit

Data signed: (hfarmer1) 27 Mar 2015 14:30:10

Generated On: 20 Jul 2016 16:51:47

Date of Visit

27 FEB 2014
DD/MMM/YYYY

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day -1)

Form: Vital Signs

Data signed: (hfarmer1) 27 Mar 2015 14:30:10

Generated On: 20 Jul 2016 16:51:47

Were Vitals Signs assessed? Yes ☒

If No, please specify the reason: _____

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

Time of assessment 09:46
hour:min 24-hour clock

Pulse rate 61
beats per minute

Respiratory rate 14
breaths per minute

Blood Pressure (systolic) 126
mmHg

Blood Pressure (diastolic) 78
mmHg

Vital Signs Position of Subject Supine ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day -1)

Form: CoHb Blood Sample

Data signed: (hfarmer1) 27 Mar 2015 14:29:59

Generated On: 20 Jul 2016 16:51:47

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

If Not Done, please specify the reason: _____

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

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

Time hour:min 24-hour clock	20:27
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day -1)

Form: CO Breath Test (1)

Data signed: (hfarmer1) 27 Mar 2015 14:29:59

Generated On: 20 Jul 2016 16:51:47

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

If Not Done, please specify the reason: _____

Scheduled Time	Within 15 min prior to smoking <input checked="" type="radio"/>
----------------	---

Actual Time of Assessment hour:min 24-hour clock	06:30
---	-------

Result(ppm)	4
-------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day -1)

Form: CO Breath Test (2)

Data signed: (hfarmer1) 27 Mar 2015 14:29:59

Generated On: 20 Jul 2016 16:51:47

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

If Not Done, please specify the reason: _____

Scheduled Time	12:00 - 13:30 
----------------	---

Actual Time of Assessment hour:min 24-hour clock	12:11
---	-------

Result(ppm)	3
-------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day -1)

Form: CO Breath Test (3)

Data signed: (hfarmer1) 27 Mar 2015 14:29:59

Generated On: 20 Jul 2016 16:51:47

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

If Not Done, please specify the reason: _____

Scheduled Time	16:00 - 17:30 <input checked="" type="radio"/>
----------------	--

Actual Time of Assessment hour:min 24-hour clock	16:44
---	-------

Result(ppm)	4
-------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day -1)

Form: CO Breath Test (4)

Data signed: (hfarmer1) 27 Mar 2015 14:29:59

Generated On: 20 Jul 2016 16:51:47

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

If Not Done, please specify the reason: _____

Scheduled Time	20:00 - 21:30 
----------------	---

Actual Time of Assessment hour:min 24-hour clock	20:47
---	-------

Result(ppm)	0
-------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day -1)

Form: 4 hour urine collection

Data signed: (hfarmer1) 27 Mar 2015 14:30:10

Generated On: 20 Jul 2016 16:51:47

Start Time	10:12
	hour:min 24-hour clock

End Time	14:00
	hour:min 24-hour clock

Volume	778
	mL

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day -1)

Form: Sample Urine Collection (4 Hour collection)

Data signed: (hfarmer1) 27 Mar 2015 14:30:10

Generated On: 20 Jul 2016 16:51:47

Were samples for 4h collected? Yes ☒

If No, please specify the reason: _____

How many primary tubes were collected? 13

How many back up tubes were collected? 13

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day -1)

Form: Lab_BU_COHB (1)

Data signed: (hfarmer1) 27 Mar 2015 14:30:11

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05115150001169
Analyte	CARBOXYHEMOGLOBIN
Sample type	BLOOD
Result	2.40
Result Unit	%
Lab Status	OK
Sample comment	.
Detection method	SPECTROPHOTOMETRIC
Lower limit of quantification	0.500
Planned time point (Hour)	20
Day of Visit	-1
Celerion Study Number	AA99128-16
Date of Collection	2014-FEB-27
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day -1)

Form: Lab_BU_COHB (1)

Data signed: (hfarmer1) 27 Mar 2015 14:30:11

Generated On: 20 Jul 2016 16:51:47

Start Day (24 hour urine only)

End Day (24 hour Urine Only)

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Baseline (Day -1)

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)

Data signed: (hfarmer1) 27 Mar 2015 14:30:10

Generated On: 20 Jul 2016 16:51:47

Date of Birth

(b) (6)

Date of assessment

2014 FEB 27

DD/MMM/YYYY

DD/MMM/YYYY

Time of assessment

20:05

hour:min 24-hour clock

Assessment Status

Completed ☒

1. Was smoking satisfying?

Moderately ☒

2. Did cigarettes taste good?

Moderately ☒

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

Moderately ☒

4. Did smoking calm you down?

Quite a lot ☒

5. Did smoking make you feel more awake?

Moderately ☒

6. Did smoking make you feel less irritable?

Very little ☒

7. Did smoking help you concentrate?

Very little ☒

8. Did smoking reduce your hunger for food?

Not at all ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day -1)

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)

Data signed: (hfarmer1) 27 Mar 2015 14:30:10

Generated On: 20 Jul 2016 16:51:47

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? Moderately ☐

12. Did you enjoy smoking? Moderately ☐

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Baseline (Day -1)

Form: Behavioral Risk Factor Surveillance System Questionnaire

Data signed: (hfarmer1) 27 Mar 2015 14:29:59

Generated On: 20 Jul 2016 16:51:47

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

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

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

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

Time of assessment	21:25 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: 1181**

Folder: Baseline (Day -1)

Form: Behavioral Risk Factor Surveillance System Questionnaire

Data signed: (hfarmer1) 27 Mar 2015 14:29:59

Generated On: 20 Jul 2016 16:51:47

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

Not at all ☐

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

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ)

Data signed: (hfarmer1) 27 Mar 2015 14:29:59

Generated On: 20 Jul 2016 16:51:47

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

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

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

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

Time of assessment	21:32 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: 1181**

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ)

Data signed: (hfarmer1) 27 Mar 2015 14:29:59

Generated On: 20 Jul 2016 16:51:47

Months

Days

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

Years 00 Years

Months 00 Months

Days 00 Days

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

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:29:59

Generated On: 20 Jul 2016 16:51:47

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

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

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

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

Time of assessment	21:32 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: 1181

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:29:59

Generated On: 20 Jul 2016 16:51:47

Months

Days

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

Years

00 Years

Months

00 Months

Days

00 Days

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

Time

Currently (last 3 months) ☒

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

Manufactured Cigarettes
per day

012

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

None ☒

Hand-rolled Cigarettes
per day

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:29:59

Generated On: 20 Jul 2016 16:51:47

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

None ☒

Cigars
per day

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

None ☒

Pipes
per day

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (2)

Data signed: (hfarmer1) 27 Mar 2015 14:29:59

Generated On: 20 Jul 2016 16:51:47

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

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

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

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

Time of assessment	21:32 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: 1181

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (2)

Data signed: (hfarmer1) 27 Mar 2015 14:29:59

Generated On: 20 Jul 2016 16:51:47

Months

Days

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

Years

00 Years

Months

00 Months

Days

00 Days

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

Time

1 year ago ☒

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

Manufactured Cigarettes
per day

012

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

None ☒

Hand-rolled Cigarettes
per day

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (2)

Data signed: (hfarmer1) 27 Mar 2015 14:29:59

Generated On: 20 Jul 2016 16:51:47

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

None ☒

Cigars
per day

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

None ☒

Pipes
per day

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (3)

Data signed: (hfarmer1) 27 Mar 2015 14:29:59

Generated On: 20 Jul 2016 16:51:47

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

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

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

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

Time of assessment	21:32 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: 1181

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (3)

Data signed: (hfarmer1) 27 Mar 2015 14:29:59

Generated On: 20 Jul 2016 16:51:47

Months

Days

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

Years

00 Years

Months

00 Months

Days

00 Days

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

Time

5 years ago ☒

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

Manufactured Cigarettes
per day

005

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: 1181**

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (3)

Data signed: (hfarmer1) 27 Mar 2015 14:29:59

Generated On: 20 Jul 2016 16:51:47

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

None ☒

Cigars
per day

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

None ☒

Pipes
per day

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (4)

Data signed: (hfarmer1) 27 Mar 2015 14:29:59

Generated On: 20 Jul 2016 16:51:47

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

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

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

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

Time of assessment	21:32 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: 1181

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (4)

Data signed: (hfarmer1) 27 Mar 2015 14:29:59

Generated On: 20 Jul 2016 16:51:47

Months

Days

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

Years

00 Years

Months

00 Months

Days

00 Days

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

Time

10 years ago ☒

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

Manufactured Cigarettes
per day

000

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: 1181**

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (4)

Data signed: (hfarmer1) 27 Mar 2015 14:29:59

Generated On: 20 Jul 2016 16:51:47

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

None ☒

Cigars
per day

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

None ☒

Pipes
per day

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (5)

Data signed: (hfarmer1) 27 Mar 2015 14:29:59

Generated On: 20 Jul 2016 16:51:47

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

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

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

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

Time of assessment	21:32 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: 1181

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (5)

Data signed: (hfarmer1) 27 Mar 2015 14:29:59

Generated On: 20 Jul 2016 16:51:47

Months

Days

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

Years

00 Years

Months

00 Months

Days

00 Days

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

Time

15 years ago ☒

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

Manufactured Cigarettes
per day

000

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: 1181**

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (5)

Data signed: (hfarmer1) 27 Mar 2015 14:29:59

Generated On: 20 Jul 2016 16:51:47

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

None ☒

Cigars
per day

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

None ☒

Pipes
per day

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (6)

Data signed: (hfarmer1) 27 Mar 2015 14:29:59

Generated On: 20 Jul 2016 16:51:47

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

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

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

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

Time of assessment	21:32 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: 1181

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (6)

Data signed: (hfarmer1) 27 Mar 2015 14:29:59

Generated On: 20 Jul 2016 16:51:47

Months

Days

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

Years

00 Years

Months

00 Months

Days

00 Days

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

Time

20 years ago ☒

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

Manufactured Cigarettes
per day

000

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: 1181**

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (6)

Data signed: (hfarmer1) 27 Mar 2015 14:29:59

Generated On: 20 Jul 2016 16:51:47

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

None ☒

Cigars
per day

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

None ☒

Pipes
per day

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (7)

Data signed: (hfarmer1) 27 Mar 2015 14:29:59

Generated On: 20 Jul 2016 16:51:47

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

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

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

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

Time of assessment	21:32 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: 1181

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (7)

Data signed: (hfarmer1) 27 Mar 2015 14:29:59

Generated On: 20 Jul 2016 16:51:47

Months

Days

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

Years

00 Years

Months

00 Months

Days

00 Days

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

Time

More than 20 years ago ☒

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

Manufactured Cigarettes
per day

000

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: 1181**

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (7)

Data signed: (hfarmer1) 27 Mar 2015 14:29:59

Generated On: 20 Jul 2016 16:51:47

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

None ☒

Cigars
per day

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

None ☒

Pipes
per day

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day -1)

Form: Supplemental Questions

Data signed: (hfarmer1) 27 Mar 2015 14:30:09

Generated On: 20 Jul 2016 16:51:47

Was paper questionnaire used? Yes ☒

Reason not done _____

Date of Assessment 27 FEB 2014
DD/MMM/YYYY

Time of assessment 21:33

1. How long it takes for the subject to complete the SQ 06 minutes

Comments (open-end) _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day -1)

Form: Supplemental Questions (1)

Data signed: (hfarmer1) 27 Mar 2015 14:30:09

Generated On: 20 Jul 2016 16:51:47

Was paper questionnaire used? Yes ☐

Reason not done _____

Date of Assessment 27 FEB 2014
DD/MMM/YYYY

Time of assessment 21:33

1. How long it takes for the subject to complete the SQ 06 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: 1181

Folder: Baseline (Day -1)

Form: Supplemental Questions (2)

Data signed: (hfarmer1) 27 Mar 2015 14:30:09

Generated On: 20 Jul 2016 16:51:47

Was paper questionnaire used? Yes ☐

Reason not done _____

Date of Assessment 27 FEB 2014
DD/MMM/YYYY

Time of assessment 21:33

1. How long it takes for the subject to complete the SQ 06 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: 1181**

Folder: Baseline (Day -1)

Form: Supplemental Questions (3)

Data signed: (hfarmer1) 27 Mar 2015 14:30:09

Generated On: 20 Jul 2016 16:51:47

Was paper questionnaire used? Yes ☐

Reason not done _____

Date of Assessment 27 FEB 2014
DD/MMM/YYYY

Time of assessment 21:33

1. How long it takes for the subject to complete the SQ 06 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: 1181

Folder: Baseline (Day -1)

Form: Supplemental Questions (4)

Data signed: (hfarmer1) 27 Mar 2015 14:30:09

Generated On: 20 Jul 2016 16:51:47

Was paper questionnaire used? Yes ☐

Reason not done _____

Date of Assessment 27 FEB 2014
DD/MMM/YYYY

Time of assessment 21:33

1. How long it takes for the subject to complete the SQ 06 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: 1181**

Folder: Baseline (Day -1)

Form: Supplemental Questions (5)

Data signed: (hfarmer1) 27 Mar 2015 14:30:09

Generated On: 20 Jul 2016 16:51:47

Was paper questionnaire used? Yes ☐

Reason not done _____

Date of Assessment 27 FEB 2014
DD/MMM/YYYY

Time of assessment 21:33

1. How long it takes for the subject to complete the SQ 06 minutes

Question 6. Was the SQ ☐
self-explaining?

Answer No ☐

Comments (open-end) _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day -1)

Form: Supplemental Questions (6)

Data signed: (hfarmer1) 27 Mar 2015 14:30:09

Generated On: 20 Jul 2016 16:51:47

Was paper questionnaire used? Yes ☒

Reason not done _____

Date of Assessment 27 FEB 2014
DD/MMM/YYYY

Time of assessment 21:33

1. How long it takes for the subject to complete the SQ 06 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: 1181

Folder: Baseline (Day -1)

Form: Questionnaire on smoking urges (QSU)

Data signed: (hfarmer1) 27 Mar 2015 14:30:10

Generated On: 20 Jul 2016 16:51:47

Type	QSU
Date of Birth	(b) (6)
Date of assessment	2014 FEB 27
DD/MMM/YYYY	
Time of assessment	20:03
hour:min 24-hour clock	
Assessment Status	Completed <input checked="" type="radio"/>
1. I have a desire for a cigarette right now	Somewhat disagree <input type="radio"/>
2. Nothing would be better than smoking a cigarette right now	Somewhat disagree <input type="radio"/>
3. If it were possible I would probably smoke now	Somewhat disagree <input type="radio"/>
4. I could control things better right now if I could smoke	Disagree <input type="radio"/>
5. All I want right now is a cigarette	Somewhat disagree <input type="radio"/>
6. I have an urge for a cigarette	Disagree <input type="radio"/>

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day -1)

Form: Questionnaire on smoking urges (QSU)

Data signed: (hfarmer1) 27 Mar 2015 14:30:10

Generated On: 20 Jul 2016 16:51:47

7. A cigarette would taste good now Disagree ☐

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

9. Smoking would make me less depressed Strongly disagree ☐

10. I am going to smoke as soon as possible Disagree ☐

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (CEMA, HPMA, HBMA)

Data signed: (hfarmer1) 27 Mar 2015 14:30:11

Generated On: 20 Jul 2016 16:51:47

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:30:11

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05112450002050
----------------	----------------

Analyte	HPMA
---------	------

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

Result	266
--------	-----

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-FEB-27
--------------------	-------------

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

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:30:11

Generated On: 20 Jul 2016 16:51:47

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (2)

Data signed: (hfarmer1) 27 Mar 2015 14:30:11

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05112450002050
----------------	----------------

Analyte	CEMA
---------	------

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

Result	29.1
--------	------

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-FEB-27
--------------------	-------------

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

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (2)

Data signed: (hfarmer1) 27 Mar 2015 14:30:11

Generated On: 20 Jul 2016 16:51:47

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (3)

Data signed: (hfarmer1) 27 Mar 2015 14:30:11

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05112450002050
----------------	----------------

Analyte	HBMA
---------	------

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

Result	143
--------	-----

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-FEB-27
--------------------	-------------

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

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (3)

Data signed: (hfarmer1) 27 Mar 2015 14:30:11

Generated On: 20 Jul 2016 16:51:47

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (NNN, NNAL)

Data signed: (hfarmer1) 27 Mar 2015 14:30:11

Generated On: 20 Jul 2016 16:51:47

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (NNN, NNAL) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:30:11

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05112460002427
Analyte	NNAL
Sample type	URINE
Result	20.6
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	-1
Celerion Study Number	AA99128-04
Date of Collection	2014-FEB-27
Timepoint-minutes	
Urine Start Day	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (NNN, NNAL) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:30:11

Generated On: 20 Jul 2016 16:51:47

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (NNN, NNAL) (2)

Data signed: (hfarmer1) 27 Mar 2015 14:30:11

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05112460002427
Analyte	NNN
Sample type	URINE
Result	0.378
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	AA99128-04
Date of Collection	2014-FEB-27
Timepoint-minutes	
Urine Start Day	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (NNN, NNAL) (2)

Data signed: (hfarmer1) 27 Mar 2015 14:30:11

Generated On: 20 Jul 2016 16:51:47

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (HEMA)

Data signed: (hfarmer1) 27 Mar 2015 14:30:11

Generated On: 20 Jul 2016 16:51:47

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (HEMA) (2)

Data signed: (hfarmer1) 27 Mar 2015 14:30:11

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05112470001211
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Analyte	HEMA
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Sample type	URINE
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Result	1.01
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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	-1
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Celerion Study Number	AA99128-05
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Date of Collection	2014-FEB-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: 1181**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (HEMA) (2)

Data signed: (hfarmer1) 27 Mar 2015 14:30:11

Generated On: 20 Jul 2016 16:51:47

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day -1)

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

Data signed: (hfarmer1) 27 Mar 2015 14:30:12

Generated On: 20 Jul 2016 16:51:47

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day -1)

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

Data signed: (hfarmer1) 27 Mar 2015 14:30:12

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05112480001101
Analyte	COT
Sample type	URINE
Result	249
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-FEB-27
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day -1)

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

Data signed: (hfarmer1) 27 Mar 2015 14:30:12

Generated On: 20 Jul 2016 16:51:47

Urine Start Day

Urine End Day

-1

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Baseline (Day -1)

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

Data signed: (hfarmer1) 27 Mar 2015 14:30:12

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05112480001101
Analyte	COT-GLUC
Sample type	URINE
Result	220
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-FEB-27
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day -1)

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

Data signed: (hfarmer1) 27 Mar 2015 14:30:12

Generated On: 20 Jul 2016 16:51:47

Urine Start Day

Urine End Day

-1

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Baseline (Day -1)

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

Data signed: (hfarmer1) 27 Mar 2015 14:30:12

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05112480001101
Analyte	NIC
Sample type	URINE
Result	101
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-FEB-27
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day -1)

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

Data signed: (hfarmer1) 27 Mar 2015 14:30:12

Generated On: 20 Jul 2016 16:51:47

Urine Start Day

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day -1)

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

Data signed: (hfarmer1) 27 Mar 2015 14:30:12

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05112480001101
Analyte	NIC-GLUC
Sample type	URINE
Result	BLQ<(50.0)
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	-1
Celerion Study Number	AA99128-06
Date of Collection	2014-FEB-27
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day -1)

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

Data signed: (hfarmer1) 27 Mar 2015 14:30:12

Generated On: 20 Jul 2016 16:51:47

Urine Start Day

Urine End Day

-1

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Baseline (Day -1)

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

Data signed: (hfarmer1) 27 Mar 2015 14:30:12

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05112480001101
Analyte	THCOT
Sample type	URINE
Result	252
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-FEB-27
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day -1)

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

Data signed: (hfarmer1) 27 Mar 2015 14:30:12

Generated On: 20 Jul 2016 16:51:47

Urine Start Day

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day -1)

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

Data signed: (hfarmer1) 27 Mar 2015 14:30:12

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05112480001101
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Analyte	THCOT-GLUC
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Sample type	URINE
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Result	BLQ<(200)
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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	-1
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Celerion Study Number	AA99128-06
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Date of Collection	2014-FEB-27
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Timepoint-minutes	
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day -1)

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

Data signed: (hfarmer1) 27 Mar 2015 14:30:12

Generated On: 20 Jul 2016 16:51:47

Urine Start Day

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (3-OH BaP)

Data signed: (hfarmer1) 27 Mar 2015 14:30:12

Generated On: 20 Jul 2016 16:51:47

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (3-OH BaP) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:30:12

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05112490001213
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Analyte	3-OH BAP
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Sample type	URINE
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Result	BLQ<(25.0)
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Result Unit	FG/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	AA99128-07
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Date of Collection	2014-FEB-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: 1181**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (3-OH BaP) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:30:12

Generated On: 20 Jul 2016 16:51:47

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day -1)

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

Data signed: (hfarmer1) 27 Mar 2015 14:30:12

Generated On: 20 Jul 2016 16:51:47

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day -1)

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

Data signed: (hfarmer1) 27 Mar 2015 14:30:12

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05112510001213
Analyte	1-NA
Sample type	URINE
Result	6.78
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-FEB-27
Timepoint-minutes	
Urine Start Day	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day -1)

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

Data signed: (hfarmer1) 27 Mar 2015 14:30:12

Generated On: 20 Jul 2016 16:51:47

Urine End Day

-1

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Baseline (Day -1)

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

Data signed: (hfarmer1) 27 Mar 2015 14:30:12

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05112510001213
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Analyte	2-NA
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Sample type	URINE
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Result	BLQ<(2.50)
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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-FEB-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: 1181**

Folder: Baseline (Day -1)

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

Data signed: (hfarmer1) 27 Mar 2015 14:30:12

Generated On: 20 Jul 2016 16:51:47

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (3)

Data signed: (hfarmer1) 27 Mar 2015 14:30:12

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05112510001213
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Analyte	4-ABP
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Sample type	URINE
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Result	1.77
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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-FEB-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: 1181**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (3)

Data signed: (hfarmer1) 27 Mar 2015 14:30:12

Generated On: 20 Jul 2016 16:51:47

Urine End Day

-1

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Baseline (Day -1)

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

Data signed: (hfarmer1) 27 Mar 2015 14:30:12

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05112510001213
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Analyte	O-TOL
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Sample type	URINE
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Result	BLQ<(50.0)
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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-FEB-27
--------------------	-------------

Timepoint-minutes	
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Urine Start Day	
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day -1)

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

Data signed: (hfarmer1) 27 Mar 2015 14:30:12

Generated On: 20 Jul 2016 16:51:47

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (11-dTXb2)

Data signed: (hfarmer1) 27 Mar 2015 14:30:11

Generated On: 20 Jul 2016 16:51:47

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (11-dTXb2) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:30:11

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05112530000393
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Analyte	11-DTXB2
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Sample type	URINE
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Result	208
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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	AA99128-11
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Date of Collection	2014-FEB-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: 1181**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (11-dTXb2) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:30:11

Generated On: 20 Jul 2016 16:51:47

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (iPF2a-III)

Data signed: (hfarmer1) 27 Mar 2015 14:30:11

Generated On: 20 Jul 2016 16:51:47

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (iPF2a-III) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:30:11

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05112540000393
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Analyte	IPF2A-III
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Sample type	URINE
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Result	53.6
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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	AA99128-12
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Date of Collection	2014-FEB-27
--------------------	-------------

Timepoint-minutes	
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Urine Start Day	
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (iPF2a-III) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:30:11

Generated On: 20 Jul 2016 16:51:47

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (1-OHP)

Data signed: (hfarmer1) 27 Mar 2015 14:30:13

Generated On: 20 Jul 2016 16:51:47

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day -1)

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

Data signed: (hfarmer1) 27 Mar 2015 14:30:13

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05115190001541
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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-FEB-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: 1181**

Folder: Baseline (Day -1)

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

Data signed: (hfarmer1) 27 Mar 2015 14:30:13

Generated On: 20 Jul 2016 16:51:47

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (SPMA, SBMA)

Data signed: (hfarmer1) 27 Mar 2015 14:30:11

Generated On: 20 Jul 2016 16:51:47

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day -1)

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

Data signed: (hfarmer1) 27 Mar 2015 14:30:11

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05115170001519
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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-FEB-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: 1181**

Folder: Baseline (Day -1)

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

Data signed: (hfarmer1) 27 Mar 2015 14:30:11

Generated On: 20 Jul 2016 16:51:47

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (SPMA, SBMA) (2)

Data signed: (hfarmer1) 27 Mar 2015 14:30:11

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05115170001519
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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-FEB-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: 1181**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (SPMA, SBMA) (2)

Data signed: (hfarmer1) 27 Mar 2015 14:30:11

Generated On: 20 Jul 2016 16:51:47

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (MHBMA)

Data signed: (hfarmer1) 27 Mar 2015 14:30:11

Generated On: 20 Jul 2016 16:51:47

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (MHBMA) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:30:11

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05115180001541
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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-FEB-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: 1181**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (MHBMA) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:30:11

Generated On: 20 Jul 2016 16:51:47

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (Creatinine)

Data signed: (hfarmer1) 27 Mar 2015 14:30:13

Generated On: 20 Jul 2016 16:51:47

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (Creatinine) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:30:13

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05115160001213
----------------	----------------

Analyte	CREATININE
---------	------------

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

Result	33.0
--------	------

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

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

Sample comment	ANALYSIS NOT REQUIRED
----------------	-----------------------

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

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

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

Celerion Study Number	AA99128-14
-----------------------	------------

Date of Collection	2014-FEB-27
--------------------	-------------

Timepoint-minutes	<hr/>
-------------------	-------

Urine Start Day	<hr/>
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (Creatinine) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:30:13

Generated On: 20 Jul 2016 16:51:47

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day 0)

Form: Date of Visit

Data signed: (hfarmer1) 27 Mar 2015 14:30:17

Generated On: 20 Jul 2016 16:51:47

Date of Visit

28 FEB 2014
DD/MMM/YYYY

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day 0)

Form: Randomization

Data signed: (hfarmer1) 27 Mar 2015 14:30:17

Generated On: 20 Jul 2016 16:51:47

Randomization number (4 digits)	1051
---------------------------------	------

Allocation Arm	mCC <input checked="" type="radio"/>
----------------	--------------------------------------

Cigarette Consumption	10 – 19 conventional menthol cigarettesper day <input checked="" type="radio"/>
-----------------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day 0)

Form: Vital Signs

Data signed: (hfarmer1) 27 Mar 2015 14:30:17

Generated On: 20 Jul 2016 16:51:47

Were Vitals Signs assessed? Yes ☒

If No, please specify the reason: _____

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

Time of assessment 08:58
hour:min 24-hour clock

Pulse rate 63
beats per minute

Respiratory rate 20
breaths per minute

Blood Pressure (systolic) 137
mmHg

Blood Pressure (diastolic) 73
mmHg

Vital Signs Position of Subject Supine ☒

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Baseline (Day 0)

Form: Gas Transfer

Data signed: (hfarmer1) 27 Mar 2015 14:30:16

Generated On: 20 Jul 2016 16:51:47

Was the Gas Transfer performed?

Yes ☒

If No, please specify the reason: _____

Category _____

Position

SITTING

Time of assessment

07:26

DLCO value

25.14
ml/min/mmHg

KCO value

1.47
mmol/min/kPa/L

DLCO/VA value

4.24
mL/min/mmHg/L

Interpretation

Normal ☒

If Abnormal, Clinical Significance _____

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

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Baseline (Day 0)

Form: Lung Volume Measurements

Data signed: (hfarmer1) 27 Mar 2015 14:30:16

Generated On: 20 Jul 2016 16:51:47

Were the Lung Volume Measurements performed? Yes ☒

If No, please specify the reason: _____

Category _____

Position SITTING

Time of assessment 07:36

VC value 4.28
L

TLC value 5.75
L

IC value 2.20
L

FRC value 3.55
L

Interpretation Abnormal ☒

If Abnormal, Clinical Significance Not clinically significant ☒

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

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Baseline (Day 0)

Form: Spirometry with a short-acting bronchodilator

Data signed: (hcoleman1) 18 Jun 2015 21:06:54

Generated On: 20 Jul 2016 16:51:47

Was the Spirometry with a short-acting bronchodilator performed?	Yes <input checked="" type="radio"/>
--	--------------------------------------

If No, please specify the reason:	<hr/>
-----------------------------------	-------

Category	With short-acting bronchodilator <input checked="" type="radio"/>
----------	---

Position	SITTING
----------	---------

Time of assessment	08:02
--------------------	-------

Name of bronchodilator	ALBUTEROL SULFATE
------------------------	-------------------

Dose	180 MCG
------	---------

Predicted FVC value	4.49 L
---------------------	-----------

Best measured FVC value	4.23 L
-------------------------	-----------

Percent of predicted FVC value	94 %
--------------------------------	---------

Best measured FEV1 value	3.26 L
--------------------------	-----------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day 0)

Form: Spirometry with a short-acting bronchodilator

Data signed: (hcoleman1) 18 Jun 2015 21:06:54

Generated On: 20 Jul 2016 16:51:47

Predicted FEV1 value	3.78 L
----------------------	-----------

Percent of predicted FEV1 value	86 %
---------------------------------	---------

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

MEF 25/75 value	2.69 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: 1181**

Folder: Baseline (Day 0)

Form: Haematology

Data signed: (hfarmer1) 27 Mar 2015 14:30:13

Generated On: 20 Jul 2016 16:51:47

Were samples collected?

Yes ☒

If No, please specify the reason: _____

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

Yes ☒

Please document clinically relevant abnormalities in the AE form

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day 0)

Form: Clinical Chemistry

Data signed: (hfarmer1) 27 Mar 2015 14:30:13

Generated On: 20 Jul 2016 16:51:47

Were samples collected?

Yes ☒

If No, please specify the reason: _____

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

Yes ☒

Please document clinically relevant abnormalities in the AE form

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day 0)

Form: Urine analysis

Data signed: (hfarmer1) 27 Mar 2015 14:30:13

Generated On: 20 Jul 2016 16:51:47

Were samples collected?

Yes ☒

If No, please specify the reason: _____

Please document clinically relevant abnormalities in the AE form

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day 0)

Form: Plasma Nicotine Sample

Data signed: (hfarmer1) 27 Mar 2015 14:30:16

Generated On: 20 Jul 2016 16:51:47

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	28 FEB 2014
---------------------	-------------

Time hour:min 24-hour clock	21:02
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day 0)

Form: Plasma Cotinine Sample

Data signed: (hfarmer1) 27 Mar 2015 14:30:14

Generated On: 20 Jul 2016 16:51:47

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	28 FEB 2014
---------------------	-------------

Time hour:min 24-hour clock	21:02
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day 0)

Form: CoHb Blood Sample <D0> (1)

Data signed: (hfarmer1) 27 Mar 2015 14:30:13

Generated On: 20 Jul 2016 16:51:47

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	28 FEB 2014
---------------------	-------------

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

Time hour:min 24-hour clock	06:30
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day 0)

Form: CoHb Blood Sample <D0> (2)

Data signed: (hfarmer1) 27 Mar 2015 14:30:13

Generated On: 20 Jul 2016 16:51:47

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	28 FEB 2014
---------------------	-------------

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

Time hour:min 24-hour clock	21:02
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day 0)

Form: Oxysterols

Data signed: (hfarmer1) 27 Mar 2015 14:30:16

Generated On: 20 Jul 2016 16:51:47

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

If Not Done, please specify the reason: _____

Was the subject fasting for at least 10 hours at time of sample collection?	Yes <input checked="" type="radio"/>
--	--------------------------------------

Date DD/MMM/YYYY	28 FEB 2014
---------------------	-------------

Time hour:min 24-hour clock	06:30
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day 0)

Form: CO Breath Test (1)

Data signed: (hfarmer1) 27 Mar 2015 14:30:13

Generated On: 20 Jul 2016 16:51:47

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

If Not Done, please specify the reason: _____

Scheduled Time	Within 15 min prior to smoking <input checked="" type="radio"/>
----------------	---

Actual Time of Assessment hour:min 24-hour clock	08:09
---	-------

Result(ppm)	5
-------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day 0)

Form: CO Breath Test (2)

Data signed: (hfarmer1) 27 Mar 2015 14:30:13

Generated On: 20 Jul 2016 16:51:47

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

If Not Done, please specify the reason: _____

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

Actual Time of Assessment hour:min 24-hour clock	12:09
---	-------

Result(ppm)	3
-------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day 0)

Form: CO Breath Test (3)

Data signed: (hfarmer1) 27 Mar 2015 14:30:13

Generated On: 20 Jul 2016 16:51:47

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

If Not Done, please specify the reason: _____

Scheduled Time	16:00 - 17:30 <input checked="" type="radio"/>
----------------	--

Actual Time of Assessment hour:min 24-hour clock	16:17
---	-------

Result(ppm)	5
-------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day 0)

Form: CO Breath Test (4)

Data signed: (hfarmer1) 27 Mar 2015 14:30:13

Generated On: 20 Jul 2016 16:51:47

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

If Not Done, please specify the reason: _____

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

Actual Time of Assessment hour:min 24-hour clock	20:31
---	-------

Result(ppm)	0
-------------	---

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Baseline (Day 0)

Form: CYP2A6 activity Sample

Data signed: (hfarmer1) 27 Mar 2015 14:30:14

Generated On: 20 Jul 2016 16:51:47

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

If Not Done, please specify the reason: _____

Date of sample collection
DD/MMM/YYYY

Time of sample collection
hour:min 24-hour clock

Parameter

28 FEB 2014

06:30

trans-3'-hydroxyc
otinine

28 FEB 2014

06:30

cotinine

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Baseline (Day 0)

Form: CYP1A2 activity Sample

Data signed: (hfarmer1) 27 Mar 2015 14:30:15

Generated On: 20 Jul 2016 16:51:47

Time of caffeine tablet intake	11:02
	hour:min 24-hour clock

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

If Not Done, please specify the reason: _____

Date of sample collection DD/MMM/YYYY	Time of sample collection hour:min 24-hour clock	Parameter
28 FEB 2014	16:57	Caffeine
28 FEB 2014	16:57	Paraxanthine

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day 0)

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

Data signed: (hfarmer1) 27 Mar 2015 14:30:16

Generated On: 20 Jul 2016 16:51:47

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	28 FEB 2014
---------------------	-------------

Time hour:min 24-hour clock	06:30
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day 0)

Form: 24 hour urine collections

Data signed: (hfarmer1) 27 Mar 2015 14:30:17

Generated On: 20 Jul 2016 16:51:47

Start Date	28 FEB 2014 DD/MMM/YYYY
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Start Time	06:23 hour:min 24-hour clock
------------	---------------------------------

End Date	01 MAR 2014 DD/MMM/YYYY
----------	----------------------------

End Time	06:09 hour:min 24-hour clock
----------	---------------------------------

Volume	3916 mL
--------	------------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day 0)

Form: Sample Urine Collection

Data signed: (hfarmer1) 27 Mar 2015 14:30:17

Generated On: 20 Jul 2016 16:51:47

Were samples for 24h collected?

Yes ☒

If No, please specify the reason: _____

How many primary tubes were collected?

14

How many back up tubes were collected?

13

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day 0)

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Data signed: (hfarmer1) 27 Mar 2015 14:30:18

Generated On: 20 Jul 2016 16:51:47

Date of Birth

(b) (6)

Date of assessment
DD/MMM/YYYY

2014 FEB 28
DD/MMM/YYYY

Time of assessment

05:54
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: 1181

Folder: Baseline (Day 0)

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Data signed: (hfarmer1) 27 Mar 2015 14:30:18

Generated On: 20 Jul 2016 16:51:47

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

5. Difficulty concentrating

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

6. Increased appetite, hungry, weight gain

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

7. Insomnia, sleep problems, awakening at night

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

8. Restless

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

9. Impatient

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

10. Constipation

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

11. Dizziness

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

12. Coughing

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day 0)

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Data signed: (hfarmer1) 27 Mar 2015 14:30:18

Generated On: 20 Jul 2016 16:51:47

How have you been feeling over the past 24 hours?

None ☐

13. Dreaming or nightmares

How have you been feeling over the past 24 hours?

None ☐

14. Nausea

How have you been feeling over the past 24 hours?

None ☐

15. Sore Throat

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day 0)

Form: Cough Assessment

Data signed: (hfarmer1) 27 Mar 2015 14:30:18

Generated On: 20 Jul 2016 16:51:47

Date of Birth

(b) (6)

Date of assessment
DD/MMM/YYYY

2014 FEB 28
DD/MMM/YYYY

Time of assessment

05:53
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: 1181**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (1)

Data signed: (hfarmer1) 27 Mar 2015 14:30:19

Generated On: 20 Jul 2016 16:51:47

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	<hr/>
----------------------	-------

Subject Sex	M
-------------	---

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

Visit Name	<hr/>
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	W592781
--------------	---------

Actual Collection Date	2014 02 28
------------------------	------------

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: 1181

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (1)

Data signed: (hfarmer1) 27 Mar 2015 14:30:19

Generated On: 20 Jul 2016 16:51:47

Lab Test Name	TRIGLYCERIDES (GPO)
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	160
Reported Numeric Result	160
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: 1181**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (1)

Data signed: (hfarmer1) 27 Mar 2015 14:30:19

Generated On: 20 Jul 2016 16:51:47

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (2)

Data signed: (hfarmer1) 27 Mar 2015 14:30:19

Generated On: 20 Jul 2016 16:51:47

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	<hr/>
----------------------	-------

Subject Sex	M
-------------	---

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

Visit Name	<hr/>
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	W592781
--------------	---------

Actual Collection Date	2014 02 28
------------------------	------------

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: 1181

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (2)

Data signed: (hfarmer1) 27 Mar 2015 14:30:19

Generated On: 20 Jul 2016 16:51:47

Lab Test Name	FASTING GLUCOSE
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	90
Reported Numeric Result	90
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: 1181**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (2)

Data signed: (hfarmer1) 27 Mar 2015 14:30:19

Generated On: 20 Jul 2016 16:51:47

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (3)

Data signed: (hfarmer1) 27 Mar 2015 14:30:19

Generated On: 20 Jul 2016 16:51:47

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	<hr/>
----------------------	-------

Subject Sex	M
-------------	---

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

Visit Name	<hr/>
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	W592781
--------------	---------

Actual Collection Date	2014 02 28
------------------------	------------

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: 1181**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (3)

Data signed: (hfarmer1) 27 Mar 2015 14:30:19

Generated On: 20 Jul 2016 16:51:47

Lab Test Name	CHOLESTEROL (HIGH PERFORMANCE)
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	203
Reported Numeric Result	203
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: 1181**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (3)

Data signed: (hfarmer1) 27 Mar 2015 14:30:19

Generated On: 20 Jul 2016 16:51:47

SI Text Result

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (4)

Data signed: (hfarmer1) 27 Mar 2015 14:30:19

Generated On: 20 Jul 2016 16:51:47

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	<hr/>
----------------------	-------

Subject Sex	M
-------------	---

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

Visit Name	<hr/>
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	W592781
--------------	---------

Actual Collection Date	2014 02 28
------------------------	------------

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: 1181**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (4)

Data signed: (hfarmer1) 27 Mar 2015 14:30:19

Generated On: 20 Jul 2016 16:51:47

Lab Test Name	TOTAL BILIRUBIN
Test ID	
Test Status	Done <input type="checkbox"/>
Reported Text Result	0.7
Reported Numeric Result	0.7
Reference Range low	0.2
Reference Range high	1.2
Range Units	MG/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (4)

Data signed: (hfarmer1) 27 Mar 2015 14:30:19

Generated On: 20 Jul 2016 16:51:47

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (5)

Data signed: (hfarmer1) 27 Mar 2015 14:30:19

Generated On: 20 Jul 2016 16:51:47

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	W592781
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Actual Collection Date	2014 02 28
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Actual Collection Time	06:30
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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: 1181

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (5)

Data signed: (hfarmer1) 27 Mar 2015 14:30:19

Generated On: 20 Jul 2016 16:51:47

Lab Test Name	TOTAL PROTEIN
Test ID	
Test Status	Done <input type="checkbox"/>
Reported Text Result	7.6
Reported Numeric Result	7.6
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: 1181**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (5)

Data signed: (hfarmer1) 27 Mar 2015 14:30:19

Generated On: 20 Jul 2016 16:51:47

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (6)

Data signed: (hfarmer1) 27 Mar 2015 14:30:19

Generated On: 20 Jul 2016 16:51:47

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	W592781
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Actual Collection Date	2014 02 28
------------------------	------------

Actual Collection Time	06:30
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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	RCT13
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (6)

Data signed: (hfarmer1) 27 Mar 2015 14:30:19

Generated On: 20 Jul 2016 16:51:47

Lab Test Name	ALBUMIN
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	4.7
Reported Numeric Result	4.7
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: 1181**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (6)

Data signed: (hfarmer1) 27 Mar 2015 14:30:19

Generated On: 20 Jul 2016 16:51:47

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (7)

Data signed: (hfarmer1) 27 Mar 2015 14:30:19

Generated On: 20 Jul 2016 16:51:47

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	W592781
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Actual Collection Date	2014 02 28
------------------------	------------

Actual Collection Time	06:30
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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	RCT1407
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (7)

Data signed: (hfarmer1) 27 Mar 2015 14:30:19

Generated On: 20 Jul 2016 16:51:47

Lab Test Name	ALKALINE PHOSPHATASE
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	50
Reported Numeric Result	50
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: 1181**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (7)

Data signed: (hfarmer1) 27 Mar 2015 14:30:19

Generated On: 20 Jul 2016 16:51:47

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (8)

Data signed: (hfarmer1) 27 Mar 2015 14:30:19

Generated On: 20 Jul 2016 16:51:47

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	W592781
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Actual Collection Date	2014 02 28
------------------------	------------

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	RCT1408
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (8)

Data signed: (hfarmer1) 27 Mar 2015 14:30:19

Generated On: 20 Jul 2016 16:51:47

Lab Test Name	LDH
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	126
Reported Numeric Result	126
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: 1181**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (8)

Data signed: (hfarmer1) 27 Mar 2015 14:30:19

Generated On: 20 Jul 2016 16:51:47

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (9)

Data signed: (hfarmer1) 27 Mar 2015 14:30:19

Generated On: 20 Jul 2016 16:51:47

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	W592781
--------------	---------

Actual Collection Date	2014 02 28
------------------------	------------

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	RCT15
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (9)

Data signed: (hfarmer1) 27 Mar 2015 14:30:19

Generated On: 20 Jul 2016 16:51:47

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: 1181**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (9)

Data signed: (hfarmer1) 27 Mar 2015 14:30:19

Generated On: 20 Jul 2016 16:51:47

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (10)

Data signed: (hfarmer1) 27 Mar 2015 14:30:19

Generated On: 20 Jul 2016 16:51:47

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	W592781
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Actual Collection Date	2014 02 28
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Actual Collection Time	06:30
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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	RCT16
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (10)

Data signed: (hfarmer1) 27 Mar 2015 14:30:19

Generated On: 20 Jul 2016 16:51:47

Lab Test Name	SERUM POTASSIUM
Test ID	
Test Status	Done <input checked="" type="checkbox"/>
Reported Text Result	4.7
Reported Numeric Result	4.7
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: 1181**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (10)

Data signed: (hfarmer1) 27 Mar 2015 14:30:19

Generated On: 20 Jul 2016 16:51:47

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (11)

Data signed: (hfarmer1) 27 Mar 2015 14:30:19

Generated On: 20 Jul 2016 16:51:47

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	W592781
--------------	---------

Actual Collection Date	2014 02 28
------------------------	------------

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: 1181

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (11)

Data signed: (hfarmer1) 27 Mar 2015 14:30:19

Generated On: 20 Jul 2016 16:51:47

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: 1181**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (11)

Data signed: (hfarmer1) 27 Mar 2015 14:30:19

Generated On: 20 Jul 2016 16:51:47

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (12)

Data signed: (hfarmer1) 27 Mar 2015 14:30:19

Generated On: 20 Jul 2016 16:51:47

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	W592781
--------------	---------

Actual Collection Date	2014 02 28
------------------------	------------

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	RCT3
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (12)

Data signed: (hfarmer1) 27 Mar 2015 14:30:19

Generated On: 20 Jul 2016 16:51:47

Lab Test Name	GGT
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	13
Reported Numeric Result	13
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: 1181**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (12)

Data signed: (hfarmer1) 27 Mar 2015 14:30:19

Generated On: 20 Jul 2016 16:51:47

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (13)

Data signed: (hfarmer1) 27 Mar 2015 14:30:19

Generated On: 20 Jul 2016 16:51:47

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	W592781
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Actual Collection Date	2014 02 28
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Actual Collection Time	06:30
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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	RCT392
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (13)

Data signed: (hfarmer1) 27 Mar 2015 14:30:19

Generated On: 20 Jul 2016 16:51:47

Lab Test Name	CREATININE (RATE BLANKED)
Test ID	
Test Status	Done <input type="checkbox"/>
Reported Text Result	0.9
Reported Numeric Result	0.9
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: 1181**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (13)

Data signed: (hfarmer1) 27 Mar 2015 14:30:19

Generated On: 20 Jul 2016 16:51:47

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (14)

Data signed: (hfarmer1) 27 Mar 2015 14:30:19

Generated On: 20 Jul 2016 16:51:47

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	W592781
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Actual Collection Date	2014 02 28
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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	RCT4
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (14)

Data signed: (hfarmer1) 27 Mar 2015 14:30:19

Generated On: 20 Jul 2016 16:51:47

Lab Test Name	ALT (SGPT)
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	13
Reported Numeric Result	13
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: 1181**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (14)

Data signed: (hfarmer1) 27 Mar 2015 14:30:19

Generated On: 20 Jul 2016 16:51:47

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (15)

Data signed: (hfarmer1) 27 Mar 2015 14:30:19

Generated On: 20 Jul 2016 16:51:47

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	W592781
--------------	---------

Actual Collection Date	2014 02 28
------------------------	------------

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: 1181

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (15)

Data signed: (hfarmer1) 27 Mar 2015 14:30:19

Generated On: 20 Jul 2016 16:51:47

Lab Test Name	AST (SGOT)
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	18
Reported Numeric Result	18
Reference Range low	11
Reference Range high	36
Range Units	U/L
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (15)

Data signed: (hfarmer1) 27 Mar 2015 14:30:19

Generated On: 20 Jul 2016 16:51:47

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (16)

Data signed: (hfarmer1) 27 Mar 2015 14:30:19

Generated On: 20 Jul 2016 16:51:47

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	W592781
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Actual Collection Date	2014 02 28
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Actual Collection Time	06:30
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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	RCT6
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (16)

Data signed: (hfarmer1) 27 Mar 2015 14:30:19

Generated On: 20 Jul 2016 16:51:47

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: 1181**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (16)

Data signed: (hfarmer1) 27 Mar 2015 14:30:19

Generated On: 20 Jul 2016 16:51:47

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (17)

Data signed: (hfarmer1) 27 Mar 2015 14:30:19

Generated On: 20 Jul 2016 16:51:47

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	W592781
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Actual Collection Date	2014 02 28
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Actual Collection Time	06:30
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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	HMT10
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (17)

Data signed: (hfarmer1) 27 Mar 2015 14:30:19

Generated On: 20 Jul 2016 16:51:47

Lab Test Name	MONOCYTES
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	0.25
Reported Numeric Result	0.25
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: 1181**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (17)

Data signed: (hfarmer1) 27 Mar 2015 14:30:19

Generated On: 20 Jul 2016 16:51:47

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (18)

Data signed: (hfarmer1) 27 Mar 2015 14:30:19

Generated On: 20 Jul 2016 16:51:47

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	W592781
--------------	---------

Actual Collection Date	2014 02 28
------------------------	------------

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: 1181

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (18)

Data signed: (hfarmer1) 27 Mar 2015 14:30:19

Generated On: 20 Jul 2016 16:51:47

Lab Test Name	MCH
Test ID	
Test Status	Done <input type="checkbox"/>
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: 1181**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (18)

Data signed: (hfarmer1) 27 Mar 2015 14:30:19

Generated On: 20 Jul 2016 16:51:47

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (19)

Data signed: (hfarmer1) 27 Mar 2015 14:30:19

Generated On: 20 Jul 2016 16:51:47

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	W592781
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Actual Collection Date	2014 02 28
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Actual Collection Time	06:30
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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: 1181

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (19)

Data signed: (hfarmer1) 27 Mar 2015 14:30:19

Generated On: 20 Jul 2016 16:51:47

Lab Test Name	MCHC
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	34
Reported Numeric Result	34
Reference Range low	31
Reference Range high	38
Range Units	G/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (19)

Data signed: (hfarmer1) 27 Mar 2015 14:30:19

Generated On: 20 Jul 2016 16:51:47

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (20)

Data signed: (hfarmer1) 27 Mar 2015 14:30:19

Generated On: 20 Jul 2016 16:51:47

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	W592781
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Actual Collection Date	2014 02 28
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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	HMT11
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (20)

Data signed: (hfarmer1) 27 Mar 2015 14:30:19

Generated On: 20 Jul 2016 16:51:47

Lab Test Name	EOSINOPHILS
Test ID	
Test Status	Done <input checked="" type="checkbox"/>
Reported Text Result	0.19
Reported Numeric Result	0.19
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: 1181**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (20)

Data signed: (hfarmer1) 27 Mar 2015 14:30:19

Generated On: 20 Jul 2016 16:51:47

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (21)

Data signed: (hfarmer1) 27 Mar 2015 14:30:19

Generated On: 20 Jul 2016 16:51:47

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	W592781
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Actual Collection Date	2014 02 28
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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	HMT12
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (21)

Data signed: (hfarmer1) 27 Mar 2015 14:30:19

Generated On: 20 Jul 2016 16:51:47

Lab Test Name	BASOPHILS
Test ID	
Test Status	Done <input checked="" type="checkbox"/>
Reported Text Result	0.03
Reported Numeric Result	0.03
Reference Range low	0.00
Reference Range high	0.20
Range Units	X10^3/UL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (21)

Data signed: (hfarmer1) 27 Mar 2015 14:30:19

Generated On: 20 Jul 2016 16:51:47

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (22)

Data signed: (hfarmer1) 27 Mar 2015 14:30:19

Generated On: 20 Jul 2016 16:51:47

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	W592781
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Actual Collection Date	2014 02 28
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Actual Collection Time	06:30
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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: 1181

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (22)

Data signed: (hfarmer1) 27 Mar 2015 14:30:19

Generated On: 20 Jul 2016 16:51:47

Lab Test Name	PLATELETS
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	197
Reported Numeric Result	197
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: 1181**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (22)

Data signed: (hfarmer1) 27 Mar 2015 14:30:19

Generated On: 20 Jul 2016 16:51:47

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (23)

Data signed: (hfarmer1) 27 Mar 2015 14:30:19

Generated On: 20 Jul 2016 16:51:47

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	W592781
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Actual Collection Date	2014 02 28
------------------------	------------

Actual Collection Time	06:30
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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: 1181

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (23)

Data signed: (hfarmer1) 27 Mar 2015 14:30:19

Generated On: 20 Jul 2016 16:51:47

Lab Test Name	NEUTROPHILS (%)
Test ID	
Test Status	Done <input checked="" type="checkbox"/>
Reported Text Result	53.8
Reported Numeric Result	53.8
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: 1181**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (23)

Data signed: (hfarmer1) 27 Mar 2015 14:30:19

Generated On: 20 Jul 2016 16:51:47

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (24)

Data signed: (hfarmer1) 27 Mar 2015 14:30:19

Generated On: 20 Jul 2016 16:51:47

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	W592781
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Actual Collection Date	2014 02 28
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Actual Collection Time	06:30
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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: 1181

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (24)

Data signed: (hfarmer1) 27 Mar 2015 14:30:19

Generated On: 20 Jul 2016 16:51:47

Lab Test Name	LYMPHOCYTES (%)
Test ID	
Test Status	Done <input checked="" type="checkbox"/>
Reported Text Result	38.8
Reported Numeric Result	38.8
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: 1181**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (24)

Data signed: (hfarmer1) 27 Mar 2015 14:30:19

Generated On: 20 Jul 2016 16:51:47

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (25)

Data signed: (hfarmer1) 27 Mar 2015 14:30:19

Generated On: 20 Jul 2016 16:51:47

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	W592781
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Actual Collection Date	2014 02 28
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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	HMT17
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (25)

Data signed: (hfarmer1) 27 Mar 2015 14:30:19

Generated On: 20 Jul 2016 16:51:47

Lab Test Name	MONOCYTES (%)
Test ID	
Test Status	Done <input checked="" type="checkbox"/>
Reported Text Result	4.0
Reported Numeric Result	4.0
Reference Range low	2.6
Reference Range high	10.1
Range Units	%
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (25)

Data signed: (hfarmer1) 27 Mar 2015 14:30:19

Generated On: 20 Jul 2016 16:51:47

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (26)

Data signed: (hfarmer1) 27 Mar 2015 14:30:19

Generated On: 20 Jul 2016 16:51:47

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	W592781
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Actual Collection Date	2014 02 28
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Actual Collection Time	06:30
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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: 1181

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (26)

Data signed: (hfarmer1) 27 Mar 2015 14:30:19

Generated On: 20 Jul 2016 16:51:47

Lab Test Name	EOSINOPHILS (%)
Test ID	
Test Status	Done <input checked="" type="checkbox"/>
Reported Text Result	3.0
Reported Numeric Result	3.0
Reference Range low	0.0
Reference Range high	6.8
Range Units	%
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (26)

Data signed: (hfarmer1) 27 Mar 2015 14:30:19

Generated On: 20 Jul 2016 16:51:47

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (27)

Data signed: (hfarmer1) 27 Mar 2015 14:30:19

Generated On: 20 Jul 2016 16:51:47

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	W592781
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Actual Collection Date	2014 02 28
------------------------	------------

Actual Collection Time	06:30
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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: 1181

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (27)

Data signed: (hfarmer1) 27 Mar 2015 14:30:19

Generated On: 20 Jul 2016 16:51:47

Lab Test Name	BASOPHILS (%)
Test ID	
Test Status	Done <input type="checkbox"/>
Reported Text Result	0.4
Reported Numeric Result	0.4
Reference Range low	0.0
Reference Range high	2.0
Range Units	%
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (27)

Data signed: (hfarmer1) 27 Mar 2015 14:30:19

Generated On: 20 Jul 2016 16:51:47

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (28)

Data signed: (hfarmer1) 27 Mar 2015 14:30:19

Generated On: 20 Jul 2016 16:51:47

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	W592781
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Actual Collection Date	2014 02 28
------------------------	------------

Actual Collection Time	06:30
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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: 1181

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (28)

Data signed: (hfarmer1) 27 Mar 2015 14:30:19

Generated On: 20 Jul 2016 16:51:47

Lab Test Name	HEMATOCRIT
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	47
Reported Numeric Result	47
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: 1181**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (28)

Data signed: (hfarmer1) 27 Mar 2015 14:30:19

Generated On: 20 Jul 2016 16:51:47

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (29)

Data signed: (hfarmer1) 27 Mar 2015 14:30:19

Generated On: 20 Jul 2016 16:51:47

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	W592781
--------------	---------

Actual Collection Date	2014 02 28
------------------------	------------

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	HMT3
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (29)

Data signed: (hfarmer1) 27 Mar 2015 14:30:19

Generated On: 20 Jul 2016 16:51:47

Lab Test Name	RBC
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	5.5
Reported Numeric Result	5.5
Reference Range low	4.5
Reference Range high	6.4
Range Units	X10^6/UL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (29)

Data signed: (hfarmer1) 27 Mar 2015 14:30:19

Generated On: 20 Jul 2016 16:51:47

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (30)

Data signed: (hfarmer1) 27 Mar 2015 14:30:19

Generated On: 20 Jul 2016 16:51:47

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	W592781
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Actual Collection Date	2014 02 28
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Actual Collection Time	06:30
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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: 1181

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (30)

Data signed: (hfarmer1) 27 Mar 2015 14:30:19

Generated On: 20 Jul 2016 16:51:47

Lab Test Name	MCV
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	86
Reported Numeric Result	86
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: 1181**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (30)

Data signed: (hfarmer1) 27 Mar 2015 14:30:19

Generated On: 20 Jul 2016 16:51:47

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (31)

Data signed: (hfarmer1) 27 Mar 2015 14:30:19

Generated On: 20 Jul 2016 16:51:47

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	W592781
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Actual Collection Date	2014 02 28
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Actual Collection Time	06:30
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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: 1181

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (31)

Data signed: (hfarmer1) 27 Mar 2015 14:30:19

Generated On: 20 Jul 2016 16:51:47

Lab Test Name	HEMOGLOBIN
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	16.0
Reported Numeric Result	16.0
Reference Range low	12.7
Reference Range high	18.1
Range Units	G/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (31)

Data signed: (hfarmer1) 27 Mar 2015 14:30:19

Generated On: 20 Jul 2016 16:51:47

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (32)

Data signed: (hfarmer1) 27 Mar 2015 14:30:19

Generated On: 20 Jul 2016 16:51:47

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	W592781
--------------	---------

Actual Collection Date	2014 02 28
------------------------	------------

Actual Collection Time	06:30
------------------------	-------

Specimen Condition	<hr/>
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Battery ID	HM1604
------------	--------

Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
--------------	-----------------------------------

Lab Test ID	HMT7
-------------	------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (32)

Data signed: (hfarmer1) 27 Mar 2015 14:30:19

Generated On: 20 Jul 2016 16:51:47

Lab Test Name	WBC
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	6.14
Reported Numeric Result	6.14
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: 1181**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (32)

Data signed: (hfarmer1) 27 Mar 2015 14:30:19

Generated On: 20 Jul 2016 16:51:47

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (33)

Data signed: (hfarmer1) 27 Mar 2015 14:30:19

Generated On: 20 Jul 2016 16:51:47

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	<hr/>
----------------------	-------

Subject Sex	M
-------------	---

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

Visit Name	<hr/>
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	W592781
--------------	---------

Actual Collection Date	2014 02 28
------------------------	------------

Actual Collection Time	06:30
------------------------	-------

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: 1181

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (33)

Data signed: (hfarmer1) 27 Mar 2015 14:30:19


Generated On: 20 Jul 2016 16:51:47

Lab Test Name

RBC MORPHOLOGY 1

Test ID

Test Status

Done 

Reported Text Result

NORMOCYTIC

Reported Numeric Result

Reference Range low

Reference Range high

Range Units

Conventional Text Result

Conventional Numeric Result

Conventional Reference Range Low

Conventional Reference Range High

Conventional Units

SI Text Result

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (33)

Data signed: (hfarmer1) 27 Mar 2015 14:30:19

Generated On: 20 Jul 2016 16:51:47

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (34)

Data signed: (hfarmer1) 27 Mar 2015 14:30:19

Generated On: 20 Jul 2016 16:51:47

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	W592781
--------------	---------

Actual Collection Date	2014 02 28
------------------------	------------

Actual Collection Time	06:30
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

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: 1181

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (34)

Data signed: (hfarmer1) 27 Mar 2015 14:30:19

Generated On: 20 Jul 2016 16:51:47

Lab Test Name	NEUTROPHILS
Test ID	
Test Status	Done <input type="checkbox"/>
Reported Text Result	3.30
Reported Numeric Result	3.30
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: 1181**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (34)

Data signed: (hfarmer1) 27 Mar 2015 14:30:19

Generated On: 20 Jul 2016 16:51:47

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (35)

Data signed: (hfarmer1) 27 Mar 2015 14:30:19

Generated On: 20 Jul 2016 16:51:47

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	W592781
--------------	---------

Actual Collection Date	2014 02 28
------------------------	------------

Actual Collection Time	06:30
------------------------	-------

Specimen Condition	<hr/>
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Battery ID	HM1604
------------	--------

Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
--------------	-----------------------------------

Lab Test ID	HMT9
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (35)

Data signed: (hfarmer1) 27 Mar 2015 14:30:19

Generated On: 20 Jul 2016 16:51:47

Lab Test Name	LYMPHOCYTES
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	2.39
Reported Numeric Result	2.39
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: 1181**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (35)

Data signed: (hfarmer1) 27 Mar 2015 14:30:19

Generated On: 20 Jul 2016 16:51:47

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (36)

Data signed: (hfarmer1) 27 Mar 2015 14:30:19

Generated On: 20 Jul 2016 16:51:47

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	W592781
--------------	---------

Actual Collection Date	2014 02 28
------------------------	------------

Actual Collection Time	06:30
------------------------	-------

Specimen Condition	<hr/>
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Battery ID	UA1538
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Battery Name	URINE MACRO PANEL
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Lab Test ID	UAT10
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (36)

Data signed: (hfarmer1) 27 Mar 2015 14:30:19


Generated On: 20 Jul 2016 16:51:47

Lab Test Name

UR NITRITE

Test ID

Test Status

Done 

Reported Text Result

NEGATIVE

Reported Numeric Result

Reference Range low

Reference Range high

Range Units

Conventional Text Result

Conventional Numeric Result

Conventional Reference Range Low

Conventional Reference Range High

Conventional Units

SI Text Result

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (36)

Data signed: (hfarmer1) 27 Mar 2015 14:30:19

Generated On: 20 Jul 2016 16:51:47

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (37)

Data signed: (hfarmer1) 27 Mar 2015 14:30:19

Generated On: 20 Jul 2016 16:51:47

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	W592781
--------------	---------

Actual Collection Date	2014 02 28
------------------------	------------

Actual Collection Time	06:30
------------------------	-------

Specimen Condition	<hr/>
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Battery ID	UA1538
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Battery Name	URINE MACRO PANEL
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Lab Test ID	UAT2
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (37)

Data signed: (hfarmer1) 27 Mar 2015 14:30:19

Generated On: 20 Jul 2016 16:51:47

Lab Test Name	UR SPECIFIC GRAVITY
Test ID	
Test Status	Done <input type="checkbox"/>
Reported Text Result	1.018
Reported Numeric Result	1.018
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: 1181**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (37)

Data signed: (hfarmer1) 27 Mar 2015 14:30:19

Generated On: 20 Jul 2016 16:51:47

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (38)

Data signed: (hfarmer1) 27 Mar 2015 14:30:19

Generated On: 20 Jul 2016 16:51:47

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	W592781
--------------	---------

Actual Collection Date	2014 02 28
------------------------	------------

Actual Collection Time	06:30
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	UA1538
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Battery Name	URINE MACRO PANEL
--------------	-------------------

Lab Test ID	UAT3
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (38)

Data signed: (hfarmer1) 27 Mar 2015 14:30:19

Generated On: 20 Jul 2016 16:51:47

Lab Test Name	UR PH
Test ID	
Test Status	Done <input type="checkbox"/>
Reported Text Result	5.5
Reported Numeric Result	5.5
Reference Range low	5.0
Reference Range high	8.0
Range Units	
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (38)

Data signed: (hfarmer1) 27 Mar 2015 14:30:19

Generated On: 20 Jul 2016 16:51:47

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (39)

Data signed: (hfarmer1) 27 Mar 2015 14:30:19

Generated On: 20 Jul 2016 16:51:47

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

Accession ID	W592781
--------------	---------

Actual Collection Date	2014 02 28
------------------------	------------

Actual Collection Time	06:30
------------------------	-------

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: 1181

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (39)

Data signed: (hfarmer1) 27 Mar 2015 14:30:19

Generated On: 20 Jul 2016 16:51:47

Lab Test Name

UR BLOOD

Test ID

Test Status

Done 

Reported Text Result

NEGATIVE

Reported Numeric Result

Reference Range low

Reference Range high

Range Units

Conventional Text Result

Conventional Numeric Result

Conventional Reference Range Low

Conventional Reference Range High

Conventional Units

SI Text Result

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (39)

Data signed: (hfarmer1) 27 Mar 2015 14:30:19

Generated On: 20 Jul 2016 16:51:47

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (40)

Data signed: (hfarmer1) 27 Mar 2015 14:30:19

Generated On: 20 Jul 2016 16:51:47

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	<hr/>
----------------------	-------

Subject Sex	M
-------------	---

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

Visit Name	<hr/>
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	W592781
--------------	---------

Actual Collection Date	2014 02 28
------------------------	------------

Actual Collection Time	06:30
------------------------	-------

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: 1181

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (40)

Data signed: (hfarmer1) 27 Mar 2015 14:30:19


Generated On: 20 Jul 2016 16:51:47

Lab Test Name

UR PROTEIN

Test ID

Test Status

Done 

Reported Text Result

NEGATIVE

Reported Numeric Result

Reference Range low

Reference Range high

Range Units

Conventional Text Result

Conventional Numeric Result

Conventional Reference Range Low

Conventional Reference Range High

Conventional Units

SI Text Result

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (40)

Data signed: (hfarmer1) 27 Mar 2015 14:30:19

Generated On: 20 Jul 2016 16:51:47

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (41)

Data signed: (hfarmer1) 27 Mar 2015 14:30:19

Generated On: 20 Jul 2016 16:51:47

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	<hr/>
----------------------	-------

Subject Sex	M
-------------	---

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

Visit Name	<hr/>
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	W592781
--------------	---------

Actual Collection Date	2014 02 28
------------------------	------------

Actual Collection Time	06:30
------------------------	-------

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: 1181

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (41)

Data signed: (hfarmer1) 27 Mar 2015 14:30:19


Generated On: 20 Jul 2016 16:51:47

Lab Test Name

UR GLUCOSE

Test ID

Test Status

Done 

Reported Text Result

NORMAL

Reported Numeric Result

Reference Range low

Reference Range high

Range Units

Conventional Text Result

Conventional Numeric Result

Conventional Reference Range Low

Conventional Reference Range High

Conventional Units

SI Text Result

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (41)

Data signed: (hfarmer1) 27 Mar 2015 14:30:19

Generated On: 20 Jul 2016 16:51:47

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (42)

Data signed: (hfarmer1) 27 Mar 2015 14:30:19

Generated On: 20 Jul 2016 16:51:47

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	<hr/>
----------------------	-------

Subject Sex	M
-------------	---

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

Visit Name	<hr/>
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	W592781
--------------	---------

Actual Collection Date	2014 02 28
------------------------	------------

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: 1181**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (42)

Data signed: (hfarmer1) 27 Mar 2015 14:30:19


Generated On: 20 Jul 2016 16:51:47

Lab Test Name

UR BILIRUBIN

Test ID

Test Status

Done 

Reported Text Result

NEGATIVE

Reported Numeric Result

Reference Range low

Reference Range high

Range Units

Conventional Text Result

Conventional Numeric Result

Conventional Reference Range Low

Conventional Reference Range High

Conventional Units

SI Text Result

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (42)

Data signed: (hfarmer1) 27 Mar 2015 14:30:19

Generated On: 20 Jul 2016 16:51:47

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day 0)

Form: Oxysterol results (1)

Generated On: 20 Jul 2016 16:51:47

Sample Accession number	3259278139
-------------------------	------------

Analyte	22(R)-HYDROXYCHOLESTERO L
---------	------------------------------

Analyte code	22RHCR L
--------------	----------

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: 1181**

Folder: Baseline (Day 0)

Form: Oxysterol results (2)

Generated On: 20 Jul 2016 16:51:47

Sample Accession number	3259278139
-------------------------	------------

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: 1181**

Folder: Baseline (Day 0)

Form: Oxysterol results (3)

Generated On: 20 Jul 2016 16:51:47

Sample Accession number	3259278139
-------------------------	------------

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: 1181**

Folder: Baseline (Day 0)

Form: Oxysterol results (4)

Generated On: 20 Jul 2016 16:51:47

Sample Accession number	3259278139
-------------------------	------------

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: 1181**

Folder: Baseline (Day 0)

Form: Oxysterol results (5)

Generated On: 20 Jul 2016 16:51:47

Sample Accession number	3259278139
-------------------------	------------

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: 1181**

Folder: Baseline (Day 0)

Form: Oxysterol results (6)

Generated On: 20 Jul 2016 16:51:47

Sample Accession number	3259278139
-------------------------	------------

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: 1181**

Folder: Baseline (Day 0)

Form: Oxysterol results (7)

Generated On: 20 Jul 2016 16:51:47

Sample Accession number	3259278139
-------------------------	------------

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: 1181**

Folder: Baseline (Day 0)

Form: Oxysterol results (8)

Generated On: 20 Jul 2016 16:51:47

Sample Accession number	3259278139
-------------------------	------------

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: 1181**

Folder: Baseline (Day 0)

Form: Oxysterol results (9)

Generated On: 20 Jul 2016 16:51:47

Sample Accession number	3259278139
-------------------------	------------

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: 1181**

Folder: Baseline (Day 0)

Form: Oxysterol results (10)

Generated On: 20 Jul 2016 16:51:47

Sample Accession number	3259278139
-------------------------	------------

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: 1181**

Folder: Baseline (Day 0)

Form: Oxysterol results (11)

Generated On: 20 Jul 2016 16:51:47

Sample Accession number	3259278139
-------------------------	------------

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: 1181**

Folder: Baseline (Day 0)

Form: Oxysterol results (12)

Generated On: 20 Jul 2016 16:51:47

Sample Accession number	3259278139
-------------------------	------------

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: 1181**

Folder: Baseline (Day 0)

Form: Lab_BU_COHB (1)

Data signed: (hfarmer1) 27 Mar 2015 14:30:57

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05115150001170
Analyte	CARBOXYHEMOGLOBIN
Sample type	BLOOD
Result	2.30
Result Unit	%
Lab Status	OK
Sample comment	.
Detection method	SPECTROPHOTOMETRIC
Lower limit of quantification	0.500
Planned time point (Hour)	6
Day of Visit	0
Celerion Study Number	AA99128-16
Date of Collection	2014-FEB-28
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day 0)

Form: Lab_BU_COHB (1)

Data signed: (hfarmer1) 27 Mar 2015 14:30:57

Generated On: 20 Jul 2016 16:51:47

Start Day (24 hour urine only) _____

End Day (24 hour Urine Only) _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day 0)

Form: Lab_BU_COHB (2)

Data signed: (hfarmer1) 27 Mar 2015 14:30:57

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05115150001171
Analyte	CARBOXYHEMOGLOBIN
Sample type	BLOOD
Result	2.90
Result Unit	%
Lab Status	OK
Sample comment	.
Detection method	SPECTROPHOTOMETRIC
Lower limit of quantification	0.500
Planned time point (Hour)	20
Day of Visit	0
Celerion Study Number	AA99128-16
Date of Collection	2014-FEB-28
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day 0)

Form: Lab_BU_COHB (2)

Data signed: (hfarmer1) 27 Mar 2015 14:30:57

Generated On: 20 Jul 2016 16:51:47

Start Day (24 hour urine only) _____

End Day (24 hour Urine Only) _____

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Baseline (Day 0)

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)

Data signed: (hfarmer1) 27 Mar 2015 14:30:17

Generated On: 20 Jul 2016 16:51:47

Date of Birth

(b) (6)

Date of assessment

2014 FEB 28

DD/MMM/YYYY

DD/MMM/YYYY

Time of assessment

20:05

hour:min 24-hour clock

Assessment Status

Completed ☒

1. Was smoking satisfying?

Moderately ☒

2. Did cigarettes taste good?

Moderately ☒

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

Moderately ☒

4. Did smoking calm you down?

Moderately ☒

5. Did smoking make you feel more awake?

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: 1181**

Folder: Baseline (Day 0)

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)

Data signed: (hfarmer1) 27 Mar 2015 14:30:17

Generated On: 20 Jul 2016 16:51:47

9. Did smoking make you dizzy? Moderately ☒

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

11. Did smoking immediately relieve your craving for a
cigarette? Little ☒

12. Did you enjoy smoking? Moderately ☒

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Baseline (Day 0)

Form: Human Smoking Topography Questionnaire

Data signed: (hfarmer1) 27 Mar 2015 14:30:17

Generated On: 20 Jul 2016 16:51:47

Type	HUMAN SMOKING TOPOGRAPHY QUESTIONNAIRE
------	--

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

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

Date of assessment	28 FEB 2014 DD/MMM/YYYY
--------------------	----------------------------

Time of assessment	21:09 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.	Agree <input type="radio"/>
--	-----------------------------

If you agree or strongly agree, please describe :	DOESN'T WORK RIGHT, THE NICOTINE AS STRONG.
---	--

2. You enjoy smoking with the device as much as without it.	Strongly disagree <input type="radio"/>
---	---

If you disagree or strongly disagree, please describe :	THE NICOTINE ISN'T AS STRONG.
---	----------------------------------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day 0)

Form: Human Smoking Topography Questionnaire

Data signed: (hfarmer1) 27 Mar 2015 14:30:17

Generated On: 20 Jul 2016 16:51:47

3. The taste of the conventional cigarettes/products is
different with the device.

Agree ☒

If you agree or strongly agree, please describe :

LITTLE DIFFERENT.

4. The device is easy to use.

Disagree ☒

If you disagree or strongly disagree, please describe : _____

5. Your smoking is disturbed by the device.

Neither agree nor disagree ☒

If you agree or strongly agree, please describe : _____

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Baseline (Day 0)

Form: Questionnaire on smoking urges (QSU)

Data signed: (hfarmer1) 27 Mar 2015 14:30:18

Generated On: 20 Jul 2016 16:51:47

Type	QSU
Date of Birth	(b) (6)
Date of assessment	2014 FEB 28
DD/MMM/YYYY	
Time of assessment	20:03
hour:min 24-hour clock	
Assessment Status	Completed <input type="radio"/>
1. I have a desire for a cigarette right now	Disagree <input type="radio"/>
2. Nothing would be better than smoking a cigarette right now	Disagree <input type="radio"/>
3. If it were possible I would probably smoke now	Disagree <input type="radio"/>
4. I could control things better right now if I could smoke	Strongly disagree <input type="radio"/>
5. All I want right now is a cigarette	Disagree <input type="radio"/>
6. I have an urge for a cigarette	Disagree <input type="radio"/>

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day 0)

Form: Questionnaire on smoking urges (QSU)

Data signed: (hfarmer1) 27 Mar 2015 14:30:18

Generated On: 20 Jul 2016 16:51:47

7. A cigarette would taste good now Disagree ☐

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

9. Smoking would make me less depressed Strongly disagree ☐

10. I am going to smoke as soon as possible Disagree ☐

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:30:37

Generated On: 20 Jul 2016 16:51:47

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	1181
----------------------	------

Subject Sex	M
-------------	---

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

Visit Name	DAY0
------------	------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	W592781
--------------	---------

Actual Collection Date	2014 02 28
------------------------	------------

Actual Collection Time	06:30
------------------------	-------

Specimen Condition	
--------------------	--

Battery ID	HM1054
------------	--------

Battery Name	HEMOGLOBIN A1C
--------------	----------------

Lab Test ID	HMT370
-------------	--------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:30:37

Generated On: 20 Jul 2016 16:51:47

Lab Test Name

HEMOGLOBIN
A1C,VARIANT(-70)

Test ID

Test Status

Done ☒

Reported Text Result

5.0

Reported Numeric Result

5.0

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: 1181**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:30:37

Generated On: 20 Jul 2016 16:51:47

SI Text Result

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (2)

Data signed: (hfarmer1) 27 Mar 2015 14:30:37

Generated On: 20 Jul 2016 16:51:47

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	1181
----------------------	------

Subject Sex	M
-------------	---

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

Visit Name	DAY0
------------	------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	W592781
--------------	---------

Actual Collection Date	2014 02 28
------------------------	------------

Actual Collection Time	06:30
------------------------	-------

Specimen Condition	
--------------------	--

Battery ID	RC6871
------------	--------

Battery Name	HDL
--------------	-----

Lab Test ID	RCT1684
-------------	---------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (2)

Data signed: (hfarmer1) 27 Mar 2015 14:30:37


Generated On: 20 Jul 2016 16:51:47

Lab Test Name

DIRECT HDL-C 3RD
GENERATION

Test ID

Test Status

Done 

Reported Text Result

51

Reported Numeric Result

51

Reference Range low

30

Reference Range high

63

Range Units

MG/DL

Conventional Text Result

Conventional Numeric Result

Conventional Reference Range Low

Conventional Reference Range High

Conventional Units

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (2)

Data signed: (hfarmer1) 27 Mar 2015 14:30:37

Generated On: 20 Jul 2016 16:51:47

SI Text Result

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (3)

Data signed: (hfarmer1) 27 Mar 2015 14:30:37

Generated On: 20 Jul 2016 16:51:47

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	1181
----------------------	------

Subject Sex	M
-------------	---

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

Visit Name	DAY0
------------	------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	W592781
--------------	---------

Actual Collection Date	2014 02 28
------------------------	------------

Actual Collection Time	06:30
------------------------	-------

Specimen Condition	
--------------------	--

Battery ID	SC3249
------------	--------

Battery Name	HS-CRP
--------------	--------

Lab Test ID	SCT1528
-------------	---------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (3)

Data signed: (hfarmer1) 27 Mar 2015 14:30:37

Generated On: 20 Jul 2016 16:51:47

Lab Test Name	C-REACTIVE PROTEIN (NHS)-QT
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	0.033
Reported Numeric Result	0.033
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: 1181**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (3)

Data signed: (hfarmer1) 27 Mar 2015 14:30:37

Generated On: 20 Jul 2016 16:51:47

SI Text Result

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (4)

Data signed: (hfarmer1) 27 Mar 2015 14:30:37

Generated On: 20 Jul 2016 16:51:47

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	1181
----------------------	------

Subject Sex	M
-------------	---

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

Visit Name	DAY0
------------	------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	W592781
--------------	---------

Actual Collection Date	2014 02 28
------------------------	------------

Actual Collection Time	06:30
------------------------	-------

Specimen Condition	
--------------------	--

Battery ID	SC3582
------------	--------

Battery Name	APOLIPOPROTEIN
--------------	----------------

Lab Test ID	SCT3639
-------------	---------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (4)

Data signed: (hfarmer1) 27 Mar 2015 14:30:37

Generated On: 20 Jul 2016 16:51:47

Lab Test Name	APOLIPOPROTEIN A1, RAND
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	138
Reported Numeric Result	138
Reference Range low	110
Reference Range high	205
Range Units	MG/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (4)

Data signed: (hfarmer1) 27 Mar 2015 14:30:37

Generated On: 20 Jul 2016 16:51:47

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (5)

Data signed: (hfarmer1) 27 Mar 2015 14:30:37

Generated On: 20 Jul 2016 16:51:47

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	1181
----------------------	------

Subject Sex	M
-------------	---

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

Visit Name	DAY0
------------	------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	W592781
--------------	---------

Actual Collection Date	2014 02 28
------------------------	------------

Actual Collection Time	06:30
------------------------	-------

Specimen Condition	
--------------------	--

Battery ID	SC3582
------------	--------

Battery Name	APOLIPOPROTEIN
--------------	----------------

Lab Test ID	SCT3643
-------------	---------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (5)

Data signed: (hfarmer1) 27 Mar 2015 14:30:37

Generated On: 20 Jul 2016 16:51:47

Lab Test Name	APOLIPOPROTEIN B, RAND
---------------	------------------------

Test ID	<hr/>
---------	-------

Test Status	Done <input checked="" type="radio"/>
-------------	---------------------------------------

Reported Text Result	92
----------------------	----

Reported Numeric Result	92
-------------------------	----

Reference Range low	55
---------------------	----

Reference Range high	140
----------------------	-----

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: 1181**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (5)

Data signed: (hfarmer1) 27 Mar 2015 14:30:37

Generated On: 20 Jul 2016 16:51:47

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (6)

Data signed: (hfarmer1) 27 Mar 2015 14:30:37

Generated On: 20 Jul 2016 16:51:47

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	1181
----------------------	------

Subject Sex	M
-------------	---

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

Visit Name	DAY0
------------	------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	W592781
--------------	---------

Actual Collection Date	2014 02 28
------------------------	------------

Actual Collection Time	06:30
------------------------	-------

Specimen Condition	
--------------------	--

Battery ID	CG267
------------	-------

Battery Name	FIBRINOGEN
--------------	------------

Lab Test ID	CGT285
-------------	--------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (6)

Data signed: (hfarmer1) 27 Mar 2015 14:30:37

Generated On: 20 Jul 2016 16:51:47

Lab Test Name	FIBRINOGEN
Test ID	
Test Status	Done <input checked="" type="checkbox"/>
Reported Text Result	244
Reported Numeric Result	244
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: 1181**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (6)

Data signed: (hfarmer1) 27 Mar 2015 14:30:37

Generated On: 20 Jul 2016 16:51:47

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (7)

Data signed: (hfarmer1) 27 Mar 2015 14:30:37

Generated On: 20 Jul 2016 16:51:47

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	1181
----------------------	------

Subject Sex	M
-------------	---

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

Visit Name	DAY0
------------	------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	W592781
--------------	---------

Actual Collection Date	2014 02 28
------------------------	------------

Actual Collection Time	06:30
------------------------	-------

Specimen Condition	
--------------------	--

Battery ID	CN236
------------	-------

Battery Name	HOMOCYSTEINE
--------------	--------------

Lab Test ID	CNT145
-------------	--------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (7)

Data signed: (hfarmer1) 27 Mar 2015 14:30:37

Generated On: 20 Jul 2016 16:51:47

Lab Test Name	HOMOCYSTEINE, EDTAPL
Test ID	
Test Status	Done <input checked="" type="checkbox"/>
Reported Text Result	10.59
Reported Numeric Result	10.59
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: 1181**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (7)

Data signed: (hfarmer1) 27 Mar 2015 14:30:37

Generated On: 20 Jul 2016 16:51:47

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (8)

Data signed: (hfarmer1) 27 Mar 2015 14:30:37

Generated On: 20 Jul 2016 16:51:47

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	1181
----------------------	------

Subject Sex	M
-------------	---

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

Visit Name	DAY0
------------	------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	W592781
--------------	---------

Actual Collection Date	2014 02 28
------------------------	------------

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: 1181**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (8)

Data signed: (hfarmer1) 27 Mar 2015 14:30:37

Generated On: 20 Jul 2016 16:51:47

Lab Test Name	SICAM-1-RUO
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	90.6
Reported Numeric Result	90.6
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: 1181**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (8)

Data signed: (hfarmer1) 27 Mar 2015 14:30:37

Generated On: 20 Jul 2016 16:51:47

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: 1181

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (9)

Data signed: (hfarmer1) 27 Mar 2015 14:30:37

Generated On: 20 Jul 2016 16:51:47

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	1181
----------------------	------

Subject Sex	M
-------------	---

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

Visit Name	DAY0
------------	------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	W592781
--------------	---------

Actual Collection Date	2014 02 28
------------------------	------------

Actual Collection Time	06:30
------------------------	-------

Specimen Condition	
--------------------	--

Battery ID	RC9267
------------	--------

Battery Name	LDL
--------------	-----

Lab Test ID	RCT2394
-------------	---------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (9)

Data signed: (hfarmer1) 27 Mar 2015 14:30:37

Generated On: 20 Jul 2016 16:51:47

Lab Test Name	DIRECT LDL-C 2ND GEN (-70)
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Test ID	<hr/>
---------	-------

Test Status	Done 
-------------	--

Reported Text Result	129
----------------------	-----

Reported Numeric Result	129
-------------------------	-----

Reference Range low	66
---------------------	----

Reference Range high	147
----------------------	-----

Range Units	MG/DL
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Conventional Text Result	<hr/>
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Conventional Numeric Result	<hr/>
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Conventional Reference Range Low	<hr/>
----------------------------------	-------

Conventional Reference Range High	<hr/>
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Conventional Units	<hr/>
--------------------	-------

SI Text Result	<hr/>
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (9)

Data signed: (hfarmer1) 27 Mar 2015 14:30:37

Generated On: 20 Jul 2016 16:51:47

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (CEMA, HPMA, HBMA)

Data signed: (hfarmer1) 27 Mar 2015 14:31:06

Generated On: 20 Jul 2016 16:51:47

Sample type

URINE

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Baseline (Day 0)

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:31:06

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05112450002061
Analyte	HPMA
Sample type	URINE
Result	286
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-FEB-28
Timepoint-minutes	
Urine Start Day	0

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:31:06

Generated On: 20 Jul 2016 16:51:47

Urine End Day	1
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (2)

Data signed: (hfarmer1) 27 Mar 2015 14:31:06

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05112450002061
Analyte	CEMA
Sample type	URINE
Result	35.1
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-FEB-28
Timepoint-minutes	
Urine Start Day	0

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (2)

Data signed: (hfarmer1) 27 Mar 2015 14:31:06

Generated On: 20 Jul 2016 16:51:47

Urine End Day	1
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (3)

Data signed: (hfarmer1) 27 Mar 2015 14:31:06

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05112450002061
Analyte	HBMA
Sample type	URINE
Result	200
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-FEB-28
Timepoint-minutes	
Urine Start Day	0

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (3)

Data signed: (hfarmer1) 27 Mar 2015 14:31:06

Generated On: 20 Jul 2016 16:51:47

Urine End Day	1
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (NNN, NNAL)

Data signed: (hfarmer1) 27 Mar 2015 14:30:58

Generated On: 20 Jul 2016 16:51:47

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (NNN, NNAL) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:30:58

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05112460002456
Analyte	NNAL
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	0
Celerion Study Number	AA99128-04
Date of Collection	2014-FEB-28
Timepoint-minutes	
Urine Start Day	0

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (NNN, NNAL) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:30:58

Generated On: 20 Jul 2016 16:51:47

Urine End Day	1
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (NNN, NNAL) (2)

Data signed: (hfarmer1) 27 Mar 2015 14:30:58

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05112460002456
Analyte	NNN
Sample type	URINE
Result	0.742
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	AA99128-04
Date of Collection	2014-FEB-28
Timepoint-minutes	
Urine Start Day	0

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (NNN, NNAL) (2)

Data signed: (hfarmer1) 27 Mar 2015 14:30:58

Generated On: 20 Jul 2016 16:51:47

Urine End Day	1
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (HEMA)

Data signed: (hfarmer1) 27 Mar 2015 14:30:58

Generated On: 20 Jul 2016 16:51:47

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (HEMA) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:30:58

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05112470001224
Analyte	HEMA
Sample type	URINE
Result	1.54
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-FEB-28
Timepoint-minutes	
Urine Start Day	0

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (HEMA) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:30:58

Generated On: 20 Jul 2016 16:51:47

Urine End Day	1
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day 0)

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

Data signed: (hfarmer1) 27 Mar 2015 14:31:06

Generated On: 20 Jul 2016 16:51:47

Sample type

URINE

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Baseline (Day 0)

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

Data signed: (hfarmer1) 27 Mar 2015 14:31:06

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05112480001103
Analyte	COT
Sample type	URINE
Result	236
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-01
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day 0)

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

Data signed: (hfarmer1) 27 Mar 2015 14:31:06

Generated On: 20 Jul 2016 16:51:47

Urine Start Day	0
<hr/>	
Urine End Day	1
<hr/>	

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Baseline (Day 0)

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

Data signed: (hfarmer1) 27 Mar 2015 14:31:06

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05112480001103
Analyte	COT-GLUC
Sample type	URINE
Result	322
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-01
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day 0)

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

Data signed: (hfarmer1) 27 Mar 2015 14:31:06

Generated On: 20 Jul 2016 16:51:47

Urine Start Day	0
<hr/>	
Urine End Day	1
<hr/>	

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Baseline (Day 0)

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

Data signed: (hfarmer1) 27 Mar 2015 14:31:06

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05112480001103
Analyte	NIC
Sample type	URINE
Result	80.5
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-01
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day 0)

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

Data signed: (hfarmer1) 27 Mar 2015 14:31:06

Generated On: 20 Jul 2016 16:51:47

Urine Start Day	0
<hr/>	
Urine End Day	1
<hr/>	

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Baseline (Day 0)

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

Data signed: (hfarmer1) 27 Mar 2015 14:31:06

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05112480001103
Analyte	NIC-GLUC
Sample type	URINE
Result	90.4
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-01
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day 0)

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

Data signed: (hfarmer1) 27 Mar 2015 14:31:06

Generated On: 20 Jul 2016 16:51:47

Urine Start Day	0
<hr/>	
Urine End Day	1
<hr/>	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day 0)

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

Data signed: (hfarmer1) 27 Mar 2015 14:31:06

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05112480001103
Analyte	THCOT
Sample type	URINE
Result	213
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-01
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day 0)

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

Data signed: (hfarmer1) 27 Mar 2015 14:31:06

Generated On: 20 Jul 2016 16:51:47

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: 1181

Folder: Baseline (Day 0)

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

Data signed: (hfarmer1) 27 Mar 2015 14:31:06

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05112480001103
Analyte	THCOT-GLUC
Sample type	URINE
Result	BLQ<(200)
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-01
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day 0)

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

Data signed: (hfarmer1) 27 Mar 2015 14:31:06

Generated On: 20 Jul 2016 16:51:47

Urine Start Day	0
<hr/>	
Urine End Day	1
<hr/>	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (3-OH BaP)

Data signed: (hfarmer1) 27 Mar 2015 14:31:07

Generated On: 20 Jul 2016 16:51:47

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (3-OH BaP) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:31:07

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05112490001224
Analyte	3-OH BAP
Sample type	URINE
Result	BLQ<(25.0)
Result Unit	FG/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	AA99128-07
Date of Collection	2014-FEB-28
Timepoint-minutes	
Urine Start Day	0

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (3-OH BaP) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:31:07

Generated On: 20 Jul 2016 16:51:47

Urine End Day	1
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day 0)

Form: Biomarker-Plasma (Caffeine, Paraxanthine)

Generated On: 20 Jul 2016 16:51:47

Sample type

PLASMA

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day 0)

Form: Biomarker-Plasma (Caffeine, Paraxanthine) (1)

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05112500000334
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Analyte	CAFFEINE
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Sample type	PLASMA
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Result	2450
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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	0
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Celerion Study Number	AA99128-08
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Date of Collection	2014-FEB-28
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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: 1181**

Folder: Baseline (Day 0)

Form: Biomarker-Plasma (Caffeine, Paraxanthine) (1)

Generated On: 20 Jul 2016 16:51:47

Urine End Day	0
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day 0)

Form: Biomarker-Plasma (Caffeine, Paraxanthine) (2)

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05112500000334
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Analyte	PARAXANTHINE
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Sample type	PLASMA
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Result	1400
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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	0
--------------	---

Celerion Study Number	AA99128-08
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Date of Collection	2014-FEB-28
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Timepoint-minutes	0
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Urine Start Day	
-----------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day 0)

Form: Biomarker-Plasma (Caffeine, Paraxanthine) (2)

Generated On: 20 Jul 2016 16:51:47

Urine End Day	0
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day 0)

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

Data signed: (hfarmer1) 27 Mar 2015 14:31:07

Generated On: 20 Jul 2016 16:51:47

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day 0)

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

Data signed: (hfarmer1) 27 Mar 2015 14:31:07

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05112510001224
Analyte	1-NA
Sample type	URINE
Result	6.11
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-FEB-28
Timepoint-minutes	
Urine Start Day	0

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day 0)

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

Data signed: (hfarmer1) 27 Mar 2015 14:31:07

Generated On: 20 Jul 2016 16:51:47

Urine End Day	1
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day 0)

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

Data signed: (hfarmer1) 27 Mar 2015 14:31:07

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05112510001224
Analyte	2-NA
Sample type	URINE
Result	BLQ<(2.50)
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-FEB-28
Timepoint-minutes	
Urine Start Day	0

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day 0)

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

Data signed: (hfarmer1) 27 Mar 2015 14:31:07

Generated On: 20 Jul 2016 16:51:47

Urine End Day	1
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (3)

Data signed: (hfarmer1) 27 Mar 2015 14:31:07

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05112510001224
Analyte	4-ABP
Sample type	URINE
Result	1.84
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-FEB-28
Timepoint-minutes	
Urine Start Day	0

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (3)

Data signed: (hfarmer1) 27 Mar 2015 14:31:07

Generated On: 20 Jul 2016 16:51:47

Urine End Day	1
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day 0)

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

Data signed: (hfarmer1) 27 Mar 2015 14:31:07

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05112510001224
Analyte	O-TOL
Sample type	URINE
Result	BLQ<(50.0)
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	0
Celerion Study Number	AA99128-09
Date of Collection	2014-FEB-28
Timepoint-minutes	
Urine Start Day	0

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day 0)

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

Data signed: (hfarmer1) 27 Mar 2015 14:31:07

Generated On: 20 Jul 2016 16:51:47

Urine End Day	1
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (11-dTXb2)

Data signed: (hfarmer1) 27 Mar 2015 14:31:02

Generated On: 20 Jul 2016 16:51:47

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (11-dTXb2) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:31:02

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05112530000395
Analyte	11-DTXB2
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	AA99128-11
Date of Collection	2014-FEB-28
Timepoint-minutes	
Urine Start Day	0

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (11-dTXb2) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:31:02

Generated On: 20 Jul 2016 16:51:47

Urine End Day	1
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (iPF2a-III)

Data signed: (hfarmer1) 27 Mar 2015 14:31:03

Generated On: 20 Jul 2016 16:51:47

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (iPF2a-III) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:31:03

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05112540000395
Analyte	IPF2A-III
Sample type	URINE
Result	61.3
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	AA99128-12
Date of Collection	2014-FEB-28
Timepoint-minutes	
Urine Start Day	0

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (iPF2a-III) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:31:03

Generated On: 20 Jul 2016 16:51:47

Urine End Day	1
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (Ames)

Data signed: (hfarmer1) 27 Mar 2015 14:31:08

Generated On: 20 Jul 2016 16:51:47

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (Ames) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:31:08

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05113320000085
Analyte	AMES
Sample type	URINE
Result	.
Result Unit	REV/ML
Lab Status	OK
Sample comment	ANALYSIS NOT PERFORMED IN ERROR
Detection method	COUNT
Planned time point (Hour)	0
Day of Visit	0
Celerion Study Number	AA99128-15
Date of Collection	2014-FEB-28
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (Ames) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:31:08

Generated On: 20 Jul 2016 16:51:47

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: 1181**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (1-OHP)

Data signed: (hfarmer1) 27 Mar 2015 14:31:08

Generated On: 20 Jul 2016 16:51:47

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day 0)

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

Data signed: (hfarmer1) 27 Mar 2015 14:31:08

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05115190001543
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Analyte	1-OHP
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Sample type	URINE
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Result	.
--------	---

Result Unit	PG/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	AA99598-03
-----------------------	------------

Date of Collection	2014-FEB-28
--------------------	-------------

Timepoint-minutes	
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Urine Start Day	0
-----------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day 0)

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

Data signed: (hfarmer1) 27 Mar 2015 14:31:08

Generated On: 20 Jul 2016 16:51:47

Urine End Day	1
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (SPMA, SBMA)

Data signed: (hfarmer1) 27 Mar 2015 14:31:03

Generated On: 20 Jul 2016 16:51:47

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day 0)

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

Data signed: (hfarmer1) 27 Mar 2015 14:31:03

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05115170001521
----------------	----------------

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	0
--------------	---

Celerion Study Number	AA99598-01
-----------------------	------------

Date of Collection	2014-FEB-28
--------------------	-------------

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

Urine Start Day	0
-----------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day 0)

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

Data signed: (hfarmer1) 27 Mar 2015 14:31:03

Generated On: 20 Jul 2016 16:51:47

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (SPMA, SBMA) (2)

Data signed: (hfarmer1) 27 Mar 2015 14:31:03

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05115170001521
----------------	----------------

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-FEB-28
--------------------	-------------

Timepoint-minutes	
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Urine Start Day	0
-----------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (SPMA, SBMA) (2)

Data signed: (hfarmer1) 27 Mar 2015 14:31:03

Generated On: 20 Jul 2016 16:51:47

Urine End Day	1
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (MHBMA)

Data signed: (hfarmer1) 27 Mar 2015 14:31:04

Generated On: 20 Jul 2016 16:51:47

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (MHBMA) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:31:04

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05115180001543
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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-FEB-28
--------------------	-------------

Timepoint-minutes	
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Urine Start Day	0
-----------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (MHBMA) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:31:04

Generated On: 20 Jul 2016 16:51:47

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (Creatinine)

Data signed: (hfarmer1) 27 Mar 2015 14:31:08

Generated On: 20 Jul 2016 16:51:47

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (Creatinine) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:31:08

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05115160001224
Analyte	CREATININE
Sample type	URINE
Result	42.3
Result Unit	MG/DL
Lab Status	OK
Sample comment	ANALYSIS NOT REQUIRED
Detection method	SPECTROPHOTOMETRIC
Planned time point (Hour)	0
Day of Visit	0
Celerion Study Number	AA99128-14
Date of Collection	2014-FEB-28
Timepoint-minutes	
Urine Start Day	0

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (Creatinine) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:31:08

Generated On: 20 Jul 2016 16:51:47

Urine End Day	1
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day 0)

Form: Biomarker-Plasma (Nic, Cot, tHCot)

Generated On: 20 Jul 2016 16:51:47

Sample type

PLASMA

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day 0)

Form: Biomarker-Plasma (Nic, Cot, tHCot) (1)

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05112430001901
----------------	----------------

Analyte	COT
---------	-----

Sample type	PLASMA
-------------	--------

Result	67.8
--------	------

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-FEB-28
--------------------	-------------

Timepoint-minutes	0
-------------------	---

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day 0)

Form: Biomarker-Plasma (Nic, Cot, tHCot) (1)

Generated On: 20 Jul 2016 16:51:47

Urine End Day	0
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day 0)

Form: Biomarker-Plasma (Nic, Cot, tHCot) (2)

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05112430001901
----------------	----------------

Analyte	NIC
---------	-----

Sample type	PLASMA
-------------	--------

Result	7.82
--------	------

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-FEB-28
--------------------	-------------

Timepoint-minutes	0
-------------------	---

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day 0)

Form: Biomarker-Plasma (Nic, Cot, tHCot) (2)

Generated On: 20 Jul 2016 16:51:47

Urine End Day	0
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day 0)

Form: Biomarker-Plasma (Nic, Cot, tHCot) (3)

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05112520000334
----------------	----------------

Analyte	COT
---------	-----

Sample type	PLASMA
-------------	--------

Result	55.1
--------	------

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-FEB-28
--------------------	-------------

Timepoint-minutes	0
-------------------	---

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day 0)

Form: Biomarker-Plasma (Nic, Cot, tHCot) (3)

Generated On: 20 Jul 2016 16:51:47

Urine End Day	0
---------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day 0)

Form: Biomarker-Plasma (Nic, Cot, tHCot) (4)

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05112520000334
----------------	----------------

Analyte	THCOT
---------	-------

Sample type	PLASMA
-------------	--------

Result	11.2
--------	------

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-FEB-28
--------------------	-------------

Timepoint-minutes	0
-------------------	---

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Baseline (Day 0)

Form: Biomarker-Plasma (Nic, Cot, tHCot) (4)

Generated On: 20 Jul 2016 16:51:47

Urine End Day	0
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 1

Form: Date of Visit

Data signed: (hfarmer1) 27 Mar 2015 14:31:08

Generated On: 20 Jul 2016 16:51:47

Date of Visit

01 MAR 2014
DD/MMM/YYYY

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 1

Form: Vital Signs

Data signed: (hfarmer1) 27 Mar 2015 14:31:08

Generated On: 20 Jul 2016 16:51:47

Were Vitals Signs assessed? Yes ☒

If No, please specify the reason: _____

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

Time of assessment 10:14
hour:min 24-hour clock

Pulse rate 67
beats per minute

Respiratory rate 14
breaths per minute

Blood Pressure (systolic) 130
mmHg

Blood Pressure (diastolic) 76
mmHg

Vital Signs Position of Subject Supine ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 1

Form: Plasma Nicotine Sample

Data signed: (hfarmer1) 27 Mar 2015 14:31:08

Generated On: 20 Jul 2016 16:51:47

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	01 MAR 2014
---------------------	-------------

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 1

Form: Plasma Cotinine Sample

Data signed: (hfarmer1) 27 Mar 2015 14:31:08

Generated On: 20 Jul 2016 16:51:47

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	01 MAR 2014
---------------------	-------------

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 1

Form: CoHb Blood Sample

Data signed: (hfarmer1) 27 Mar 2015 14:31:08

Generated On: 20 Jul 2016 16:51:47

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	01 MAR 2014
---------------------	-------------

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

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 1

Form: CO Breath Test (1)

Data signed: (hfarmer1) 27 Mar 2015 14:31:08

Generated On: 20 Jul 2016 16:51:47

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

If Not Done, please specify the reason: _____

Scheduled Time	Within 15 min prior to smoking <input checked="" type="radio"/>
----------------	---

Actual Time of Assessment hour:min 24-hour clock	06:48
---	-------

Result(ppm)	4
-------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 1

Form: CO Breath Test (2)

Data signed: (hfarmer1) 27 Mar 2015 14:31:08

Generated On: 20 Jul 2016 16:51:47

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

If Not Done, please specify the reason: _____

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

Actual Time of Assessment hour:min 24-hour clock	12:15
---	-------

Result(ppm)	2
-------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 1

Form: CO Breath Test (3)

Data signed: (hfarmer1) 27 Mar 2015 14:31:08

Generated On: 20 Jul 2016 16:51:47

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

If Not Done, please specify the reason: _____

Scheduled Time	16:00 - 17:30 <input checked="" type="radio"/>
----------------	--

Actual Time of Assessment hour:min 24-hour clock	16:29
---	-------

Result(ppm)	5
-------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 1

Form: CO Breath Test (4)

Data signed: (hfarmer1) 27 Mar 2015 14:31:08

Generated On: 20 Jul 2016 16:51:47

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

If Not Done, please specify the reason: _____

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

Actual Time of Assessment hour:min 24-hour clock	20:45
---	-------

Result(ppm)	3
-------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 1

Form: 24 hour urine collections

Data signed: (hfarmer1) 27 Mar 2015 14:31:08

Generated On: 20 Jul 2016 16:51:47

Start Time	06:09
	hour:min 24-hour clock

End Date	02 MAR 2014
	DD/MMM/YYYY

End Time	06:23
	hour:min 24-hour clock

Volume	1973
	mL

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 1

Form: Sample Urine Collection

Data signed: (hfarmer1) 27 Mar 2015 14:31:08

Generated On: 20 Jul 2016 16:51:47

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: 1181

Folder: Day 1

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Data signed: (hfarmer1) 27 Mar 2015 14:31:09

Generated On: 20 Jul 2016 16:51:47

Date of Birth

(b) (6)

Date of assessment
DD/MMM/YYYY

2014 MAR 01
DD/MMM/YYYY

Time of assessment

06:26
hour:min 24-hour clock

Assessment Status

Completed ☒

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

How have you been feeling over the past 24 hours?

None ☐

1. Angry, irritable, frustrated

How have you been feeling over the past 24 hours?

None ☐

2. Anxious, nervous

How have you been feeling over the past 24 hours?

None ☐

3. Depressed Mood, sad

How have you been feeling over the past 24 hours?

Mild ☐

4. Desire or craving to smoke

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 1

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Data signed: (hfarmer1) 27 Mar 2015 14:31:09

Generated On: 20 Jul 2016 16:51:47

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

5. Difficulty concentrating

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

6. Increased appetite, hungry, weight gain

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

7. Insomnia, sleep problems, awakening at night

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

8. Restless

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

9. Impatient

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

10. Constipation

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

11. Dizziness

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

12. Coughing

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 1

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Data signed: (hfarmer1) 27 Mar 2015 14:31:09

Generated On: 20 Jul 2016 16:51:47

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

13. Dreaming or nightmares

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

14. Nausea

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

15. Sore Throat

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Day 1

Form: Cough Assessment

Data signed: (hfarmer1) 27 Mar 2015 14:31:09

Generated On: 20 Jul 2016 16:51:47

Date of Birth

(b) (6)

Date of assessment
DD/MMM/YYYY

2014 MAR 01
DD/MMM/YYYY

Time of assessment

06:25
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: 1181**

Folder: Day 1

Form: Lab_BU_COHB (1)

Data signed: (hfarmer1) 27 Mar 2015 14:31:09

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05115150001172
Analyte	CARBOXYHEMOGLOBIN
Sample type	BLOOD
Result	2.30
Result Unit	%
Lab Status	OK
Sample comment	.
Detection method	SPECTROPHOTOMETRIC
Lower limit of quantification	0.500
Planned time point (Hour)	20
Day of Visit	1
Celerion Study Number	AA99128-16
Date of Collection	2014-MAR-01
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 1

Form: Lab_BU_COHB (1)

Data signed: (hfarmer1) 27 Mar 2015 14:31:09

Generated On: 20 Jul 2016 16:51:47

Start Day (24 hour urine only) _____

End Day (24 hour Urine Only) _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 1

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)

Data signed: (hfarmer1) 27 Mar 2015 14:31:09

Generated On: 20 Jul 2016 16:51:47

Date of Birth

(b) (6)

Date of assessment

2014 MAR 01

DD/MMM/YYYY

DD/MMM/YYYY

Time of assessment

20:03

hour:min 24-hour clock

Assessment Status

Completed ☒

1. Was smoking satisfying?

Moderately ☒

2. Did cigarettes taste good?

Moderately ☒

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

Moderately ☒

4. Did smoking calm you down?

Moderately ☒

5. Did smoking make you feel more awake?

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: 1181**

Folder: Day 1

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)

Data signed: (hfarmer1) 27 Mar 2015 14:31:09

Generated On: 20 Jul 2016 16:51:47

9. Did smoking make you dizzy? Little ☐

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

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

12. Did you enjoy smoking? Moderately ☐

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 1

Form: Questionnaire on smoking urges (QSU)

Data signed: (hfarmer1) 27 Mar 2015 14:31:09

Generated On: 20 Jul 2016 16:51:47

Type	QSU
Date of Birth	(b) (6)
Date of assessment DD/MMM/YYYY	2014 MAR 01
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	Disagree <input type="radio"/>
2. Nothing would be better than smoking a cigarette right now	Disagree <input type="radio"/>
3. If it were possible I would probably smoke now	Disagree <input type="radio"/>
4. I could control things better right now if I could smoke	Strongly disagree <input type="radio"/>
5. All I want right now is a cigarette	Disagree <input type="radio"/>
6. I have an urge for a cigarette	Strongly disagree <input type="radio"/>

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 1

Form: Questionnaire on smoking urges (QSU)

Data signed: (hfarmer1) 27 Mar 2015 14:31:09

Generated On: 20 Jul 2016 16:51:47

7. A cigarette would taste good now Strongly disagree ☐

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

9. Smoking would make me less depressed Strongly disagree ☐

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 1

Form: Biomarker-Urine (CEMA, HPMa, HBMA)

Data signed: (hfarmer1) 27 Mar 2015 14:31:10

Generated On: 20 Jul 2016 16:51:47

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 1

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:31:10

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05112450002062
Analyte	HPMA
Sample type	URINE
Result	544
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-01
Timepoint-minutes	
Urine Start Day	1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 1

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:31:10

Generated On: 20 Jul 2016 16:51:47

Urine End Day

2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 1

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (2)

Data signed: (hfarmer1) 27 Mar 2015 14:31:10

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05112450002062
Analyte	CEMA
Sample type	URINE
Result	58.7
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-01
Timepoint-minutes	
Urine Start Day	1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 1

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (2)

Data signed: (hfarmer1) 27 Mar 2015 14:31:10

Generated On: 20 Jul 2016 16:51:47

Urine End Day

2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 1

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (3)

Data signed: (hfarmer1) 27 Mar 2015 14:31:10

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05112450002062
Analyte	HBMA
Sample type	URINE
Result	280
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-01
Timepoint-minutes	
Urine Start Day	1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 1

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (3)

Data signed: (hfarmer1) 27 Mar 2015 14:31:10

Generated On: 20 Jul 2016 16:51:47

Urine End Day

2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 1

Form: Biomarker-Urine (NNN, NNAL)

Data signed: (hfarmer1) 27 Mar 2015 14:31:09

Generated On: 20 Jul 2016 16:51:47

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 1

Form: Biomarker-Urine (NNN, NNAL) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:31:09

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05112460002457
Analyte	NNAL
Sample type	URINE
Result	32.8
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	1
Celerion Study Number	AA99128-04
Date of Collection	2014-MAR-01
Timepoint-minutes	
Urine Start Day	1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 1

Form: Biomarker-Urine (NNN, NNAL) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:31:09

Generated On: 20 Jul 2016 16:51:47

Urine End Day

2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 1

Form: Biomarker-Urine (NNN, NNAL) (2)

Data signed: (hfarmer1) 27 Mar 2015 14:31:09

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05112460002457
Analyte	NNN
Sample type	URINE
Result	0.638
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	AA99128-04
Date of Collection	2014-MAR-01
Timepoint-minutes	
Urine Start Day	1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 1

Form: Biomarker-Urine (NNN, NNAL) (2)

Data signed: (hfarmer1) 27 Mar 2015 14:31:09

Generated On: 20 Jul 2016 16:51:47

Urine End Day

2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 1

Form: Biomarker-Urine (HEMA)

Data signed: (hfarmer1) 27 Mar 2015 14:31:09

Generated On: 20 Jul 2016 16:51:47

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 1

Form: Biomarker-Urine (HEMA) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:31:09

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05112470001225
Analyte	HEMA
Sample type	URINE
Result	2.14
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-01
Timepoint-minutes	
Urine Start Day	1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 1

Form: Biomarker-Urine (HEMA) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:31:09

Generated On: 20 Jul 2016 16:51:47

Urine End Day

2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 1

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

Data signed: (hfarmer1) 27 Mar 2015 14:31:10

Generated On: 20 Jul 2016 16:51:47

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 1

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

Data signed: (hfarmer1) 27 Mar 2015 14:31:10

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05112480001104
Analyte	COT
Sample type	URINE
Result	419
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-02
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 1

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

Data signed: (hfarmer1) 27 Mar 2015 14:31:10

Generated On: 20 Jul 2016 16:51:47

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: 1181**

Folder: Day 1

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

Data signed: (hfarmer1) 27 Mar 2015 14:31:10

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05112480001104
Analyte	COT-GLUC
Sample type	URINE
Result	731
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-02
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 1

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

Data signed: (hfarmer1) 27 Mar 2015 14:31:10

Generated On: 20 Jul 2016 16:51:47

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: 1181**

Folder: Day 1

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

Data signed: (hfarmer1) 27 Mar 2015 14:31:10

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05112480001104
Analyte	NIC
Sample type	URINE
Result	87.8
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-02
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 1

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

Data signed: (hfarmer1) 27 Mar 2015 14:31:10

Generated On: 20 Jul 2016 16:51:47

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: 1181**

Folder: Day 1

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

Data signed: (hfarmer1) 27 Mar 2015 14:31:10

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05112480001104
Analyte	NIC-GLUC
Sample type	URINE
Result	105
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-02
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 1

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

Data signed: (hfarmer1) 27 Mar 2015 14:31:10

Generated On: 20 Jul 2016 16:51:47

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: 1181**

Folder: Day 1

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

Data signed: (hfarmer1) 27 Mar 2015 14:31:10

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05112480001104
Analyte	THCOT
Sample type	URINE
Result	700
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-02
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 1

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

Data signed: (hfarmer1) 27 Mar 2015 14:31:10

Generated On: 20 Jul 2016 16:51:47

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: 1181**

Folder: Day 1

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

Data signed: (hfarmer1) 27 Mar 2015 14:31:10

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05112480001104
Analyte	THCOT-GLUC
Sample type	URINE
Result	351
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-02
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 1

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

Data signed: (hfarmer1) 27 Mar 2015 14:31:10

Generated On: 20 Jul 2016 16:51:47

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: 1181**

Folder: Day 1

Form: Biomarker-Urine (3-OH BaP)

Data signed: (hfarmer1) 27 Mar 2015 14:31:10

Generated On: 20 Jul 2016 16:51:47

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 1

Form: Biomarker-Urine (3-OH BaP) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:31:10

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05112490001225
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Analyte	3-OH BAP
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Sample type	URINE
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Result	BLQ<(25.0)
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Result Unit	FG/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	AA99128-07
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Date of Collection	2014-MAR-01
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Timepoint-minutes	
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Urine Start Day	1
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 1

Form: Biomarker-Urine (3-OH BaP) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:31:10

Generated On: 20 Jul 2016 16:51:47

Urine End Day

2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 1

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

Data signed: (hfarmer1) 27 Mar 2015 14:31:10

Generated On: 20 Jul 2016 16:51:47

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 1

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

Data signed: (hfarmer1) 27 Mar 2015 14:31:10

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05112510001225
Analyte	1-NA
Sample type	URINE
Result	12.7
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-01
Timepoint-minutes	
Urine Start Day	1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 1

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

Data signed: (hfarmer1) 27 Mar 2015 14:31:10

Generated On: 20 Jul 2016 16:51:47

Urine End Day

2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 1

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

Data signed: (hfarmer1) 27 Mar 2015 14:31:10

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05112510001225
Analyte	2-NA
Sample type	URINE
Result	3.93
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-01
Timepoint-minutes	
Urine Start Day	1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 1

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

Data signed: (hfarmer1) 27 Mar 2015 14:31:10

Generated On: 20 Jul 2016 16:51:47

Urine End Day

2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 1

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (3)

Data signed: (hfarmer1) 27 Mar 2015 14:31:10

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05112510001225
Analyte	4-ABP
Sample type	URINE
Result	2.79
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-01
Timepoint-minutes	
Urine Start Day	1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 1

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (3)

Data signed: (hfarmer1) 27 Mar 2015 14:31:10

Generated On: 20 Jul 2016 16:51:47

Urine End Day

2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 1

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

Data signed: (hfarmer1) 27 Mar 2015 14:31:10

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05112510001225
Analyte	O-TOL
Sample type	URINE
Result	BLQ<(50.0)
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	1
Celerion Study Number	AA99128-09
Date of Collection	2014-MAR-01
Timepoint-minutes	
Urine Start Day	1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 1

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

Data signed: (hfarmer1) 27 Mar 2015 14:31:10

Generated On: 20 Jul 2016 16:51:47

Urine End Day

2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 1

Form: Biomarker-Urine (1-OHP)

Data signed: (hfarmer1) 27 Mar 2015 14:31:11

Generated On: 20 Jul 2016 16:51:47

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 1

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

Data signed: (hfarmer1) 27 Mar 2015 14:31:11

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05115190001544
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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
-----------------------	------------

Date of Collection	2014-MAR-01
--------------------	-------------

Timepoint-minutes	
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Urine Start Day	1
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 1

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

Data signed: (hfarmer1) 27 Mar 2015 14:31:11

Generated On: 20 Jul 2016 16:51:47

Urine End Day

2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 1

Form: Biomarker-Urine (SPMA, SBMA)

Data signed: (hfarmer1) 27 Mar 2015 14:31:09

Generated On: 20 Jul 2016 16:51:47

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 1

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

Data signed: (hfarmer1) 27 Mar 2015 14:31:09

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05115170001522
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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
-----------------------	------------

Date of Collection	2014-MAR-01
--------------------	-------------

Timepoint-minutes	
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Urine Start Day	1
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 1

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

Data signed: (hfarmer1) 27 Mar 2015 14:31:09

Generated On: 20 Jul 2016 16:51:47

Urine End Day

2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 1

Form: Biomarker-Urine (SPMA, SBMA) (2)

Data signed: (hfarmer1) 27 Mar 2015 14:31:09

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05115170001522
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-01
Timepoint-minutes	
Urine Start Day	1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 1

Form: Biomarker-Urine (SPMA, SBMA) (2)

Data signed: (hfarmer1) 27 Mar 2015 14:31:09

Generated On: 20 Jul 2016 16:51:47

Urine End Day

2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 1

Form: Biomarker-Urine (MHBMA)

Data signed: (hfarmer1) 27 Mar 2015 14:31:09

Generated On: 20 Jul 2016 16:51:47

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 1

Form: Biomarker-Urine (MHBMA) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:31:09

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05115180001544
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-01
Timepoint-minutes	
Urine Start Day	1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 1

Form: Biomarker-Urine (MHBMA) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:31:09

Generated On: 20 Jul 2016 16:51:47

Urine End Day

2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 1

Form: Biomarker-Urine (Creatinine)

Data signed: (hfarmer1) 27 Mar 2015 14:31:10

Generated On: 20 Jul 2016 16:51:47

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 1

Form: Biomarker-Urine (Creatinine) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:31:10

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05115160001225
Analyte	CREATININE
Sample type	URINE
Result	78.5
Result Unit	MG/DL
Lab Status	OK
Sample comment	ANALYSIS NOT REQUIRED
Detection method	SPECTROPHOTOMETRIC
Planned time point (Hour)	0
Day of Visit	1
Celerion Study Number	AA99128-14
Date of Collection	2014-MAR-01
Timepoint-minutes	
Urine Start Day	1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 1

Form: Biomarker-Urine (Creatinine) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:31:10

Generated On: 20 Jul 2016 16:51:47

Urine End Day

2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 1

Form: Biomarker-Plasma (Nic, Cot, tHCot)

Data signed: (hfarmer1) 27 Mar 2015 14:31:09

Generated On: 20 Jul 2016 16:51:47

Sample type

PLASMA

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 1

Form: Biomarker-Plasma (Nic, Cot, tHCot) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:31:09

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05112430001902
Analyte	COT
Sample type	PLASMA
Result	78.4
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-01
Timepoint-minutes	0
Urine Start Day	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 1

Form: Biomarker-Plasma (Nic, Cot, tHCot) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:31:09

Generated On: 20 Jul 2016 16:51:47

Urine End Day

1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 1

Form: Biomarker-Plasma (Nic, Cot, tHCot) (2)

Data signed: (hfarmer1) 27 Mar 2015 14:31:09

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05112430001902
Analyte	NIC
Sample type	PLASMA
Result	2.01
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-01
Timepoint-minutes	0
Urine Start Day	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 1

Form: Biomarker-Plasma (Nic, Cot, tHCot) (2)

Data signed: (hfarmer1) 27 Mar 2015 14:31:09

Generated On: 20 Jul 2016 16:51:47

Urine End Day

1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 2

Form: Date of Visit

Data signed: (hfarmer1) 27 Mar 2015 14:31:11

Generated On: 20 Jul 2016 16:51:47

Date of Visit

02 MAR 2014
DD/MMM/YYYY

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 2

Form: Vital Signs

Data signed: (hfarmer1) 27 Mar 2015 14:31:11

Generated On: 20 Jul 2016 16:51:47

Were Vitals Signs assessed?

Yes ☒

If No, please specify the reason: _____

Has the subject smoked within 15 minutes prior to
assessment

No ☒

Time of assessment

09:56
hour:min 24-hour clock

Pulse rate

65
beats per minute

Respiratory rate

14
breaths per minute

Blood Pressure (systolic)

131
mmHg

Blood Pressure (diastolic)

73
mmHg

Vital Signs Position of Subject

Supine ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 2

Form: Plasma Nicotine Sample

Data signed: (hfarmer1) 27 Mar 2015 14:31:11

Generated On: 20 Jul 2016 16:51:47

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	02 MAR 2014
---------------------	-------------

Time hour:min 24-hour clock	20:45
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 2

Form: Plasma Cotinine Sample

Data signed: (hfarmer1) 27 Mar 2015 14:31:11

Generated On: 20 Jul 2016 16:51:47

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	02 MAR 2014
---------------------	-------------

Time hour:min 24-hour clock	20:45
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 2

Form: CoHb Blood Sample

Data signed: (hfarmer1) 27 Mar 2015 14:31:11

Generated On: 20 Jul 2016 16:51:47

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	02 MAR 2014
---------------------	-------------

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

Time hour:min 24-hour clock	20:45
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 2

Form: CO Breath Test (1)

Data signed: (hfarmer1) 27 Mar 2015 14:31:11

Generated On: 20 Jul 2016 16:51:47

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

If Not Done, please specify the reason: _____

Scheduled Time	Within 15 min prior to smoking <input checked="" type="radio"/>
----------------	---

Actual Time of Assessment hour:min 24-hour clock	06:50
---	-------

Result(ppm)	2
-------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 2

Form: CO Breath Test (2)

Data signed: (hfarmer1) 27 Mar 2015 14:31:11

Generated On: 20 Jul 2016 16:51:47

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

If Not Done, please specify the reason: _____

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

Actual Time of Assessment hour:min 24-hour clock	12:05
---	-------

Result(ppm)	5
-------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 2

Form: CO Breath Test (3)

Data signed: (hfarmer1) 27 Mar 2015 14:31:11

Generated On: 20 Jul 2016 16:51:47

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

If Not Done, please specify the reason: _____

Scheduled Time	16:00 - 17:30 <input checked="" type="radio"/>
----------------	--

Actual Time of Assessment hour:min 24-hour clock	16:30
---	-------

Result(ppm)	4
-------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 2

Form: CO Breath Test (4)

Data signed: (hfarmer1) 27 Mar 2015 14:31:11

Generated On: 20 Jul 2016 16:51:47

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

If Not Done, please specify the reason: _____

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

Actual Time of Assessment hour:min 24-hour clock	20:33
---	-------

Result(ppm)	4
-------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 2

Form: 24 hour urine collections

Data signed: (hfarmer1) 27 Mar 2015 14:31:11

Generated On: 20 Jul 2016 16:51:47

Start Time	06:23
	hour:min 24-hour clock

End Date	03 MAR 2014
	DD/MMM/YYYY

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

Volume	2569
	mL

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 2

Form: Sample Urine Collection

Data signed: (hfarmer1) 27 Mar 2015 14:31:11

Generated On: 20 Jul 2016 16:51:47

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: 1181**

Folder: Day 2

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Data signed: (hfarmer1) 27 Mar 2015 14:31:11

Generated On: 20 Jul 2016 16:51:47

Date of Birth

(b) (6)

Date of assessment
DD/MMM/YYYY

2014 MAR 02
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?

Slight ☐

4. Desire or craving to smoke

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 2

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Data signed: (hfarmer1) 27 Mar 2015 14:31:11

Generated On: 20 Jul 2016 16:51:47

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

5. Difficulty concentrating

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

6. Increased appetite, hungry, weight gain

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

7. Insomnia, sleep problems, awakening at night

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

8. Restless

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

9. Impatient

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

10. Constipation

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

11. Dizziness

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

12. Coughing

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 2

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Data signed: (hfarmer1) 27 Mar 2015 14:31:11

Generated On: 20 Jul 2016 16:51:47

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

13. Dreaming or nightmares

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

14. Nausea

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

15. Sore Throat

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Day 2

Form: Cough Assessment

Data signed: (hfarmer1) 27 Mar 2015 14:31:11

Generated On: 20 Jul 2016 16:51:47

Date of Birth

(b) (6)

Date of assessment
DD/MMM/YYYY

2014 MAR 02
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: 1181**

Folder: Day 2

Form: Lab_BU_COHB (1)

Data signed: (hfarmer1) 27 Mar 2015 14:31:11

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05115150001173
Analyte	CARBOXYHEMOGLOBIN
Sample type	BLOOD
Result	2.30
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-02
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 2

Form: Lab_BU_COHB (1)

Data signed: (hfarmer1) 27 Mar 2015 14:31:11

Generated On: 20 Jul 2016 16:51:47

Start Day (24 hour urine only)

End Day (24 hour Urine Only)

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 2

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)

Data signed: (hfarmer1) 27 Mar 2015 14:31:11

Generated On: 20 Jul 2016 16:51:47

Date of Birth

(b) (6)

Date of assessment

2014 MAR 02

DD/MMM/YYYY

DD/MMM/YYYY

Time of assessment

20:03

hour:min 24-hour clock

Assessment Status

Completed ☒

1. Was smoking satisfying?

Moderately ☒

2. Did cigarettes taste good?

Moderately ☒

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

Moderately ☒

4. Did smoking calm you down?

Moderately ☒

5. Did smoking make you feel more awake?

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: 1181**

Folder: Day 2

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)

Data signed: (hfarmer1) 27 Mar 2015 14:31:11

Generated On: 20 Jul 2016 16:51:47

9. Did smoking make you dizzy? Little ☐

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

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

12. Did you enjoy smoking? Moderately ☐

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Day 2

Form: Questionnaire on smoking urges (QSU)

Data signed: (hfarmer1) 27 Mar 2015 14:31:11

Generated On: 20 Jul 2016 16:51:47

Type	QSU
Date of Birth	(b) (6)
Date of assessment	2014 MAR 02
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	Disagree <input type="radio"/>
2. Nothing would be better than smoking a cigarette right now	Disagree <input type="radio"/>
3. If it were possible I would probably smoke now	Disagree <input type="radio"/>
4. I could control things better right now if I could smoke	Strongly disagree <input type="radio"/>
5. All I want right now is a cigarette	Disagree <input type="radio"/>
6. I have an urge for a cigarette	Disagree <input type="radio"/>

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 2

Form: Questionnaire on smoking urges (QSU)

Data signed: (hfarmer1) 27 Mar 2015 14:31:11

Generated On: 20 Jul 2016 16:51:47

7. A cigarette would taste good now Disagree ☐

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

9. Smoking would make me less depressed Strongly disagree ☐

10. I am going to smoke as soon as possible Disagree ☐

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 2

Form: Biomarker-Urine (CEMA, HPMa, HBMA)

Data signed: (hfarmer1) 27 Mar 2015 14:31:12

Generated On: 20 Jul 2016 16:51:47

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 2

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:31:12

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05112450002063
Analyte	HPMA
Sample type	URINE
Result	377
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-02
Timepoint-minutes	
Urine Start Day	2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 2

Form: Biomarker-Urine (CEMA, HPMa, HBMA) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:31:12

Generated On: 20 Jul 2016 16:51:47

Urine End Day

3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 2

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (2)

Data signed: (hfarmer1) 27 Mar 2015 14:31:12

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05112450002063
Analyte	CEMA
Sample type	URINE
Result	38.2
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-02
Timepoint-minutes	
Urine Start Day	2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 2

Form: Biomarker-Urine (CEMA, HPMa, HBMA) (2)

Data signed: (hfarmer1) 27 Mar 2015 14:31:12

Generated On: 20 Jul 2016 16:51:47

Urine End Day

3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 2

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (3)

Data signed: (hfarmer1) 27 Mar 2015 14:31:12

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05112450002063
Analyte	HBMA
Sample type	URINE
Result	163
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-02
Timepoint-minutes	
Urine Start Day	2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 2

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (3)

Data signed: (hfarmer1) 27 Mar 2015 14:31:12

Generated On: 20 Jul 2016 16:51:47

Urine End Day

3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 2

Form: Biomarker-Urine (NNN, NNAL)

Data signed: (hfarmer1) 27 Mar 2015 14:31:12

Generated On: 20 Jul 2016 16:51:47

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 2

Form: Biomarker-Urine (NNN, NNAL) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:31:12

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05112460002458
Analyte	NNAL
Sample type	URINE
Result	27.0
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	2
Celerion Study Number	AA99128-04
Date of Collection	2014-MAR-02
Timepoint-minutes	
Urine Start Day	2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 2

Form: Biomarker-Urine (NNN, NNAL) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:31:12

Generated On: 20 Jul 2016 16:51:47

Urine End Day

3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 2

Form: Biomarker-Urine (NNN, NNAL) (2)

Data signed: (hfarmer1) 27 Mar 2015 14:31:12

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05112460002458
Analyte	NNN
Sample type	URINE
Result	0.665
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	AA99128-04
Date of Collection	2014-MAR-02
Timepoint-minutes	
Urine Start Day	2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 2

Form: Biomarker-Urine (NNN, NNAL) (2)

Data signed: (hfarmer1) 27 Mar 2015 14:31:12

Generated On: 20 Jul 2016 16:51:47

Urine End Day

3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 2

Form: Biomarker-Urine (HEMA)

Data signed: (hfarmer1) 27 Mar 2015 14:31:12

Generated On: 20 Jul 2016 16:51:47

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 2

Form: Biomarker-Urine (HEMA) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:31:12

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05112470001226
Analyte	HEMA
Sample type	URINE
Result	1.64
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-02
Timepoint-minutes	
Urine Start Day	2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 2

Form: Biomarker-Urine (HEMA) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:31:12

Generated On: 20 Jul 2016 16:51:47

Urine End Day

3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 2

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

Data signed: (hfarmer1) 27 Mar 2015 14:31:12

Generated On: 20 Jul 2016 16:51:47

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 2

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

Data signed: (hfarmer1) 27 Mar 2015 14:31:12

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05112480001105
Analyte	COT
Sample type	URINE
Result	342
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-03
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 2

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

Data signed: (hfarmer1) 27 Mar 2015 14:31:12

Generated On: 20 Jul 2016 16:51:47

Urine Start Day	2
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Urine End Day	3
---------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 2

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

Data signed: (hfarmer1) 27 Mar 2015 14:31:12

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05112480001105
Analyte	COT-GLUC
Sample type	URINE
Result	515
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-03
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 2

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

Data signed: (hfarmer1) 27 Mar 2015 14:31:12

Generated On: 20 Jul 2016 16:51:47

Urine Start Day	2
-----------------	---

Urine End Day	3
---------------	---

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Day 2

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

Data signed: (hfarmer1) 27 Mar 2015 14:31:12

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05112480001105
Analyte	NIC
Sample type	URINE
Result	88.1
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-03
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 2

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

Data signed: (hfarmer1) 27 Mar 2015 14:31:12

Generated On: 20 Jul 2016 16:51:47

Urine Start Day	2
-----------------	---

Urine End Day	3
---------------	---

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Day 2

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

Data signed: (hfarmer1) 27 Mar 2015 14:31:12

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05112480001105
Analyte	NIC-GLUC
Sample type	URINE
Result	80.8
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-03
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 2

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

Data signed: (hfarmer1) 27 Mar 2015 14:31:12

Generated On: 20 Jul 2016 16:51:47

Urine Start Day	2
-----------------	---

Urine End Day	3
---------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 2

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

Data signed: (hfarmer1) 27 Mar 2015 14:31:12

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05112480001105
Analyte	THCOT
Sample type	URINE
Result	560
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-03
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 2

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

Data signed: (hfarmer1) 27 Mar 2015 14:31:12

Generated On: 20 Jul 2016 16:51:47

Urine Start Day	2
-----------------	---

Urine End Day	3
---------------	---

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Day 2

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

Data signed: (hfarmer1) 27 Mar 2015 14:31:12

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05112480001105
Analyte	THCOT-GLUC
Sample type	URINE
Result	291
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-03
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 2

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

Data signed: (hfarmer1) 27 Mar 2015 14:31:12

Generated On: 20 Jul 2016 16:51:47

Urine Start Day	2
-----------------	---

Urine End Day	3
---------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 2

Form: Biomarker-Urine (3-OH BaP)

Data signed: (hfarmer1) 27 Mar 2015 14:31:12

Generated On: 20 Jul 2016 16:51:47

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 2

Form: Biomarker-Urine (3-OH BaP) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:31:12

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05112490001226
----------------	----------------

Analyte	3-OH BAP
---------	----------

Sample type	URINE
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Result	BLQ<(25.0)
--------	------------

Result Unit	FG/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	AA99128-07
-----------------------	------------

Date of Collection	2014-MAR-02
--------------------	-------------

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

Urine Start Day	2
-----------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 2

Form: Biomarker-Urine (3-OH BaP) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:31:12

Generated On: 20 Jul 2016 16:51:47

Urine End Day

3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 2

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

Data signed: (hfarmer1) 27 Mar 2015 14:31:12

Generated On: 20 Jul 2016 16:51:47

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 2

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

Data signed: (hfarmer1) 27 Mar 2015 14:31:12

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05112510001226
Analyte	1-NA
Sample type	URINE
Result	11.0
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	2
Celerion Study Number	AA99128-09
Date of Collection	2014-MAR-02
Timepoint-minutes	
Urine Start Day	2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 2

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

Data signed: (hfarmer1) 27 Mar 2015 14:31:12

Generated On: 20 Jul 2016 16:51:47

Urine End Day

3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 2

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

Data signed: (hfarmer1) 27 Mar 2015 14:31:12

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05112510001226
Analyte	2-NA
Sample type	URINE
Result	3.14
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-02
Timepoint-minutes	
Urine Start Day	2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 2

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

Data signed: (hfarmer1) 27 Mar 2015 14:31:12

Generated On: 20 Jul 2016 16:51:47

Urine End Day

3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 2

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (3)

Data signed: (hfarmer1) 27 Mar 2015 14:31:12

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05112510001226
Analyte	4-ABP
Sample type	URINE
Result	2.17
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-02
Timepoint-minutes	
Urine Start Day	2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 2

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (3)

Data signed: (hfarmer1) 27 Mar 2015 14:31:12

Generated On: 20 Jul 2016 16:51:47

Urine End Day

3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 2

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

Data signed: (hfarmer1) 27 Mar 2015 14:31:12

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05112510001226
Analyte	O-TOL
Sample type	URINE
Result	BLQ<(50.0)
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	2
Celerion Study Number	AA99128-09
Date of Collection	2014-MAR-02
Timepoint-minutes	
Urine Start Day	2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 2

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

Data signed: (hfarmer1) 27 Mar 2015 14:31:12

Generated On: 20 Jul 2016 16:51:47

Urine End Day

3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 2

Form: Biomarker-Urine (1-OHP)

Data signed: (hfarmer1) 27 Mar 2015 14:31:13

Generated On: 20 Jul 2016 16:51:47

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 2

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

Data signed: (hfarmer1) 27 Mar 2015 14:31:13

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05115190001545
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Analyte	1-OHP
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Sample type	URINE
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Result	.
--------	---

Result Unit	PG/ML
-------------	-------

Lab Status	OK
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Sample comment	NOT ANALYZED IN ERROR
----------------	-----------------------

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

Date of Collection	2014-MAR-02
--------------------	-------------

Timepoint-minutes	
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Urine Start Day	2
-----------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 2

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

Data signed: (hfarmer1) 27 Mar 2015 14:31:13

Generated On: 20 Jul 2016 16:51:47

Urine End Day

3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 2

Form: Biomarker-Urine (SPMA, SBMA)

Data signed: (hfarmer1) 27 Mar 2015 14:31:12

Generated On: 20 Jul 2016 16:51:47

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 2

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

Data signed: (hfarmer1) 27 Mar 2015 14:31:12

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05115170001523
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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
-------------	-------

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-02
--------------------	-------------

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

Urine Start Day	2
-----------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 2

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

Data signed: (hfarmer1) 27 Mar 2015 14:31:12

Generated On: 20 Jul 2016 16:51:47

Urine End Day

3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 2

Form: Biomarker-Urine (SPMA, SBMA) (2)

Data signed: (hfarmer1) 27 Mar 2015 14:31:12

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05115170001523
----------------	----------------

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
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Date of Collection	2014-MAR-02
--------------------	-------------

Timepoint-minutes	
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Urine Start Day	2
-----------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 2

Form: Biomarker-Urine (SPMA, SBMA) (2)

Data signed: (hfarmer1) 27 Mar 2015 14:31:12

Generated On: 20 Jul 2016 16:51:47

Urine End Day

3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 2

Form: Biomarker-Urine (MHBMA)

Data signed: (hfarmer1) 27 Mar 2015 14:31:12

Generated On: 20 Jul 2016 16:51:47

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 2

Form: Biomarker-Urine (MHBMA) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:31:12

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05115180001545
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	2
Celerion Study Number	AA99598-02
Date of Collection	2014-MAR-02
Timepoint-minutes	
Urine Start Day	2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 2

Form: Biomarker-Urine (MHBMA) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:31:12

Generated On: 20 Jul 2016 16:51:47

Urine End Day

3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 2

Form: Biomarker-Urine (Creatinine)

Data signed: (hfarmer1) 27 Mar 2015 14:31:13

Generated On: 20 Jul 2016 16:51:47

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 2

Form: Biomarker-Urine (Creatinine) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:31:13

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05115160001226
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Analyte	CREATININE
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Sample type	URINE
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Result	57.2
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Result Unit	MG/DL
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Lab Status	OK
------------	----

Sample comment	ANALYSIS NOT REQUIRED
----------------	-----------------------

Detection method	SPECTROPHOTOMETRIC
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Planned time point (Hour)	0
---------------------------	---

Day of Visit	2
--------------	---

Celerion Study Number	AA99128-14
-----------------------	------------

Date of Collection	2014-MAR-02
--------------------	-------------

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

Urine Start Day	2
-----------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 2

Form: Biomarker-Urine (Creatinine) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:31:13

Generated On: 20 Jul 2016 16:51:47

Urine End Day

3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 2

Form: Biomarker-Plasma (Nic, Cot, tHCot)

Data signed: (hfarmer1) 27 Mar 2015 14:31:12

Generated On: 20 Jul 2016 16:51:47

Sample type

PLASMA

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 2

Form: Biomarker-Plasma (Nic, Cot, tHCot) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:31:12

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05112430001903
Analyte	COT
Sample type	PLASMA
Result	70.3
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	2
Celerion Study Number	AA99128-01
Date of Collection	2014-MAR-02
Timepoint-minutes	0
Urine Start Day	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 2

Form: Biomarker-Plasma (Nic, Cot, tHCot) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:31:12

Generated On: 20 Jul 2016 16:51:47

Urine End Day

2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 2

Form: Biomarker-Plasma (Nic, Cot, tHCot) (2)

Data signed: (hfarmer1) 27 Mar 2015 14:31:12

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05112430001903
----------------	----------------

Analyte	NIC
---------	-----

Sample type	PLASMA
-------------	--------

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	2
--------------	---

Celerion Study Number	AA99128-01
-----------------------	------------

Date of Collection	2014-MAR-02
--------------------	-------------

Timepoint-minutes	0
-------------------	---

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 2

Form: Biomarker-Plasma (Nic, Cot, tHCot) (2)

Data signed: (hfarmer1) 27 Mar 2015 14:31:12

Generated On: 20 Jul 2016 16:51:47

Urine End Day

2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 3

Form: Date of Visit

Data signed: (hfarmer1) 27 Mar 2015 14:31:13

Generated On: 20 Jul 2016 16:51:47

Date of Visit

03 MAR 2014
DD/MMM/YYYY

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 3

Form: Vital Signs

Data signed: (hcoleman1) 18 Jun 2015 21:06:54

Generated On: 20 Jul 2016 16:51:47

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

10:56
hour:min 24-hour clock

Pulse rate

67
beats per minute

Respiratory rate

16
breaths per minute

Blood Pressure (systolic)

132
mmHg

Blood Pressure (diastolic)

77
mmHg

Vital Signs Position of Subject

Supine ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 3

Form: Plasma Nicotine Sample

Data signed: (hfarmer1) 27 Mar 2015 14:31:13

Generated On: 20 Jul 2016 16:51:47

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	03 MAR 2014
---------------------	-------------

Time hour:min 24-hour clock	20:42
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 3

Form: Plasma Cotinine Sample

Data signed: (hfarmer1) 27 Mar 2015 14:31:13

Generated On: 20 Jul 2016 16:51:47

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	03 MAR 2014
---------------------	-------------

Time hour:min 24-hour clock	20:42
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 3

Form: CoHb Blood Sample

Data signed: (hfarmer1) 27 Mar 2015 14:31:13

Generated On: 20 Jul 2016 16:51:47

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	03 MAR 2014
---------------------	-------------

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

Time hour:min 24-hour clock	20:42
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 3

Form: CO Breath Test (1)

Data signed: (hfarmer1) 27 Mar 2015 14:31:13

Generated On: 20 Jul 2016 16:51:47

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

If Not Done, please specify the reason: _____

Scheduled Time	Within 15 min prior to smoking <input checked="" type="radio"/>
----------------	---

Actual Time of Assessment hour:min 24-hour clock	06:50
---	-------

Result(ppm)	3
-------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 3

Form: CO Breath Test (2)

Data signed: (hfarmer1) 27 Mar 2015 14:31:13

Generated On: 20 Jul 2016 16:51:47

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

If Not Done, please specify the reason: _____

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

Actual Time of Assessment hour:min 24-hour clock	12:10
---	-------

Result(ppm)	3
-------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 3

Form: CO Breath Test (3)

Data signed: (hfarmer1) 27 Mar 2015 14:31:13

Generated On: 20 Jul 2016 16:51:47

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

If Not Done, please specify the reason: _____

Scheduled Time	16:00 - 17:30 <input checked="" type="radio"/>
----------------	--

Actual Time of Assessment hour:min 24-hour clock	16:06
---	-------

Result(ppm)	5
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 3

Form: CO Breath Test (4)

Data signed: (hfarmer1) 27 Mar 2015 14:31:13

Generated On: 20 Jul 2016 16:51:47

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

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

Actual Time of Assessment hour:min 24-hour clock	20:19
---	-------

Result(ppm)	9
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 3

Form: 24 hour urine collections

Data signed: (hfarmer1) 27 Mar 2015 14:31:13

Generated On: 20 Jul 2016 16:51:47

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

End Date	04 MAR 2014
	DD/MMM/YYYY

End Time	06:39
	hour:min 24-hour clock

Volume	4068
	mL

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 3

Form: Sample Urine Collection

Data signed: (hfarmer1) 27 Mar 2015 14:31:13

Generated On: 20 Jul 2016 16:51:47

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: 1181**

Folder: Day 3

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Data signed: (hfarmer1) 27 Mar 2015 14:31:13

Generated On: 20 Jul 2016 16:51:47

Date of Birth	(b) (6)
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Date of assessment DD/MMM/YYYY	2014 MAR 03 DD/MMM/YYYY
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Time of assessment	06:06 hour:min 24-hour clock
--------------------	---------------------------------

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

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

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

1. Angry, irritable, frustrated

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

2. Anxious, nervous

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

3. Depressed Mood, sad

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

4. Desire or craving to smoke

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 3

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Data signed: (hfarmer1) 27 Mar 2015 14:31:13

Generated On: 20 Jul 2016 16:51:47

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

5. Difficulty concentrating

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

6. Increased appetite, hungry, weight gain

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

7. Insomnia, sleep problems, awakening at night

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

8. Restless

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

9. Impatient

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

10. Constipation

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

11. Dizziness

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

12. Coughing

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 3

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Data signed: (hfarmer1) 27 Mar 2015 14:31:13

Generated On: 20 Jul 2016 16:51:47

How have you been feeling over the past 24 hours?

None ☐

13. Dreaming or nightmares

How have you been feeling over the past 24 hours?

None ☐

14. Nausea

How have you been feeling over the past 24 hours?

None ☐

15. Sore Throat

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Day 3

Form: Cough Assessment

Data signed: (hfarmer1) 27 Mar 2015 14:31:13

Generated On: 20 Jul 2016 16:51:47

Date of Birth

(b) (6)

Date of assessment
DD/MMM/YYYY

2014 MAR 03
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: 1181**

Folder: Day 3

Form: Lab_BU_COHB (1)

Data signed: (hfarmer1) 27 Mar 2015 14:31:13

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05115150001174
Analyte	CARBOXYHEMOGLOBIN
Sample type	BLOOD
Result	3.10
Result Unit	%
Lab Status	OK
Sample comment	.
Detection method	SPECTROPHOTOMETRIC
Lower limit of quantification	0.500
Planned time point (Hour)	20
Day of Visit	3
Celerion Study Number	AA99128-16
Date of Collection	2014-MAR-03
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 3

Form: Lab_BU_COHB (1)

Data signed: (hfarmer1) 27 Mar 2015 14:31:13

Generated On: 20 Jul 2016 16:51:47

Start Day (24 hour urine only) _____

End Day (24 hour Urine Only) _____

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Day 3

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)

Data signed: (hfarmer1) 27 Mar 2015 14:31:13

Generated On: 20 Jul 2016 16:51:47

Date of Birth

(b) (6)

Date of assessment

2014 MAR 03

DD/MMM/YYYY

DD/MMM/YYYY

Time of assessment

20:05

hour:min 24-hour clock

Assessment Status

Completed ☒

1. Was smoking satisfying?

Moderately ☒

2. Did cigarettes taste good?

Moderately ☒

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

Moderately ☒

4. Did smoking calm you down?

A lot ☒

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: 1181**

Folder: Day 3

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)

Data signed: (hfarmer1) 27 Mar 2015 14:31:13

Generated On: 20 Jul 2016 16:51:47

9. Did smoking make you dizzy? Little ☐

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

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

12. Did you enjoy smoking? Moderately ☐

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 3

Form: Questionnaire on smoking urges (QSU)

Data signed: (hfarmer1) 27 Mar 2015 14:31:13

Generated On: 20 Jul 2016 16:51:47

Type	QSU
Date of Birth	(b) (6)
Date of assessment DD/MMM/YYYY	2014 MAR 03
Time of assessment hour:min 24-hour clock	20:04
Assessment Status	Completed <input type="radio"/>
1. I have a desire for a cigarette right now	Disagree <input type="radio"/>
2. Nothing would be better than smoking a cigarette right now	Disagree <input type="radio"/>
3. If it were possible I would probably smoke now	Disagree <input type="radio"/>
4. I could control things better right now if I could smoke	Disagree <input type="radio"/>
5. All I want right now is a cigarette	Disagree <input type="radio"/>
6. I have an urge for a cigarette	Disagree <input type="radio"/>

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 3

Form: Questionnaire on smoking urges (QSU)

Data signed: (hfarmer1) 27 Mar 2015 14:31:13

Generated On: 20 Jul 2016 16:51:47

7. A cigarette would taste good now Disagree ☐

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

9. Smoking would make me less depressed Strongly disagree ☐

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 3

Form: Biomarker-Urine (CEMA, HPMa, HBMA)

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

Generated On: 20 Jul 2016 16:51:47

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 3

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (1)

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

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05112450002064
Analyte	HPMA
Sample type	URINE
Result	282
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-03
Timepoint-minutes	
Urine Start Day	3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 3

Form: Biomarker-Urine (CEMA, HPMa, HBMA) (1)

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

Generated On: 20 Jul 2016 16:51:47

Urine End Day

4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 3

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (2)

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

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05112450002064
Analyte	CEMA
Sample type	URINE
Result	33.3
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	AA99128-03
Date of Collection	2014-MAR-03
Timepoint-minutes	
Urine Start Day	3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 3

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (2)

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

Generated On: 20 Jul 2016 16:51:47

Urine End Day

4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 3

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (3)

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

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05112450002064
Analyte	HBMA
Sample type	URINE
Result	193
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-03
Timepoint-minutes	
Urine Start Day	3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 3

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (3)

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

Generated On: 20 Jul 2016 16:51:47

Urine End Day

4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 3

Form: Biomarker-Urine (NNN, NNAL)

Data signed: (hfarmer1) 27 Mar 2015 14:31:13

Generated On: 20 Jul 2016 16:51:47

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 3

Form: Biomarker-Urine (NNN, NNAL) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:31:13

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05112460002459
Analyte	NNAL
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	3
Celerion Study Number	AA99128-04
Date of Collection	2014-MAR-03
Timepoint-minutes	
Urine Start Day	3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 3

Form: Biomarker-Urine (NNN, NNAL) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:31:13

Generated On: 20 Jul 2016 16:51:47

Urine End Day

4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 3

Form: Biomarker-Urine (NNN, NNAL) (2)

Data signed: (hfarmer1) 27 Mar 2015 14:31:13

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05112460002459
Analyte	NNN
Sample type	URINE
Result	1.04
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	AA99128-04
Date of Collection	2014-MAR-03
Timepoint-minutes	
Urine Start Day	3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 3

Form: Biomarker-Urine (NNN, NNAL) (2)

Data signed: (hfarmer1) 27 Mar 2015 14:31:13

Generated On: 20 Jul 2016 16:51:47

Urine End Day

4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 3

Form: Biomarker-Urine (HEMA)

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

Generated On: 20 Jul 2016 16:51:47

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 3

Form: Biomarker-Urine (HEMA) (1)

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

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05112470001227
Analyte	HEMA
Sample type	URINE
Result	1.83
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-03
Timepoint-minutes	
Urine Start Day	3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 3

Form: Biomarker-Urine (HEMA) (1)

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

Generated On: 20 Jul 2016 16:51:47

Urine End Day

4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 3

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

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

Generated On: 20 Jul 2016 16:51:47

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 3

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

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

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05112480001106
Analyte	COT
Sample type	URINE
Result	357
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-MAR-04
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 3

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

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

Generated On: 20 Jul 2016 16:51:47

Urine Start Day	3
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Urine End Day	4
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 3

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

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

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05112480001106
Analyte	COT-GLUC
Sample type	URINE
Result	570
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-MAR-04
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 3

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

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

Generated On: 20 Jul 2016 16:51:47

Urine Start Day	3
-----------------	---

Urine End Day	4
---------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 3

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

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

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05112480001106
Analyte	NIC
Sample type	URINE
Result	68.2
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-MAR-04
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 3

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

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

Generated On: 20 Jul 2016 16:51:47

Urine Start Day	3
-----------------	---

Urine End Day	4
---------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 3

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

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

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05112480001106
Analyte	NIC-GLUC
Sample type	URINE
Result	130
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-MAR-04
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 3

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

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

Generated On: 20 Jul 2016 16:51:47

Urine Start Day	3
-----------------	---

Urine End Day	4
---------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 3

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

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

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05112480001106
Analyte	THCOT
Sample type	URINE
Result	467
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-MAR-04
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 3

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

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

Generated On: 20 Jul 2016 16:51:47

Urine Start Day	3
-----------------	---

Urine End Day	4
---------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 3

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

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

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05112480001106
Analyte	THCOT-GLUC
Sample type	URINE
Result	269
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-MAR-04
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 3

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

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

Generated On: 20 Jul 2016 16:51:47

Urine Start Day	3
-----------------	---

Urine End Day	4
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 3

Form: Biomarker-Urine (3-OH BaP)

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

Generated On: 20 Jul 2016 16:51:47

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 3

Form: Biomarker-Urine (3-OH BaP) (1)

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

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05112490001227
Analyte	3-OH BAP
Sample type	URINE
Result	29.9
Result Unit	FG/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	AA99128-07
Date of Collection	2014-MAR-03
Timepoint-minutes	
Urine Start Day	3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 3

Form: Biomarker-Urine (3-OH BaP) (1)

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

Generated On: 20 Jul 2016 16:51:47

Urine End Day

4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 3

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

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

Generated On: 20 Jul 2016 16:51:47

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 3

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

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

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05112510001227
Analyte	1-NA
Sample type	URINE
Result	11.5
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	3
Celerion Study Number	AA99128-09
Date of Collection	2014-MAR-03
Timepoint-minutes	
Urine Start Day	3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 3

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

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

Generated On: 20 Jul 2016 16:51:47

Urine End Day

4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 3

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

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

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05112510001227
----------------	----------------

Analyte	2-NA
---------	------

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

Result	BLQ<(2.50)
--------	------------

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-03
--------------------	-------------

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

Urine Start Day	3
-----------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 3

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

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

Generated On: 20 Jul 2016 16:51:47

Urine End Day

4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 3

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (3)

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

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05112510001227
Analyte	4-ABP
Sample type	URINE
Result	2.61
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-03
Timepoint-minutes	
Urine Start Day	3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 3

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (3)

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

Generated On: 20 Jul 2016 16:51:47

Urine End Day

4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 3

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

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

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05112510001227
Analyte	O-TOL
Sample type	URINE
Result	BLQ<(50.0)
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-03
Timepoint-minutes	
Urine Start Day	3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 3

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

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

Generated On: 20 Jul 2016 16:51:47

Urine End Day

4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 3

Form: Biomarker-Urine (1-OHP)

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

Generated On: 20 Jul 2016 16:51:47

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 3

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

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

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05115190001546
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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	3
--------------	---

Celerion Study Number	AA99598-03
-----------------------	------------

Date of Collection	2014-MAR-03
--------------------	-------------

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

Urine Start Day	3
-----------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 3

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

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

Generated On: 20 Jul 2016 16:51:47

Urine End Day

4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 3

Form: Biomarker-Urine (SPMA, SBMA)

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

Generated On: 20 Jul 2016 16:51:47

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 3

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

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

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05115170001524
----------------	----------------

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-03
--------------------	-------------

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

Urine Start Day	3
-----------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 3

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

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

Generated On: 20 Jul 2016 16:51:47

Urine End Day

4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 3

Form: Biomarker-Urine (SPMA, SBMA) (2)

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

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05115170001524
----------------	----------------

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-03
--------------------	-------------

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

Urine Start Day	3
-----------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 3

Form: Biomarker-Urine (SPMA, SBMA) (2)

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

Generated On: 20 Jul 2016 16:51:47

Urine End Day

4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 3

Form: Biomarker-Urine (MHBMA)

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

Generated On: 20 Jul 2016 16:51:47

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 3

Form: Biomarker-Urine (MHBMA) (1)

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

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05115180001546
----------------	----------------

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	3
--------------	---

Celerion Study Number	AA99598-02
-----------------------	------------

Date of Collection	2014-MAR-03
--------------------	-------------

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

Urine Start Day	3
-----------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 3

Form: Biomarker-Urine (MHBMA) (1)

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

Generated On: 20 Jul 2016 16:51:47

Urine End Day

4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 3

Form: Biomarker-Urine (Creatinine)

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

Generated On: 20 Jul 2016 16:51:47

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 3

Form: Biomarker-Urine (Creatinine) (1)

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

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05115160001227
Analyte	CREATININE
Sample type	URINE
Result	45.9
Result Unit	MG/DL
Lab Status	OK
Sample comment	ANALYSIS NOT REQUIRED
Detection method	SPECTROPHOTOMETRIC
Planned time point (Hour)	0
Day of Visit	3
Celerion Study Number	AA99128-14
Date of Collection	2014-MAR-03
Timepoint-minutes	
Urine Start Day	3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 3

Form: Biomarker-Urine (Creatinine) (1)

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

Generated On: 20 Jul 2016 16:51:47

Urine End Day

4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 3

Form: Biomarker-Plasma (Nic, Cot, tHCot)

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

Generated On: 20 Jul 2016 16:51:47

Sample type

PLASMA

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 3

Form: Biomarker-Plasma (Nic, Cot, tHCot) (1)

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

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05112430001904
Analyte	COT
Sample type	PLASMA
Result	96.3
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-03
Timepoint-minutes	0
Urine Start Day	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 3

Form: Biomarker-Plasma (Nic, Cot, tHCot) (1)

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

Generated On: 20 Jul 2016 16:51:47

Urine End Day

3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 3

Form: Biomarker-Plasma (Nic, Cot, tHCot) (2)

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

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05112430001904
Analyte	NIC
Sample type	PLASMA
Result	9.53
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-03
Timepoint-minutes	0
Urine Start Day	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 3

Form: Biomarker-Plasma (Nic, Cot, tHCot) (2)

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

Generated On: 20 Jul 2016 16:51:47

Urine End Day

3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 4

Form: Date of Visit

Data signed: (hfarmer1) 27 Mar 2015 14:31:15

Generated On: 20 Jul 2016 16:51:47

Date of Visit

04 MAR 2014
DD/MMM/YYYY

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 4

Form: Vital Signs

Data signed: (hfarmer1) 27 Mar 2015 14:31:15

Generated On: 20 Jul 2016 16:51:47

Were Vitals Signs assessed?

Yes ☒

If No, please specify the reason: _____

Has the subject smoked within 15 minutes prior to
assessment

No ☒

Time of assessment

10:12
hour:min 24-hour clock

Pulse rate

67
beats per minute

Respiratory rate

16
breaths per minute

Blood Pressure (systolic)

137
mmHg

Blood Pressure (diastolic)

81
mmHg

Vital Signs Position of Subject

Supine ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 4

Form: Socio-Economic Status

Data signed: (hfarmer1) 27 Mar 2015 14:31:15

Generated On: 20 Jul 2016 16:51:47

Was paper questionnaire used? Yes ☒

Reason not done _____

Date 04 MAR 2014
DD/MMM/YYYY

Time 05:41
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? 03

Q4. Of these people, how many are children? 00

Q5. Of these people, how many are adults? 03

Q6. Of the adults, how many bring income into the household? 01

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 4

Form: Socio-Economic Status

Data signed: (hfarmer1) 27 Mar 2015 14:31:15

Generated On: 20 Jul 2016 16:51:47

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.

No response ☐

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 4

Form: Plasma Nicotine Sample

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

Generated On: 20 Jul 2016 16:51:47

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	04 MAR 2014
---------------------	-------------

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 4

Form: Plasma Cotinine Sample

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

Generated On: 20 Jul 2016 16:51:47

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	04 MAR 2014
---------------------	-------------

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 4

Form: CoHb Blood Sample

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

Generated On: 20 Jul 2016 16:51:47

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	04 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: 1181**

Folder: Day 4

Form: CO Breath Test (1)

Data signed: (hfarmer1) 27 Mar 2015 14:31:15

Generated On: 20 Jul 2016 16:51:47

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

If Not Done, please specify the reason: _____

Scheduled Time	Within 15 min prior to smoking <input checked="" type="radio"/>
----------------	---

Actual Time of Assessment hour:min 24-hour clock	07:13
---	-------

Result(ppm)	4
-------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 4

Form: CO Breath Test (2)

Data signed: (hfarmer1) 27 Mar 2015 14:31:15

Generated On: 20 Jul 2016 16:51:47

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

If Not Done, please specify the reason: _____

Scheduled Time	12:00 - 13:30 
----------------	---

Actual Time of Assessment hour:min 24-hour clock	12:15
---	-------

Result(ppm)	7
-------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 4

Form: CO Breath Test (3)

Data signed: (hfarmer1) 27 Mar 2015 14:31:15

Generated On: 20 Jul 2016 16:51:47

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

If Not Done, please specify the reason: _____

Scheduled Time	16:00 - 17:30 <input checked="" type="radio"/>
----------------	--

Actual Time of Assessment hour:min 24-hour clock	16:47
---	-------

Result(ppm)	7
-------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 4

Form: CO Breath Test (4)

Data signed: (hfarmer1) 27 Mar 2015 14:31:15

Generated On: 20 Jul 2016 16:51:47

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

If Not Done, please specify the reason: _____

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

Actual Time of Assessment hour:min 24-hour clock	20:05
---	-------

Result(ppm)	6
-------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 4

Form: 24 hour urine collections

Data signed: (hfarmer1) 27 Mar 2015 14:31:15

Generated On: 20 Jul 2016 16:51:47

Start Time	06:39
	hour:min 24-hour clock

End Date	05 MAR 2014
	DD/MMM/YYYY

End Time	06:32
	hour:min 24-hour clock

Volume	2488
	mL

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 4

Form: Sample Urine Collection

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

Generated On: 20 Jul 2016 16:51:47

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: 1181**

Folder: Day 4

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Data signed: (hfarmer1) 27 Mar 2015 14:31:15

Generated On: 20 Jul 2016 16:51:47

Date of Birth

(b) (6)

Date of assessment
DD/MMM/YYYY

2014 MAR 04
DD/MMM/YYYY

Time of assessment

05:39
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: 1181**

Folder: Day 4

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Data signed: (hfarmer1) 27 Mar 2015 14:31:15

Generated On: 20 Jul 2016 16:51:47

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

5. Difficulty concentrating

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

6. Increased appetite, hungry, weight gain

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

7. Insomnia, sleep problems, awakening at night

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

8. Restless

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

9. Impatient

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

10. Constipation

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

11. Dizziness

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

12. Coughing

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 4

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Data signed: (hfarmer1) 27 Mar 2015 14:31:15

Generated On: 20 Jul 2016 16:51:47

How have you been feeling over the past 24 hours?

None ☐

13. Dreaming or nightmares

How have you been feeling over the past 24 hours?

None ☐

14. Nausea

How have you been feeling over the past 24 hours?

None ☐

15. Sore Throat

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Day 4

Form: Cough Assessment

Data signed: (hfarmer1) 27 Mar 2015 14:31:15

Generated On: 20 Jul 2016 16:51:47

Date of Birth

(b) (6)

Date of assessment
DD/MMM/YYYY

2014 MAR 04
DD/MMM/YYYY

Time of assessment

05:39
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: 1181**

Folder: Day 4

Form: Lab_BU_COHB (1)

Data signed: (hfarmer1) 27 Mar 2015 14:31:15

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05115150001175
Analyte	CARBOXYHEMOGLOBIN
Sample type	BLOOD
Result	2.60
Result Unit	%
Lab Status	OK
Sample comment	.
Detection method	SPECTROPHOTOMETRIC
Lower limit of quantification	0.500
Planned time point (Hour)	20
Day of Visit	4
Celerion Study Number	AA99128-16
Date of Collection	2014-MAR-04
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 4

Form: Lab_BU_COHB (1)

Data signed: (hfarmer1) 27 Mar 2015 14:31:15

Generated On: 20 Jul 2016 16:51:47

Start Day (24 hour urine only) _____

End Day (24 hour Urine Only) _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 4

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)

Data signed: (hfarmer1) 27 Mar 2015 14:31:15

Generated On: 20 Jul 2016 16:51:47

Date of Birth

(b) (6)

Date of assessment

2014 MAR 04

DD/MMM/YYYY

DD/MMM/YYYY

Time of assessment

20:03

hour:min 24-hour clock

Assessment Status

Completed ☒

1. Was smoking satisfying?

Little ☒

2. Did cigarettes taste good?

Moderately ☒

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

Not at all ☒

4. Did smoking calm you down?

Moderately ☒

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: 1181**

Folder: Day 4

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)

Data signed: (hfarmer1) 27 Mar 2015 14:31:15

Generated On: 20 Jul 2016 16:51:47

9. Did smoking make you dizzy? Little ☐

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

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

12. Did you enjoy smoking? A lot ☐

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Day 4

Form: Human Smoking Topography Questionnaire

Data signed: (hfarmer1) 27 Mar 2015 14:31:15

Generated On: 20 Jul 2016 16:51:47

Type	HUMAN SMOKING TOPOGRAPHY QUESTIONNAIRE
------	--

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

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

Date of assessment	04 MAR 2014 DD/MMM/YYYY
--------------------	----------------------------

Time of assessment	20:40 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 :	DEVICE HAS STRONGER TASTE.
---	-------------------------------

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 :	
---	--

3. The taste of the conventional cigarettes/products is different with the device.	Agree <input type="radio"/>
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 4

Form: Human Smoking Topography Questionnaire

Data signed: (hfarmer1) 27 Mar 2015 14:31:15

Generated On: 20 Jul 2016 16:51:47

If you agree or strongly agree, please describe : _____

4. The device is easy to use.

Neither agree nor disagree ☒

If you disagree or strongly disagree, please describe : _____

5. Your smoking is disturbed by the device.

Neither agree nor disagree ☒

If you agree or strongly agree, please describe : _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 4

Form: Questionnaire on smoking urges (QSU)

Data signed: (hfarmer1) 27 Mar 2015 14:31:15

Generated On: 20 Jul 2016 16:51:47

Type	QSU
Date of Birth	(b) (6)
Date of assessment	2014 MAR 04
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	Disagree <input type="radio"/>
2. Nothing would be better than smoking a cigarette right now	Disagree <input type="radio"/>
3. If it were possible I would probably smoke now	Disagree <input type="radio"/>
4. I could control things better right now if I could smoke	Strongly disagree <input type="radio"/>
5. All I want right now is a cigarette	Strongly disagree <input type="radio"/>
6. I have an urge for a cigarette	Strongly disagree <input type="radio"/>

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 4

Form: Questionnaire on smoking urges (QSU)

Data signed: (hfarmer1) 27 Mar 2015 14:31:15

Generated On: 20 Jul 2016 16:51:47

7. A cigarette would taste good now Disagree ☐

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

9. Smoking would make me less depressed Strongly disagree ☐

10. I am going to smoke as soon as possible Disagree ☐

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 4

Form: Biomarker-Urine (CEMA, HPMa, HBMA)

Data signed: (hfarmer1) 27 Mar 2015 14:31:16

Generated On: 20 Jul 2016 16:51:47

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 4

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:31:16

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05112450002065
Analyte	HPMA
Sample type	URINE
Result	454
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-MAR-04
Timepoint-minutes	
Urine Start Day	4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 4

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:31:16

Generated On: 20 Jul 2016 16:51:47

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 4

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (2)

Data signed: (hfarmer1) 27 Mar 2015 14:31:16

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05112450002065
Analyte	CEMA
Sample type	URINE
Result	48.0
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	4
Celerion Study Number	AA99128-03
Date of Collection	2014-MAR-04
Timepoint-minutes	
Urine Start Day	4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 4

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (2)

Data signed: (hfarmer1) 27 Mar 2015 14:31:16

Generated On: 20 Jul 2016 16:51:47

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 4

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (3)

Data signed: (hfarmer1) 27 Mar 2015 14:31:16

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05112450002065
Analyte	HBMA
Sample type	URINE
Result	262
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-MAR-04
Timepoint-minutes	
Urine Start Day	4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 4

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (3)

Data signed: (hfarmer1) 27 Mar 2015 14:31:16

Generated On: 20 Jul 2016 16:51:47

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 4

Form: Biomarker-Urine (NNN, NNAL)

Data signed: (hfarmer1) 27 Mar 2015 14:31:15

Generated On: 20 Jul 2016 16:51:47

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 4

Form: Biomarker-Urine (NNN, NNAL) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:31:15

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05112460002460
Analyte	NNAL
Sample type	URINE
Result	35.9
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	AA99128-04
Date of Collection	2014-MAR-04
Timepoint-minutes	
Urine Start Day	4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 4

Form: Biomarker-Urine (NNN, NNAL) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:31:15

Generated On: 20 Jul 2016 16:51:47

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 4

Form: Biomarker-Urine (NNN, NNAL) (2)

Data signed: (hfarmer1) 27 Mar 2015 14:31:15

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05112460002460
Analyte	NNN
Sample type	URINE
Result	1.06
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	AA99128-04
Date of Collection	2014-MAR-04
Timepoint-minutes	
Urine Start Day	4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 4

Form: Biomarker-Urine (NNN, NNAL) (2)

Data signed: (hfarmer1) 27 Mar 2015 14:31:15

Generated On: 20 Jul 2016 16:51:47

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 4

Form: Biomarker-Urine (HEMA)

Data signed: (hfarmer1) 27 Mar 2015 14:31:15

Generated On: 20 Jul 2016 16:51:47

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 4

Form: Biomarker-Urine (HEMA) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:31:15

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05112470001228
Analyte	HEMA
Sample type	URINE
Result	1.86
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-MAR-04
Timepoint-minutes	
Urine Start Day	4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 4

Form: Biomarker-Urine (HEMA) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:31:15

Generated On: 20 Jul 2016 16:51:47

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 4

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

Data signed: (hfarmer1) 27 Mar 2015 14:31:16

Generated On: 20 Jul 2016 16:51:47

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 4

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

Data signed: (hfarmer1) 27 Mar 2015 14:31:16

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05112480001107
Analyte	COT
Sample type	URINE
Result	423
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-FEB-05
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 4

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

Data signed: (hfarmer1) 27 Mar 2015 14:31:16

Generated On: 20 Jul 2016 16:51:47

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: 1181**

Folder: Day 4

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

Data signed: (hfarmer1) 27 Mar 2015 14:31:16

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05112480001107
Analyte	COT-GLUC
Sample type	URINE
Result	695
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-FEB-05
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 4

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

Data signed: (hfarmer1) 27 Mar 2015 14:31:16

Generated On: 20 Jul 2016 16:51:47

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: 1181

Folder: Day 4

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

Data signed: (hfarmer1) 27 Mar 2015 14:31:16

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05112480001107
Analyte	NIC
Sample type	URINE
Result	189
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-FEB-05
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 4

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

Data signed: (hfarmer1) 27 Mar 2015 14:31:16

Generated On: 20 Jul 2016 16:51:47

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: 1181**

Folder: Day 4

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

Data signed: (hfarmer1) 27 Mar 2015 14:31:16

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05112480001107
Analyte	NIC-GLUC
Sample type	URINE
Result	149
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-FEB-05
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 4

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

Data signed: (hfarmer1) 27 Mar 2015 14:31:16

Generated On: 20 Jul 2016 16:51:47

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: 1181**

Folder: Day 4

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

Data signed: (hfarmer1) 27 Mar 2015 14:31:16

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05112480001107
Analyte	THCOT
Sample type	URINE
Result	630
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-FEB-05
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 4

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

Data signed: (hfarmer1) 27 Mar 2015 14:31:16

Generated On: 20 Jul 2016 16:51:47

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: 1181**

Folder: Day 4

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

Data signed: (hfarmer1) 27 Mar 2015 14:31:16

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05112480001107
Analyte	THCOT-GLUC
Sample type	URINE
Result	385
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-FEB-05
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 4

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

Data signed: (hfarmer1) 27 Mar 2015 14:31:16

Generated On: 20 Jul 2016 16:51:47

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: 1181**

Folder: Day 4

Form: Biomarker-Urine (3-OH BaP)

Data signed: (hfarmer1) 27 Mar 2015 14:31:16

Generated On: 20 Jul 2016 16:51:47

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 4

Form: Biomarker-Urine (3-OH BaP) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:31:16

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05112490001228
Analyte	3-OH BAP
Sample type	URINE
Result	37.2
Result Unit	FG/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	AA99128-07
Date of Collection	2014-MAR-04
Timepoint-minutes	
Urine Start Day	4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 4

Form: Biomarker-Urine (3-OH BaP) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:31:16

Generated On: 20 Jul 2016 16:51:47

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 4

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

Data signed: (hfarmer1) 27 Mar 2015 14:31:16

Generated On: 20 Jul 2016 16:51:47

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 4

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

Data signed: (hfarmer1) 27 Mar 2015 14:31:16

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05112510001228
Analyte	1-NA
Sample type	URINE
Result	13.8
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-MAR-04
Timepoint-minutes	
Urine Start Day	4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 4

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

Data signed: (hfarmer1) 27 Mar 2015 14:31:16

Generated On: 20 Jul 2016 16:51:47

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 4

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

Data signed: (hfarmer1) 27 Mar 2015 14:31:16

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05112510001228
Analyte	2-NA
Sample type	URINE
Result	3.59
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-MAR-04
Timepoint-minutes	
Urine Start Day	4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 4

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

Data signed: (hfarmer1) 27 Mar 2015 14:31:16

Generated On: 20 Jul 2016 16:51:47

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 4

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (3)

Data signed: (hfarmer1) 27 Mar 2015 14:31:16

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05112510001228
Analyte	4-ABP
Sample type	URINE
Result	2.24
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-MAR-04
Timepoint-minutes	
Urine Start Day	4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 4

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (3)

Data signed: (hfarmer1) 27 Mar 2015 14:31:16

Generated On: 20 Jul 2016 16:51:47

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 4

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

Data signed: (hfarmer1) 27 Mar 2015 14:31:16

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05112510001228
Analyte	O-TOL
Sample type	URINE
Result	BLQ<(50.0)
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	4
Celerion Study Number	AA99128-09
Date of Collection	2014-MAR-04
Timepoint-minutes	
Urine Start Day	4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 4

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

Data signed: (hfarmer1) 27 Mar 2015 14:31:16

Generated On: 20 Jul 2016 16:51:47

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 4

Form: Biomarker-Urine (1-OHP)

Data signed: (hfarmer1) 27 Mar 2015 14:31:16

Generated On: 20 Jul 2016 16:51:47

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 4

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

Data signed: (hfarmer1) 27 Mar 2015 14:31:16

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05115190001547
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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	4
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Celerion Study Number	AA99598-03
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Date of Collection	2014-MAR-04
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Timepoint-minutes	
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Urine Start Day	4
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 4

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

Data signed: (hfarmer1) 27 Mar 2015 14:31:16

Generated On: 20 Jul 2016 16:51:47

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 4

Form: Biomarker-Urine (SPMA, SBMA)

Data signed: (hfarmer1) 27 Mar 2015 14:31:15

Generated On: 20 Jul 2016 16:51:47

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 4

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

Data signed: (hfarmer1) 27 Mar 2015 14:31:15

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05115170001525
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-MAR-04
Timepoint-minutes	
Urine Start Day	4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 4

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

Data signed: (hfarmer1) 27 Mar 2015 14:31:15

Generated On: 20 Jul 2016 16:51:47

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 4

Form: Biomarker-Urine (SPMA, SBMA) (2)

Data signed: (hfarmer1) 27 Mar 2015 14:31:15

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05115170001525
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-MAR-04
Timepoint-minutes	
Urine Start Day	4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 4

Form: Biomarker-Urine (SPMA, SBMA) (2)

Data signed: (hfarmer1) 27 Mar 2015 14:31:15

Generated On: 20 Jul 2016 16:51:47

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 4

Form: Biomarker-Urine (MHBMA)

Data signed: (hfarmer1) 27 Mar 2015 14:31:16

Generated On: 20 Jul 2016 16:51:47

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 4

Form: Biomarker-Urine (MHBMA) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:31:16

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05115180001547
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-MAR-04
Timepoint-minutes	
Urine Start Day	4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 4

Form: Biomarker-Urine (MHBMA) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:31:16

Generated On: 20 Jul 2016 16:51:47

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 4

Form: Biomarker-Urine (Creatinine)

Data signed: (hfarmer1) 27 Mar 2015 14:31:16

Generated On: 20 Jul 2016 16:51:47

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 4

Form: Biomarker-Urine (Creatinine) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:31:16

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05115160001228
Analyte	CREATININE
Sample type	URINE
Result	62.4
Result Unit	MG/DL
Lab Status	OK
Sample comment	ANALYSIS NOT REQUIRED
Detection method	SPECTROPHOTOMETRIC
Planned time point (Hour)	0
Day of Visit	4
Celerion Study Number	AA99128-14
Date of Collection	2014-MAR-04
Timepoint-minutes	
Urine Start Day	4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 4

Form: Biomarker-Urine (Creatinine) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:31:16

Generated On: 20 Jul 2016 16:51:47

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 4

Form: Biomarker-Plasma (Nic, Cot, tHCot)

Data signed: (hfarmer1) 27 Mar 2015 14:31:16

Generated On: 20 Jul 2016 16:51:47

Sample type

PLASMA

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 4

Form: Biomarker-Plasma (Nic, Cot, tHCot) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:31:16

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05112430001905
Analyte	COT
Sample type	PLASMA
Result	90.3
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	4
Celerion Study Number	AA99128-01
Date of Collection	2014-MAR-04
Timepoint-minutes	0
Urine Start Day	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 4

Form: Biomarker-Plasma (Nic, Cot, tHCot) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:31:16

Generated On: 20 Jul 2016 16:51:47

Urine End Day

4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 4

Form: Biomarker-Plasma (Nic, Cot, tHCot) (2)

Data signed: (hfarmer1) 27 Mar 2015 14:31:16

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05112430001905
Analyte	NIC
Sample type	PLASMA
Result	3.25
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-MAR-04
Timepoint-minutes	0
Urine Start Day	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 4

Form: Biomarker-Plasma (Nic, Cot, tHCot) (2)

Data signed: (hfarmer1) 27 Mar 2015 14:31:16

Generated On: 20 Jul 2016 16:51:47

Urine End Day

4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 5

Form: Date of Visit

Data signed: (hfarmer1) 27 Mar 2015 14:31:18

Generated On: 20 Jul 2016 16:51:47

Date of Visit

05 MAR 2014
DD/MMM/YYYY

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 5

Form: Vital Signs

Data signed: (hfarmer1) 27 Mar 2015 14:31:18

Generated On: 20 Jul 2016 16:51:47

Were Vitals Signs assessed?

Yes ☒

If No, please specify the reason: _____

Has the subject smoked within 15 minutes prior to
assessment

No ☒

Time of assessment

09:08
hour:min 24-hour clock

Pulse rate

67
beats per minute

Respiratory rate

20
breaths per minute

Blood Pressure (systolic)

129
mmHg

Blood Pressure (diastolic)

76
mmHg

Vital Signs Position of Subject

Supine ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 5

Form: Plasma Nicotine Samples <Day 5> (1)

Data signed: (hfarmer1) 27 Mar 2015 14:31:19

Generated On: 20 Jul 2016 16:51:47

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	05 MAR 2014
---------------------	-------------

Scheduled Time	T0 -15 min <input checked="" type="radio"/>
----------------	---

Time hour:min 24-hour clock	06:36
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 5

Form: Plasma Nicotine Samples <Day 5> (2)

Data signed: (hfarmer1) 27 Mar 2015 14:31:19

Generated On: 20 Jul 2016 16:51:47

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	05 MAR 2014
---------------------	-------------

Scheduled Time	T1 <input checked="" type="radio"/>
----------------	-------------------------------------

Time hour:min 24-hour clock	08:38
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 5

Form: Plasma Nicotine Samples <Day 5> (3)

Data signed: (hfarmer1) 27 Mar 2015 14:31:19

Generated On: 20 Jul 2016 16:51:47

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	05 MAR 2014
---------------------	-------------

Scheduled Time	T2 <input checked="" type="radio"/>
----------------	-------------------------------------

Time hour:min 24-hour clock	10:38
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 5

Form: Plasma Nicotine Samples <Day 5> (4)

Data signed: (hfarmer1) 27 Mar 2015 14:31:19

Generated On: 20 Jul 2016 16:51:47

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	05 MAR 2014
---------------------	-------------

Scheduled Time	T3 <input checked="" type="radio"/>
----------------	-------------------------------------

Time hour:min 24-hour clock	12:41
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 5

Form: Plasma Nicotine Samples <Day 5> (5)

Data signed: (hfarmer1) 27 Mar 2015 14:31:19

Generated On: 20 Jul 2016 16:51:47

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	05 MAR 2014
---------------------	-------------

Scheduled Time	T4 <input checked="" type="radio"/>
----------------	-------------------------------------

Time hour:min 24-hour clock	14:34
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 5

Form: Plasma Nicotine Samples <Day 5> (6)

Data signed: (hfarmer1) 27 Mar 2015 14:31:19

Generated On: 20 Jul 2016 16:51:47

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	05 MAR 2014
---------------------	-------------

Scheduled Time	T5 <input checked="" type="radio"/>
----------------	-------------------------------------

Time hour:min 24-hour clock	16:38
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 5

Form: Plasma Nicotine Samples <Day 5> (7)

Data signed: (hfarmer1) 27 Mar 2015 14:31:19

Generated On: 20 Jul 2016 16:51:47

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	05 MAR 2014
---------------------	-------------

Scheduled Time	T6 <input checked="" type="radio"/>
----------------	-------------------------------------

Time hour:min 24-hour clock	18:38
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 5

Form: Plasma Nicotine Samples <Day 5> (8)

Data signed: (hfarmer1) 27 Mar 2015 14:31:19

Generated On: 20 Jul 2016 16:51:47

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	05 MAR 2014
---------------------	-------------

Scheduled Time	T7 <input checked="" type="radio"/>
----------------	-------------------------------------

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 5

Form: Plasma Nicotine Samples <Day 5> (9)

Data signed: (hfarmer1) 27 Mar 2015 14:31:19

Generated On: 20 Jul 2016 16:51:47

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	05 MAR 2014
---------------------	-------------

Scheduled Time	T8 <input checked="" type="radio"/>
----------------	-------------------------------------

Time hour:min 24-hour clock	22:38
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 5

Form: Plasma Cotinine Samples <Day 5> (1)

Data signed: (hfarmer1) 27 Mar 2015 14:31:18

Generated On: 20 Jul 2016 16:51:47

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	05 MAR 2014
---------------------	-------------

Scheduled Time	T0 -15 min <input checked="" type="radio"/>
----------------	---

Time hour:min 24-hour clock	06:36
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 5

Form: Plasma Cotinine Samples <Day 5> (2)

Data signed: (hfarmer1) 27 Mar 2015 14:31:18

Generated On: 20 Jul 2016 16:51:47

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	05 MAR 2014
---------------------	-------------

Scheduled Time	T1 <input checked="" type="radio"/>
----------------	-------------------------------------

Time hour:min 24-hour clock	08:38
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 5

Form: Plasma Cotinine Samples <Day 5> (3)

Data signed: (hfarmer1) 27 Mar 2015 14:31:18

Generated On: 20 Jul 2016 16:51:47

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	05 MAR 2014
---------------------	-------------

Scheduled Time	T2 <input checked="" type="radio"/>
----------------	-------------------------------------

Time hour:min 24-hour clock	10:38
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 5

Form: Plasma Cotinine Samples <Day 5> (4)

Data signed: (hfarmer1) 27 Mar 2015 14:31:18

Generated On: 20 Jul 2016 16:51:47

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	05 MAR 2014
---------------------	-------------

Scheduled Time	T3 <input checked="" type="radio"/>
----------------	-------------------------------------

Time hour:min 24-hour clock	12:41
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 5

Form: Plasma Cotinine Samples <Day 5> (5)

Data signed: (hfarmer1) 27 Mar 2015 14:31:18

Generated On: 20 Jul 2016 16:51:47

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	05 MAR 2014
---------------------	-------------

Scheduled Time	T4 <input checked="" type="radio"/>
----------------	-------------------------------------

Time hour:min 24-hour clock	14:34
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 5

Form: Plasma Cotinine Samples <Day 5> (6)

Data signed: (hfarmer1) 27 Mar 2015 14:31:18

Generated On: 20 Jul 2016 16:51:47

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	05 MAR 2014
---------------------	-------------

Scheduled Time	T5 <input checked="" type="radio"/>
----------------	-------------------------------------

Time hour:min 24-hour clock	16:38
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 5

Form: Plasma Cotinine Samples <Day 5> (7)

Data signed: (hfarmer1) 27 Mar 2015 14:31:18

Generated On: 20 Jul 2016 16:51:47

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	05 MAR 2014
---------------------	-------------

Scheduled Time	T6 <input checked="" type="radio"/>
----------------	-------------------------------------

Time hour:min 24-hour clock	18:38
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 5

Form: Plasma Cotinine Samples <Day 5> (8)

Data signed: (hfarmer1) 27 Mar 2015 14:31:18

Generated On: 20 Jul 2016 16:51:47

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	05 MAR 2014
---------------------	-------------

Scheduled Time	T7 <input checked="" type="radio"/>
----------------	-------------------------------------

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 5

Form: Plasma Cotinine Samples <Day 5> (9)

Data signed: (hfarmer1) 27 Mar 2015 14:31:18

Generated On: 20 Jul 2016 16:51:47

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	05 MAR 2014
---------------------	-------------

Scheduled Time	T8 <input checked="" type="radio"/>
----------------	-------------------------------------

Time hour:min 24-hour clock	22:38
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 5

Form: CoHb Blood Sample(CC/THS) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:31:18

Generated On: 20 Jul 2016 16:51:47

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	05 MAR 2014
---------------------	-------------

Scheduled Time	Within 15 min prior to smoking <input checked="" type="radio"/>
----------------	---

Time hour:min 24-hour clock	06:36
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 5

Form: CoHb Blood Sample(CC/THS) (2)

Data signed: (hfarmer1) 27 Mar 2015 14:31:18

Generated On: 20 Jul 2016 16:51:47

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	05 MAR 2014
---------------------	-------------

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

Time hour:min 24-hour clock	12:41
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 5

Form: CoHb Blood Sample(CC/THS) (3)

Data signed: (hfarmer1) 27 Mar 2015 14:31:18

Generated On: 20 Jul 2016 16:51:47

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	05 MAR 2014
---------------------	-------------

Scheduled Time	16:00 - 17:30 <input checked="" type="radio"/>
----------------	--

Time hour:min 24-hour clock	16:18
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 5

Form: CoHb Blood Sample(CC/THS) (4)

Data signed: (hfarmer1) 27 Mar 2015 14:31:18

Generated On: 20 Jul 2016 16:51:47

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	05 MAR 2014
---------------------	-------------

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

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 5

Form: CO Breath Test (1)

Data signed: (hfarmer1) 27 Mar 2015 14:31:18

Generated On: 20 Jul 2016 16:51:47

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

If Not Done, please specify the reason: _____

Scheduled Time	Within 15 min prior to smoking <input checked="" type="radio"/>
----------------	---

Actual Time of Assessment hour:min 24-hour clock	06:39
---	-------

Result(ppm)	3
-------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 5

Form: CO Breath Test (2)

Data signed: (hfarmer1) 27 Mar 2015 14:31:18

Generated On: 20 Jul 2016 16:51:47

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

If Not Done, please specify the reason: _____

Scheduled Time	12:00 - 13:30 
----------------	---

Actual Time of Assessment hour:min 24-hour clock	12:05
---	-------

Result(ppm)	4
-------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 5

Form: CO Breath Test (3)

Data signed: (hfarmer1) 27 Mar 2015 14:31:18

Generated On: 20 Jul 2016 16:51:47

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

If Not Done, please specify the reason: _____

Scheduled Time	16:00 - 17:30 <input checked="" type="radio"/>
----------------	--

Actual Time of Assessment hour:min 24-hour clock	16:21
---	-------

Result(ppm)	9
-------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 5

Form: CO Breath Test (4)

Data signed: (hfarmer1) 27 Mar 2015 14:31:18

Generated On: 20 Jul 2016 16:51:47

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

If Not Done, please specify the reason: _____

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

Actual Time of Assessment hour:min 24-hour clock	20:27
---	-------

Result(ppm)	9
-------------	---

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Day 5

Form: CYP1A2 activity Sample

Data signed: (hfarmer1) 27 Mar 2015 14:31:16

Generated On: 20 Jul 2016 16:51:47

Time of caffeine tablet intake	10:08
	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
05 MAR 2014	16:18	Caffeine
05 MAR 2014	16:18	Paraxanthine

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 5

Form: 24 hour urine collections

Data signed: (hfarmer1) 27 Mar 2015 14:31:18

Generated On: 20 Jul 2016 16:51:47

Start Time	06:32
	hour:min 24-hour clock

End Date	06 MAR 2014
	DD/MMM/YYYY

End Time	06:01
	hour:min 24-hour clock

Volume	4636
	mL

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 5

Form: Sample Urine Collection

Data signed: (hfarmer1) 27 Mar 2015 14:31:18

Generated On: 20 Jul 2016 16:51:47

Were samples for 24h collected?

Yes ☒

If No, please specify the reason: _____

How many primary tubes were collected?

14

How many back up tubes were collected?

13

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 5

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Data signed: (hfarmer1) 27 Mar 2015 14:31:19

Generated On: 20 Jul 2016 16:51:47

Date of Birth

(b) (6)

Date of assessment
DD/MMM/YYYY

2014 MAR 05
DD/MMM/YYYY

Time of assessment

05:22
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: 1181

Folder: Day 5

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Data signed: (hfarmer1) 27 Mar 2015 14:31:19

Generated On: 20 Jul 2016 16:51:47

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

5. Difficulty concentrating

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

6. Increased appetite, hungry, weight gain

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

7. Insomnia, sleep problems, awakening at night

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

8. Restless

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

9. Impatient

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

10. Constipation

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

11. Dizziness

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

12. Coughing

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 5

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Data signed: (hfarmer1) 27 Mar 2015 14:31:19

Generated On: 20 Jul 2016 16:51:47

How have you been feeling over the past 24 hours?

None ☐

13. Dreaming or nightmares

How have you been feeling over the past 24 hours?

None ☐

14. Nausea

How have you been feeling over the past 24 hours?

None ☐

15. Sore Throat

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 5

Form: Cough Assessment

Data signed: (hfarmer1) 27 Mar 2015 14:31:19

Generated On: 20 Jul 2016 16:51:47

Date of Birth

(b) (6)

Date of assessment
DD/MMM/YYYY

2014 MAR 05
DD/MMM/YYYY

Time of assessment

05:21
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: 1181**

Folder: Day 5

Form: Lab_BU_COHB (1)

Data signed: (hfarmer1) 27 Mar 2015 14:31:20

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05115150001176
Analyte	CARBOXYHEMOGLOBIN
Sample type	BLOOD
Result	2.50
Result Unit	%
Lab Status	OK
Sample comment	.
Detection method	SPECTROPHOTOMETRIC
Lower limit of quantification	0.500
Planned time point (Hour)	6
Day of Visit	5
Celerion Study Number	AA99128-16
Date of Collection	2014-MAR-05
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 5

Form: Lab_BU_COHB (1)

Data signed: (hfarmer1) 27 Mar 2015 14:31:20

Generated On: 20 Jul 2016 16:51:47

Start Day (24 hour urine only) _____

End Day (24 hour Urine Only) _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 5

Form: Lab_BU_COHB (2)

Data signed: (hfarmer1) 27 Mar 2015 14:31:20

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05115150001177
Analyte	CARBOXYHEMOGLOBIN
Sample type	BLOOD
Result	2.60
Result Unit	%
Lab Status	OK
Sample comment	.
Detection method	SPECTROPHOTOMETRIC
Lower limit of quantification	0.500
Planned time point (Hour)	12
Day of Visit	5
Celerion Study Number	AA99128-16
Date of Collection	2014-MAR-05
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 5

Form: Lab_BU_COHB (2)

Data signed: (hfarmer1) 27 Mar 2015 14:31:20

Generated On: 20 Jul 2016 16:51:47

Start Day (24 hour urine only)

End Day (24 hour Urine Only)

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 5

Form: Lab_BU_COHB (3)

Data signed: (hfarmer1) 27 Mar 2015 14:31:20

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05115150001178
Analyte	CARBOXYHEMOGLOBIN
Sample type	BLOOD
Result	3.50
Result Unit	%
Lab Status	OK
Sample comment	.
Detection method	SPECTROPHOTOMETRIC
Lower limit of quantification	0.500
Planned time point (Hour)	16
Day of Visit	5
Celerion Study Number	AA99128-16
Date of Collection	2014-MAR-05
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 5

Form: Lab_BU_COHB (3)

Data signed: (hfarmer1) 27 Mar 2015 14:31:20

Generated On: 20 Jul 2016 16:51:47

Start Day (24 hour urine only) _____

End Day (24 hour Urine Only) _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 5

Form: Lab_BU_COHB (4)

Data signed: (hfarmer1) 27 Mar 2015 14:31:20

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05115150001179
----------------	----------------

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

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

Result	3.30
--------	------

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

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

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

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

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

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

Day of Visit	5
--------------	---

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

Date of Collection	2014-MAR-05
--------------------	-------------

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 5

Form: Lab_BU_COHB (4)

Data signed: (hfarmer1) 27 Mar 2015 14:31:20

Generated On: 20 Jul 2016 16:51:47

Start Day (24 hour urine only) _____

End Day (24 hour Urine Only) _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 5

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)

Data signed: (hfarmer1) 27 Mar 2015 14:31:19

Generated On: 20 Jul 2016 16:51:47

Date of Birth

(b) (6)

Date of assessment

2014 MAR 05

DD/MMM/YYYY

DD/MMM/YYYY

Time of assessment

20:03

hour:min 24-hour clock

Assessment Status

Completed ☒

1. Was smoking satisfying?

Moderately ☒

2. Did cigarettes taste good?

Moderately ☒

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

Moderately ☒

4. Did smoking calm you down?

Moderately ☒

5. Did smoking make you feel more awake?

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: 1181**

Folder: Day 5

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)

Data signed: (hfarmer1) 27 Mar 2015 14:31:19

Generated On: 20 Jul 2016 16:51:47

9. Did smoking make you dizzy? Little ☐

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

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

12. Did you enjoy smoking? Moderately ☐

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 5

Form: Behavioral Risk Factor Surveillance System Questionnaire

Data signed: (hfarmer1) 27 Mar 2015 14:31:16

Generated On: 20 Jul 2016 16:51:47

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

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

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

Date of assessment	05 MAR 2014 DD/MMM/YYYY
--------------------	----------------------------

Time of assessment	20:20 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: 1181**

Folder: Day 5

Form: Behavioral Risk Factor Surveillance System Questionnaire

Data signed: (hfarmer1) 27 Mar 2015 14:31:16

Generated On: 20 Jul 2016 16:51:47

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

Not at all ☐

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

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Day 5

Form: Smoking Questionnaire (SQ)

Data signed: (hfarmer1) 27 Mar 2015 14:31:17

Generated On: 20 Jul 2016 16:51:47

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

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

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

Date of assessment	05 MAR 2014 DD/MMM/YYYY
--------------------	----------------------------

Time of assessment	20:25 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?	08 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: 1181**

Folder: Day 5

Form: Smoking Questionnaire (SQ)

Data signed: (hfarmer1) 27 Mar 2015 14:31:17

Generated On: 20 Jul 2016 16:51:47

Months

Days

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

Years

00 Years

Months

00 Months

Days

00 Days

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

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Day 5

Form: Smoking Questionnaire (SQ) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:31:17

Generated On: 20 Jul 2016 16:51:47

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

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

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

Date of assessment	05 MAR 2014 DD/MMM/YYYY
--------------------	----------------------------

Time of assessment	20:25 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?	08 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: 1181

Folder: Day 5

Form: Smoking Questionnaire (SQ) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:31:17

Generated On: 20 Jul 2016 16:51:47

Months

Days

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

Years

00 Years

Months

00 Months

Days

00 Days

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

Time

Currently (last 3 months) ☒

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

Manufactured Cigarettes
per day

012

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

None ☒

Hand-rolled Cigarettes
per day

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 5

Form: Smoking Questionnaire (SQ) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:31:17

Generated On: 20 Jul 2016 16:51:47

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

None ☐

Cigars
per day

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

None ☐

Pipes
per day

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Day 5

Form: Smoking Questionnaire (SQ) (2)

Data signed: (hfarmer1) 27 Mar 2015 14:31:17

Generated On: 20 Jul 2016 16:51:47

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

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

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

Date of assessment	05 MAR 2014 DD/MMM/YYYY
--------------------	----------------------------

Time of assessment	20:25 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?	08 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: 1181

Folder: Day 5

Form: Smoking Questionnaire (SQ) (2)

Data signed: (hfarmer1) 27 Mar 2015 14:31:17

Generated On: 20 Jul 2016 16:51:47

Months

Days

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

Years

00 Years

Months

00 Months

Days

00 Days

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

Time

1 year ago ☒

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

Manufactured Cigarettes
per day

012

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

None ☒

Hand-rolled Cigarettes
per day

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 5

Form: Smoking Questionnaire (SQ) (2)

Data signed: (hfarmer1) 27 Mar 2015 14:31:17

Generated On: 20 Jul 2016 16:51:47

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

None ☐

Cigars
per day

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

None ☐

Pipes
per day

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Day 5

Form: Smoking Questionnaire (SQ) (3)

Data signed: (hfarmer1) 27 Mar 2015 14:31:17

Generated On: 20 Jul 2016 16:51:47

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

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

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

Date of assessment	05 MAR 2014 DD/MMM/YYYY
--------------------	----------------------------

Time of assessment	20:25 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?	08 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: 1181

Folder: Day 5

Form: Smoking Questionnaire (SQ) (3)

Data signed: (hfarmer1) 27 Mar 2015 14:31:17

Generated On: 20 Jul 2016 16:51:47

Months

Days

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

Years

00 Years

Months

00 Months

Days

00 Days

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

Time

5 years ago ☒

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

Manufactured Cigarettes
per day

005

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: 1181**

Folder: Day 5

Form: Smoking Questionnaire (SQ) (3)

Data signed: (hfarmer1) 27 Mar 2015 14:31:17

Generated On: 20 Jul 2016 16:51:47

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

None ☒

Cigars
per day

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

None ☒

Pipes
per day

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Day 5

Form: Smoking Questionnaire (SQ) (4)

Data signed: (hfarmer1) 27 Mar 2015 14:31:17

Generated On: 20 Jul 2016 16:51:47

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

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

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

Date of assessment	05 MAR 2014 DD/MMM/YYYY
--------------------	----------------------------

Time of assessment	20:25 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?	08 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: 1181

Folder: Day 5

Form: Smoking Questionnaire (SQ) (4)

Data signed: (hfarmer1) 27 Mar 2015 14:31:17

Generated On: 20 Jul 2016 16:51:47

Months

Days

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

Years

00 Years

Months

00 Months

Days

00 Days

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

Time

10 years ago ☒

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

Manufactured Cigarettes
per day

000

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: 1181**

Folder: Day 5

Form: Smoking Questionnaire (SQ) (4)

Data signed: (hfarmer1) 27 Mar 2015 14:31:17

Generated On: 20 Jul 2016 16:51:47

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

None ☐

Cigars
per day

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

None ☐

Pipes
per day

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Day 5

Form: Smoking Questionnaire (SQ) (5)

Data signed: (hfarmer1) 27 Mar 2015 14:31:17

Generated On: 20 Jul 2016 16:51:47

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

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

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

Date of assessment	05 MAR 2014 DD/MMM/YYYY
--------------------	----------------------------

Time of assessment	20:25 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?	08 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: 1181

Folder: Day 5

Form: Smoking Questionnaire (SQ) (5)

Data signed: (hfarmer1) 27 Mar 2015 14:31:17

Generated On: 20 Jul 2016 16:51:47

Months

Days

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

Years

00 Years

Months

00 Months

Days

00 Days

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

Time

15 years ago ☒

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

Manufactured Cigarettes
per day

000

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: 1181**

Folder: Day 5

Form: Smoking Questionnaire (SQ) (5)

Data signed: (hfarmer1) 27 Mar 2015 14:31:17

Generated On: 20 Jul 2016 16:51:47

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

None ☐

Cigars
per day

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

None ☐

Pipes
per day

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Day 5

Form: Smoking Questionnaire (SQ) (6)

Data signed: (hfarmer1) 27 Mar 2015 14:31:17

Generated On: 20 Jul 2016 16:51:47

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

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

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

Date of assessment	05 MAR 2014 DD/MMM/YYYY
--------------------	----------------------------

Time of assessment	20:25 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?	08 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: 1181

Folder: Day 5

Form: Smoking Questionnaire (SQ) (6)

Data signed: (hfarmer1) 27 Mar 2015 14:31:17

Generated On: 20 Jul 2016 16:51:47

Months

Days

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

Years

00 Years

Months

00 Months

Days

00 Days

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

Time

20 years ago ☒

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

Manufactured Cigarettes
per day

000

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: 1181**

Folder: Day 5

Form: Smoking Questionnaire (SQ) (6)

Data signed: (hfarmer1) 27 Mar 2015 14:31:17

Generated On: 20 Jul 2016 16:51:47

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

None ☐

Cigars
per day

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

None ☐

Pipes
per day

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Day 5

Form: Smoking Questionnaire (SQ) (7)

Data signed: (hfarmer1) 27 Mar 2015 14:31:17

Generated On: 20 Jul 2016 16:51:47

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

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

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

Date of assessment	05 MAR 2014 DD/MMM/YYYY
--------------------	----------------------------

Time of assessment	20:25 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?	08 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: 1181

Folder: Day 5

Form: Smoking Questionnaire (SQ) (7)

Data signed: (hfarmer1) 27 Mar 2015 14:31:17

Generated On: 20 Jul 2016 16:51:47

Months

Days

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

Years

00 Years

Months

00 Months

Days

00 Days

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

Time

More than 20 years ago ☒

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

Manufactured Cigarettes
per day

000

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: 1181**

Folder: Day 5

Form: Smoking Questionnaire (SQ) (7)

Data signed: (hfarmer1) 27 Mar 2015 14:31:17

Generated On: 20 Jul 2016 16:51:47

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

None ☐

Cigars
per day

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

None ☐

Pipes
per day

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 5

Form: Supplemental Questions

Data signed: (hfarmer1) 27 Mar 2015 14:31:18

Generated On: 20 Jul 2016 16:51:47

Was paper questionnaire used?

Yes ☒

Reason not done

Date of Assessment

05 MAR 2014
DD/MMM/YYYY

Time of assessment

20:26

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

05 minutes

Comments (open-end)

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 5

Form: Supplemental Questions (1)

Data signed: (hfarmer1) 27 Mar 2015 14:31:18

Generated On: 20 Jul 2016 16:51:47

Was paper questionnaire used? Yes ☐

Reason not done _____

Date of Assessment 05 MAR 2014
DD/MMM/YYYY

Time of assessment 20:26

1. How long it takes for the subject to complete the SQ 05 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: 1181**

Folder: Day 5

Form: Supplemental Questions (2)

Data signed: (hfarmer1) 27 Mar 2015 14:31:18

Generated On: 20 Jul 2016 16:51:47

Was paper questionnaire used? Yes ☐

Reason not done _____

Date of Assessment 05 MAR 2014
DD/MMM/YYYY

Time of assessment 20:26

1. How long it takes for the subject to complete the SQ 05 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: 1181**

Folder: Day 5

Form: Supplemental Questions (3)

Data signed: (hfarmer1) 27 Mar 2015 14:31:18

Generated On: 20 Jul 2016 16:51:47

Was paper questionnaire used? Yes ☐

Reason not done _____

Date of Assessment 05 MAR 2014
DD/MMM/YYYY

Time of assessment 20:26

1. How long it takes for the subject to complete the SQ 05 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: 1181

Folder: Day 5

Form: Supplemental Questions (4)

Data signed: (hfarmer1) 27 Mar 2015 14:31:18

Generated On: 20 Jul 2016 16:51:47

Was paper questionnaire used? Yes ☐

Reason not done _____

Date of Assessment 05 MAR 2014
DD/MMM/YYYY

Time of assessment 20:26

1. How long it takes for the subject to complete the SQ 05 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: 1181**

Folder: Day 5

Form: Supplemental Questions (5)

Data signed: (hfarmer1) 27 Mar 2015 14:31:18

Generated On: 20 Jul 2016 16:51:47

Was paper questionnaire used? Yes ☐

Reason not done _____

Date of Assessment 05 MAR 2014
DD/MMM/YYYY

Time of assessment 20:26

1. How long it takes for the subject to complete the SQ 05 minutes

Question 6. Was the SQ ☐
self-explaining?

Answer Yes ☐

Comments (open-end) _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 5

Form: Supplemental Questions (6)

Data signed: (hfarmer1) 27 Mar 2015 14:31:18

Generated On: 20 Jul 2016 16:51:47

Was paper questionnaire used? Yes ☐

Reason not done _____

Date of Assessment 05 MAR 2014
DD/MMM/YYYY

Time of assessment 20:26

1. How long it takes for the subject to complete the SQ 05 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: 1181

Folder: Day 5

Form: Questionnaire on smoking urges (QSU)

Data signed: (hfarmer1) 27 Mar 2015 14:31:19

Generated On: 20 Jul 2016 16:51:47

Type	QSU
Date of Birth	(b) (6)
Date of assessment DD/MMM/YYYY	2014 MAR 05
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	Disagree <input type="radio"/>
2. Nothing would be better than smoking a cigarette right now	Disagree <input type="radio"/>
3. If it were possible I would probably smoke now	Disagree <input type="radio"/>
4. I could control things better right now if I could smoke	Disagree <input type="radio"/>
5. All I want right now is a cigarette	Disagree <input type="radio"/>
6. I have an urge for a cigarette	Disagree <input type="radio"/>

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 5

Form: Questionnaire on smoking urges (QSU)

Data signed: (hfarmer1) 27 Mar 2015 14:31:19

Generated On: 20 Jul 2016 16:51:47

7. A cigarette would taste good now Disagree ☐

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

9. Smoking would make me less depressed Strongly disagree ☐

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 5

Form: Biomarker-Urine (CEMA, HPMA, HBMA)

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

Generated On: 20 Jul 2016 16:51:47

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 5

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (1)

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

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05112450002066
Analyte	HPMA
Sample type	URINE
Result	264
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-FEB-05
Timepoint-minutes	
Urine Start Day	5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 5

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (1)

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

Generated On: 20 Jul 2016 16:51:47

Urine End Day

6

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 5

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (2)

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

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05112450002066
Analyte	CEMA
Sample type	URINE
Result	26.9
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	5
Celerion Study Number	AA99128-03
Date of Collection	2014-FEB-05
Timepoint-minutes	
Urine Start Day	5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 5

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (2)

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

Generated On: 20 Jul 2016 16:51:47

Urine End Day

6

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 5

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (3)

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

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05112450002066
Analyte	HBMA
Sample type	URINE
Result	132
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-FEB-05
Timepoint-minutes	
Urine Start Day	5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 5

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (3)

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

Generated On: 20 Jul 2016 16:51:47

Urine End Day

6

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 5

Form: Biomarker-Urine (NNN, NNAL)

Data signed: (hfarmer1) 27 Mar 2015 14:31:20

Generated On: 20 Jul 2016 16:51:47

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 5

Form: Biomarker-Urine (NNN, NNAL) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:31:20

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05112460002461
Analyte	NNAL
Sample type	URINE
Result	20.1
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	AA99128-04
Date of Collection	2014-FEB-05
Timepoint-minutes	
Urine Start Day	5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 5

Form: Biomarker-Urine (NNN, NNAL) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:31:20

Generated On: 20 Jul 2016 16:51:47

Urine End Day

6

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 5

Form: Biomarker-Urine (NNN, NNAL) (2)

Data signed: (hfarmer1) 27 Mar 2015 14:31:20

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05112460002461
Analyte	NNN
Sample type	URINE
Result	1.33
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	AA99128-04
Date of Collection	2014-FEB-05
Timepoint-minutes	
Urine Start Day	5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 5

Form: Biomarker-Urine (NNN, NNAL) (2)

Data signed: (hfarmer1) 27 Mar 2015 14:31:20

Generated On: 20 Jul 2016 16:51:47

Urine End Day

6

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 5

Form: Biomarker-Urine (HEMA)

Data signed: (hfarmer1) 27 Mar 2015 14:31:20

Generated On: 20 Jul 2016 16:51:47

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 5

Form: Biomarker-Urine (HEMA) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:31:20

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05112470001229
Analyte	HEMA
Sample type	URINE
Result	1.34
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-FEB-05
Timepoint-minutes	
Urine Start Day	5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 5

Form: Biomarker-Urine (HEMA) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:31:20

Generated On: 20 Jul 2016 16:51:47

Urine End Day

6

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 5

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

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

Generated On: 20 Jul 2016 16:51:47

Sample type

URINE

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Day 5

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

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

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05112480001108
Analyte	COT
Sample type	URINE
Result	330
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-MAR-04
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 5

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

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

Generated On: 20 Jul 2016 16:51:47

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: 1181**

Folder: Day 5

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

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

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05112480001108
Analyte	COT-GLUC
Sample type	URINE
Result	440
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-MAR-04
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 5

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

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

Generated On: 20 Jul 2016 16:51:47

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: 1181

Folder: Day 5

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

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

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05112480001108
Analyte	NIC
Sample type	URINE
Result	162
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-MAR-04
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 5

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

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

Generated On: 20 Jul 2016 16:51:47

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: 1181**

Folder: Day 5

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

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

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05112480001108
Analyte	NIC-GLUC
Sample type	URINE
Result	108
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-MAR-04
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 5

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

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

Generated On: 20 Jul 2016 16:51:47

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: 1181**

Folder: Day 5

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

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

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05112480001108
Analyte	THCOT
Sample type	URINE
Result	311
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-MAR-04
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 5

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

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

Generated On: 20 Jul 2016 16:51:47

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: 1181**

Folder: Day 5

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

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

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05112480001108
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Analyte	THCOT-GLUC
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Sample type	URINE
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Result	BLQ<(200)
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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	AA99128-06
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Date of Collection	2014-MAR-04
--------------------	-------------

Timepoint-minutes	
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 5

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

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

Generated On: 20 Jul 2016 16:51:47

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: 1181**

Folder: Day 5

Form: Biomarker-Urine (3-OH BaP)

Data signed: (hfarmer1) 27 Mar 2015 14:31:23

Generated On: 20 Jul 2016 16:51:47

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 5

Form: Biomarker-Urine (3-OH BaP) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:31:23

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05112490001229
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Analyte	3-OH BAP
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Sample type	URINE
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Result	BLQ<(25.0)
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Result Unit	FG/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	5
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Celerion Study Number	AA99128-07
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Date of Collection	2014-FEB-05
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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: 1181**

Folder: Day 5

Form: Biomarker-Urine (3-OH BaP) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:31:23

Generated On: 20 Jul 2016 16:51:47

Urine End Day

6

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 5

Form: Biomarker-Plasma (Caffeine, Paraxanthine)

Generated On: 20 Jul 2016 16:51:47

Sample type

PLASMA

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 5

Form: Biomarker-Plasma (Caffeine, Paraxanthine) (1)

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05112500000335
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Analyte	CAFFEINE
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Sample type	PLASMA
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Result	2010
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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
---------------------------	---

Day of Visit	5
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Celerion Study Number	AA99128-08
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Date of Collection	2014-MAR-05
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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: 1181**

Folder: Day 5

Form: Biomarker-Plasma (Caffeine, Paraxanthine) (1)

Generated On: 20 Jul 2016 16:51:47

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 5

Form: Biomarker-Plasma (Caffeine, Paraxanthine) (2)

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05112500000335
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Analyte	PARAXANTHINE
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Sample type	PLASMA
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Result	1310
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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-MAR-05
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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: 1181**

Folder: Day 5

Form: Biomarker-Plasma (Caffeine, Paraxanthine) (2)

Generated On: 20 Jul 2016 16:51:47

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 5

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

Data signed: (hfarmer1) 27 Mar 2015 14:31:23

Generated On: 20 Jul 2016 16:51:47

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 5

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

Data signed: (hfarmer1) 27 Mar 2015 14:31:23

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05112510001229
Analyte	1-NA
Sample type	URINE
Result	9.78
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-FEB-05
Timepoint-minutes	
Urine Start Day	5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 5

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

Data signed: (hfarmer1) 27 Mar 2015 14:31:23

Generated On: 20 Jul 2016 16:51:47

Urine End Day

6

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 5

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

Data signed: (hfarmer1) 27 Mar 2015 14:31:23

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05112510001229
Analyte	2-NA
Sample type	URINE
Result	BLQ<(2.50)
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-FEB-05
Timepoint-minutes	
Urine Start Day	5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 5

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

Data signed: (hfarmer1) 27 Mar 2015 14:31:23

Generated On: 20 Jul 2016 16:51:47

Urine End Day

6

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 5

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (3)

Data signed: (hfarmer1) 27 Mar 2015 14:31:23

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05112510001229
Analyte	4-ABP
Sample type	URINE
Result	1.77
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-FEB-05
Timepoint-minutes	
Urine Start Day	5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 5

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (3)

Data signed: (hfarmer1) 27 Mar 2015 14:31:23

Generated On: 20 Jul 2016 16:51:47

Urine End Day

6

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 5

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

Data signed: (hfarmer1) 27 Mar 2015 14:31:23

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05112510001229
Analyte	O-TOL
Sample type	URINE
Result	BLQ<(50.0)
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	5
Celerion Study Number	AA99128-09
Date of Collection	2014-FEB-05
Timepoint-minutes	
Urine Start Day	5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 5

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

Data signed: (hfarmer1) 27 Mar 2015 14:31:23

Generated On: 20 Jul 2016 16:51:47

Urine End Day

6

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 5

Form: Biomarker-Urine (11-dTXb2)

Data signed: (hfarmer1) 27 Mar 2015 14:31:20

Generated On: 20 Jul 2016 16:51:47

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 5

Form: Biomarker-Urine (11-dTXb2) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:31:20

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05112530000396
Analyte	11-DTXB2
Sample type	URINE
Result	184
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	AA99128-11
Date of Collection	2014-FEB-05
Timepoint-minutes	
Urine Start Day	5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 5

Form: Biomarker-Urine (11-dTXb2) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:31:20

Generated On: 20 Jul 2016 16:51:47

Urine End Day

6

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 5

Form: Biomarker-Urine (iPF2a-III)

Data signed: (hfarmer1) 27 Mar 2015 14:31:20

Generated On: 20 Jul 2016 16:51:47

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 5

Form: Biomarker-Urine (iPF2a-III) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:31:20

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05112540000396
Analyte	IPF2A-III
Sample type	URINE
Result	49.9
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-FEB-05
Timepoint-minutes	
Urine Start Day	5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 5

Form: Biomarker-Urine (iPF2a-III) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:31:20

Generated On: 20 Jul 2016 16:51:47

Urine End Day

6

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 5

Form: Biomarker-Urine (Ames)

Data signed: (hfarmer1) 27 Mar 2015 14:31:24

Generated On: 20 Jul 2016 16:51:47

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 5

Form: Biomarker-Urine (Ames) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:31:24

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05113320000086
Analyte	AMES
Sample type	URINE
Result	4.89
Result Unit	REV/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	COUNT
Planned time point (Hour)	0
Day of Visit	5
Celerion Study Number	AA99128-15
Date of Collection	2014-FEB-05
Timepoint-minutes	
Urine Start Day	5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 5

Form: Biomarker-Urine (Ames) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:31:24

Generated On: 20 Jul 2016 16:51:47

Urine End Day

6

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 5

Form: Biomarker-Urine (1-OHP)

Data signed: (hfarmer1) 27 Mar 2015 14:31:24

Generated On: 20 Jul 2016 16:51:47

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 5

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

Data signed: (hfarmer1) 27 Mar 2015 14:31:24

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05115190001548
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-FEB-05
Timepoint-minutes	
Urine Start Day	5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 5

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

Data signed: (hfarmer1) 27 Mar 2015 14:31:24

Generated On: 20 Jul 2016 16:51:47

Urine End Day

6

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 5

Form: Biomarker-Urine (SPMA, SBMA)

Data signed: (hfarmer1) 27 Mar 2015 14:31:21

Generated On: 20 Jul 2016 16:51:47

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 5

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

Data signed: (hfarmer1) 27 Mar 2015 14:31:21

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05115170001526
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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	5
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Celerion Study Number	AA99598-01
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Date of Collection	2014-FEB-05
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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: 1181**

Folder: Day 5

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

Data signed: (hfarmer1) 27 Mar 2015 14:31:21

Generated On: 20 Jul 2016 16:51:47

Urine End Day

6

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 5

Form: Biomarker-Urine (SPMA, SBMA) (2)

Data signed: (hfarmer1) 27 Mar 2015 14:31:21

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05115170001526
----------------	----------------

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
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Day of Visit	5
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Celerion Study Number	AA99598-01
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Date of Collection	2014-FEB-05
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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: 1181**

Folder: Day 5

Form: Biomarker-Urine (SPMA, SBMA) (2)

Data signed: (hfarmer1) 27 Mar 2015 14:31:21

Generated On: 20 Jul 2016 16:51:47

Urine End Day

6

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 5

Form: Biomarker-Urine (MHBMA)

Data signed: (hfarmer1) 27 Mar 2015 14:31:21

Generated On: 20 Jul 2016 16:51:47

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 5

Form: Biomarker-Urine (MHBMA) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:31:21

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05115180001548
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	5
Celerion Study Number	AA99598-02
Date of Collection	2014-FEB-05
Timepoint-minutes	
Urine Start Day	5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 5

Form: Biomarker-Urine (MHBMA) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:31:21

Generated On: 20 Jul 2016 16:51:47

Urine End Day

6

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 5

Form: Biomarker-Urine (Creatinine)

Data signed: (hfarmer1) 27 Mar 2015 14:31:24

Generated On: 20 Jul 2016 16:51:47

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 5

Form: Biomarker-Urine (Creatinine) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:31:24

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05115160001229
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Analyte	CREATININE
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Sample type	URINE
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Result	30.8
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Result Unit	MG/DL
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Lab Status	OK
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Sample comment	ANALYSIS NOT REQUIRED
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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-FEB-05
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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: 1181**

Folder: Day 5

Form: Biomarker-Urine (Creatinine) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:31:24

Generated On: 20 Jul 2016 16:51:47

Urine End Day

6

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot)

Data signed: (hfarmer1) 27 Mar 2015 14:31:21

Generated On: 20 Jul 2016 16:51:47

Sample type

PLASMA

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:31:21

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05112430001906
Analyte	COT
Sample type	PLASMA
Result	79.2
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	AA99128-01
Date of Collection	2014-MAR-05
Timepoint-minutes	-15
Urine Start Day	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:31:21

Generated On: 20 Jul 2016 16:51:47

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (2)

Data signed: (hfarmer1) 27 Mar 2015 14:31:21

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05112430001906
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Analyte	NIC
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Sample type	PLASMA
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Result	BLQ<(1.00)
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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	5
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Celerion Study Number	AA99128-01
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Date of Collection	2014-MAR-05
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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: 1181**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (2)

Data signed: (hfarmer1) 27 Mar 2015 14:31:21

Generated On: 20 Jul 2016 16:51:47

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (3)

Data signed: (hfarmer1) 27 Mar 2015 14:31:21

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05112430001907
Analyte	COT
Sample type	PLASMA
Result	82.4
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-MAR-05
Timepoint-minutes	0
Urine Start Day	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (3)

Data signed: (hfarmer1) 27 Mar 2015 14:31:21

Generated On: 20 Jul 2016 16:51:47

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (4)

Data signed: (hfarmer1) 27 Mar 2015 14:31:21

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05112430001907
Analyte	NIC
Sample type	PLASMA
Result	4.16
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-MAR-05
Timepoint-minutes	0
Urine Start Day	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (4)

Data signed: (hfarmer1) 27 Mar 2015 14:31:21

Generated On: 20 Jul 2016 16:51:47

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (5)

Data signed: (hfarmer1) 27 Mar 2015 14:31:21

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05112430001908
Analyte	COT
Sample type	PLASMA
Result	80.0
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-MAR-05
Timepoint-minutes	0
Urine Start Day	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (5)

Data signed: (hfarmer1) 27 Mar 2015 14:31:21

Generated On: 20 Jul 2016 16:51:47

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (6)

Data signed: (hfarmer1) 27 Mar 2015 14:31:21

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05112430001908
Analyte	NIC
Sample type	PLASMA
Result	2.42
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-MAR-05
Timepoint-minutes	0
Urine Start Day	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (6)

Data signed: (hfarmer1) 27 Mar 2015 14:31:21

Generated On: 20 Jul 2016 16:51:47

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (7)

Data signed: (hfarmer1) 27 Mar 2015 14:31:21

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05112430001909
Analyte	COT
Sample type	PLASMA
Result	83.2
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-MAR-05
Timepoint-minutes	0
Urine Start Day	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (7)

Data signed: (hfarmer1) 27 Mar 2015 14:31:21

Generated On: 20 Jul 2016 16:51:47

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (8)

Data signed: (hfarmer1) 27 Mar 2015 14:31:21

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05112430001909
Analyte	NIC
Sample type	PLASMA
Result	3.17
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-MAR-05
Timepoint-minutes	0
Urine Start Day	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (8)

Data signed: (hfarmer1) 27 Mar 2015 14:31:21

Generated On: 20 Jul 2016 16:51:47

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (9)

Data signed: (hfarmer1) 27 Mar 2015 14:31:21

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05112430001910
Analyte	COT
Sample type	PLASMA
Result	94.1
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-MAR-05
Timepoint-minutes	0
Urine Start Day	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (9)

Data signed: (hfarmer1) 27 Mar 2015 14:31:21

Generated On: 20 Jul 2016 16:51:47

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (10)

Data signed: (hfarmer1) 27 Mar 2015 14:31:21

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05112430001910
Analyte	NIC
Sample type	PLASMA
Result	7.18
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-MAR-05
Timepoint-minutes	0
Urine Start Day	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (10)

Data signed: (hfarmer1) 27 Mar 2015 14:31:21

Generated On: 20 Jul 2016 16:51:47

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (11)

Data signed: (hfarmer1) 27 Mar 2015 14:31:21

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05112430001911
Analyte	COT
Sample type	PLASMA
Result	94.3
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-MAR-05
Timepoint-minutes	0
Urine Start Day	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (11)

Data signed: (hfarmer1) 27 Mar 2015 14:31:21

Generated On: 20 Jul 2016 16:51:47

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (12)

Data signed: (hfarmer1) 27 Mar 2015 14:31:21

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05112430001911
Analyte	NIC
Sample type	PLASMA
Result	8.31
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-MAR-05
Timepoint-minutes	0
Urine Start Day	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (12)

Data signed: (hfarmer1) 27 Mar 2015 14:31:21

Generated On: 20 Jul 2016 16:51:47

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (13)

Data signed: (hfarmer1) 27 Mar 2015 14:31:21

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05112430001912
Analyte	COT
Sample type	PLASMA
Result	103
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-MAR-05
Timepoint-minutes	0
Urine Start Day	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (13)

Data signed: (hfarmer1) 27 Mar 2015 14:31:21

Generated On: 20 Jul 2016 16:51:47

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (14)

Data signed: (hfarmer1) 27 Mar 2015 14:31:21

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05112430001912
Analyte	NIC
Sample type	PLASMA
Result	10.7
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-MAR-05
Timepoint-minutes	0
Urine Start Day	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (14)

Data signed: (hfarmer1) 27 Mar 2015 14:31:21

Generated On: 20 Jul 2016 16:51:47

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (15)

Data signed: (hfarmer1) 27 Mar 2015 14:31:21

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05112430001913
Analyte	COT
Sample type	PLASMA
Result	106
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-MAR-05
Timepoint-minutes	0
Urine Start Day	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (15)

Data signed: (hfarmer1) 27 Mar 2015 14:31:21

Generated On: 20 Jul 2016 16:51:47

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (16)

Data signed: (hfarmer1) 27 Mar 2015 14:31:21

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05112430001913
Analyte	NIC
Sample type	PLASMA
Result	7.27
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-MAR-05
Timepoint-minutes	0
Urine Start Day	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (16)

Data signed: (hfarmer1) 27 Mar 2015 14:31:21

Generated On: 20 Jul 2016 16:51:47

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (17)

Data signed: (hfarmer1) 27 Mar 2015 14:31:21

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05112430001914
Analyte	COT
Sample type	PLASMA
Result	114
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-MAR-05
Timepoint-minutes	0
Urine Start Day	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (17)

Data signed: (hfarmer1) 27 Mar 2015 14:31:21

Generated On: 20 Jul 2016 16:51:47

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (18)

Data signed: (hfarmer1) 27 Mar 2015 14:31:21

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05112430001914
Analyte	NIC
Sample type	PLASMA
Result	7.44
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-MAR-05
Timepoint-minutes	0
Urine Start Day	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (18)

Data signed: (hfarmer1) 27 Mar 2015 14:31:21

Generated On: 20 Jul 2016 16:51:47

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 6

Form: Date of Visit

Data signed: (hfarmer1) 27 Mar 2015 14:31:24

Generated On: 20 Jul 2016 16:51:47

Date of Visit

06 MAR 2014
DD/MMM/YYYY

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 6

Form: Plasma Nicotine Samples <Day 6> (1)

Data signed: (hfarmer1) 27 Mar 2015 14:31:24

Generated On: 20 Jul 2016 16:51:47

Not Done	False
----------	-------

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	06 MAR 2014
---------------------	-------------

Scheduled Time	T0 + 20H <input checked="" type="radio"/>
----------------	---

Time hour:min 24-hour clock	02:38
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 6

Form: Plasma Nicotine Samples <Day 6> (2)

Data signed: (hfarmer1) 27 Mar 2015 14:31:24

Generated On: 20 Jul 2016 16:51:47

Not Done	False
----------	-------

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	06 MAR 2014
---------------------	-------------

Scheduled Time	T0 + 24H <input checked="" type="radio"/>
----------------	---

Time hour:min 24-hour clock	06:32
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 6

Form: Plasma Cotinine Samples <Day 6> (1)

Data signed: (hfarmer1) 27 Mar 2015 14:31:24

Generated On: 20 Jul 2016 16:51:47

Not Done	False
----------	-------

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	06 MAR 2014
---------------------	-------------

Scheduled Time	T0 + 20H <input checked="" type="radio"/>
----------------	---

Time hour:min 24-hour clock	02:38
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 6

Form: Plasma Cotinine Samples <Day 6> (2)

Data signed: (hfarmer1) 27 Mar 2015 14:31:24

Generated On: 20 Jul 2016 16:51:47

Not Done	False
----------	-------

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	06 MAR 2014
---------------------	-------------

Scheduled Time	T0 + 24H <input checked="" type="radio"/>
----------------	---

Time hour:min 24-hour clock	06:32
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 6

Form: CoHb Blood Sample <prior to gas transfer and product>

Data signed: (hfarmer1) 27 Mar 2015 14:31:24

Generated On: 20 Jul 2016 16:51:47

Not Done	False
----------	-------

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	06 MAR 2014
---------------------	-------------

Timepoint	Prior to gas transfer assessment and prior to product use <input checked="" type="radio"/>
-----------	--

Time hour:min 24-hour clock	06:32
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 6

Form: Oxysterols

Data signed: (hfarmer1) 27 Mar 2015 14:31:24

Generated On: 20 Jul 2016 16:51:47

Not Done	False
----------	-------

If Not Done, please specify the reason: _____

Was the subject fasting for at least 10 hours at time of sample collection?	Yes <input checked="" type="radio"/>
--	--------------------------------------

Date DD/MMM/YYYY	06 MAR 2014
---------------------	-------------

Time hour:min 24-hour clock	06:32
--------------------------------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Day 6

Form: CYP2A6 activity Sample

Data signed: (hfarmer1) 27 Mar 2015 14:31:24

Generated On: 20 Jul 2016 16:51:47

Not Done	False
----------	-------

If Not Done, please specify the reason: _____

Date of sample collection
DD/MMM/YYYY

Time of sample collection
hour:min 24-hour clock

Parameter

06 MAR 2014

06:32

trans-3'-hydroxyc
otinine

06 MAR 2014

06:32

cotinine

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 6

Form: Risk Marker: sICAM-1

Data signed: (hfarmer1) 27 Mar 2015 14:31:24

Generated On: 20 Jul 2016 16:51:47

Not Done	False
----------	-------

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	06 MAR 2014
---------------------	-------------

Time hour:min 24-hour clock	06:32
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 6

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Data signed: (hfarmer1) 27 Mar 2015 14:31:24

Generated On: 20 Jul 2016 16:51:47

Date of Birth

(b) (6)

Date of assessment
DD/MMM/YYYY

2014 MAR 06
DD/MMM/YYYY

Time of assessment

05:11
hour:min 24-hour clock

Assessment Status

Completed ☒

Please indicate for each of the items below, how you have been feeling over the past 24 hours

How have you been feeling over the past 24 hours?

None ☐

1. Angry, irritable, frustrated

How have you been feeling over the past 24 hours?

None ☐

2. Anxious, nervous

How have you been feeling over the past 24 hours?

None ☐

3. Depressed Mood, sad

How have you been feeling over the past 24 hours?

Slight ☐

4. Desire or craving to smoke

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 6

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Data signed: (hfarmer1) 27 Mar 2015 14:31:24

Generated On: 20 Jul 2016 16:51:47

How have you been feeling over the past 24 hours? None ☐

5. Difficulty concentrating

How have you been feeling over the past 24 hours? None ☐

6. Increased appetite, hungry, weight gain

How have you been feeling over the past 24 hours? None ☐

7. Insomnia, sleep problems, awakening at night

How have you been feeling over the past 24 hours? None ☐

8. Restless

How have you been feeling over the past 24 hours? None ☐

9. Impatient

How have you been feeling over the past 24 hours? None ☐

10. Constipation

How have you been feeling over the past 24 hours? None ☐

11. Dizziness

How have you been feeling over the past 24 hours? None ☐

12. Coughing

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 6

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Data signed: (hfarmer1) 27 Mar 2015 14:31:24

Generated On: 20 Jul 2016 16:51:47

How have you been feeling over the past 24 hours?

None ☐

13. Dreaming or nightmares

How have you been feeling over the past 24 hours?

None ☐

14. Nausea

How have you been feeling over the past 24 hours?

None ☐

15. Sore Throat

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Day 6

Form: Cough Assessment

Data signed: (hfarmer1) 27 Mar 2015 14:31:25

Generated On: 20 Jul 2016 16:51:47

Date of Birth

(b) (6)

Date of assessment
DD/MMM/YYYY

2014 MAR 06
DD/MMM/YYYY

Time of assessment

05:10
hour:min 24-hour clock

Assessment Status

Completed ☒

Have you experienced a regular need to cough e.g.
coughing several times in the last 24 hrs?

No ☒

If YES, please answer the following questions:

First Question: Cough Impact Scale
How much is your cough bothering you?

-9

Second Question: Cough Intensity Scale:
How intense is your cough?

Not Applicable ☒

Third Question: Cough Frequency Scale:
How frequently do you normally have to cough each
day?

Not Applicable ☒

Fourth Question: Sputum Production
To what extent do you produce sputum when coughing?

Not Applicable ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 6

Form: Oxysterol results (1)

Generated On: 20 Jul 2016 16:51:47

Sample Accession number	3194604115
-------------------------	------------

Analyte	22(R)-HYDROXYCHOLESTERO L
---------	------------------------------

Analyte code	22RHCR L
--------------	----------

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: 1181**

Folder: Day 6

Form: Oxysterol results (2)

Generated On: 20 Jul 2016 16:51:47

Sample Accession number	3194604115
-------------------------	------------

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: 1181**

Folder: Day 6

Form: Oxysterol results (3)

Generated On: 20 Jul 2016 16:51:47

Sample Accession number	3194604115
-------------------------	------------

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: 1181**

Folder: Day 6

Form: Oxysterol results (4)

Generated On: 20 Jul 2016 16:51:47

Sample Accession number	3194604115
-------------------------	------------

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: 1181**

Folder: Day 6

Form: Oxysterol results (5)

Generated On: 20 Jul 2016 16:51:47

Sample Accession number	3194604115
-------------------------	------------

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: 1181**

Folder: Day 6

Form: Oxysterol results (6)

Generated On: 20 Jul 2016 16:51:47

Sample Accession number	3194604115
-------------------------	------------

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: 1181**

Folder: Day 6

Form: Oxysterol results (7)

Generated On: 20 Jul 2016 16:51:47

Sample Accession number	3194604115
-------------------------	------------

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: 1181**

Folder: Day 6

Form: Oxysterol results (8)

Generated On: 20 Jul 2016 16:51:47

Sample Accession number	3194604115
-------------------------	------------

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: 1181**

Folder: Day 6

Form: Oxysterol results (9)

Generated On: 20 Jul 2016 16:51:47

Sample Accession number	3194604115
-------------------------	------------

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: 1181**

Folder: Day 6

Form: Oxysterol results (10)

Generated On: 20 Jul 2016 16:51:47

Sample Accession number	3194604115
-------------------------	------------

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: 1181**

Folder: Day 6

Form: Oxysterol results (11)

Generated On: 20 Jul 2016 16:51:47

Sample Accession number	3194604115
-------------------------	------------

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: 1181**

Folder: Day 6

Form: Oxysterol results (12)

Generated On: 20 Jul 2016 16:51:47

Sample Accession number	3194604115
-------------------------	------------

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: 1181**

Folder: Day 6

Form: Lab_BU_COHB (1)

Data signed: (hfarmer1) 27 Mar 2015 14:31:25

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05115150001180
Analyte	CARBOXYHEMOGLOBIN
Sample type	BLOOD
Result	2.50
Result Unit	%
Lab Status	OK
Sample comment	.
Detection method	SPECTROPHOTOMETRIC
Lower limit of quantification	0.500
Planned time point (Hour)	6
Day of Visit	6
Celerion Study Number	AA99128-16
Date of Collection	2014-MAR-06
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 6

Form: Lab_BU_COHB (1)

Data signed: (hfarmer1) 27 Mar 2015 14:31:25

Generated On: 20 Jul 2016 16:51:47

Start Day (24 hour urine only) _____

End Day (24 hour Urine Only) _____

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Day 6

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)

Data signed: (hfarmer1) 27 Mar 2015 14:31:24

Generated On: 20 Jul 2016 16:51:47

Date of Birth

(b) (6)

Date of assessment

2014 MAR 06

DD/MMM/YYYY

DD/MMM/YYYY

Time of assessment

05:12

hour:min 24-hour clock

Assessment Status

Completed ☒

1. Was smoking satisfying?

Little ☒

2. Did cigarettes taste good?

Moderately ☒

3. Did you enjoy the sensation in your throat and chest?

Moderately ☒

4. Did smoking calm you down?

Moderately ☒

5. Did smoking make you feel more awake?

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: 1181**

Folder: Day 6

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)

Data signed: (hfarmer1) 27 Mar 2015 14:31:24

Generated On: 20 Jul 2016 16:51:47

9. Did smoking make you dizzy? Not at all ☐

10. Did smoking make you nauseous? Not at all ☐

11. Did smoking immediately relieve your craving for a cigarette? Very little ☐

12. Did you enjoy smoking? Moderately ☐

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 6

Form: Questionnaire on smoking urges (QSU)

Data signed: (hfarmer1) 27 Mar 2015 14:31:25

Generated On: 20 Jul 2016 16:51:47

Type	QSU
Date of Birth	(b) (6)
Date of assessment DD/MMM/YYYY	2014 MAR 06
Time of assessment hour:min 24-hour clock	05:19
Assessment Status	Completed <input type="radio"/>
1. I have a desire for a cigarette right now	Disagree <input type="radio"/>
2. Nothing would be better than smoking a cigarette right now	Disagree <input type="radio"/>
3. If it were possible I would probably smoke now	Disagree <input type="radio"/>
4. I could control things better right now if I could smoke	Strongly disagree <input type="radio"/>
5. All I want right now is a cigarette	Disagree <input type="radio"/>
6. I have an urge for a cigarette	Disagree <input type="radio"/>

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 6

Form: Questionnaire on smoking urges (QSU)

Data signed: (hfarmer1) 27 Mar 2015 14:31:25

Generated On: 20 Jul 2016 16:51:47

7. A cigarette would taste good now Disagree ☐

8. I would do almost anything for a cigarette now Disagree ☐

9. Smoking would make me less depressed Strongly disagree ☐

10. I am going to smoke as soon as possible Disagree ☐

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 6

Form: Risk Markers(CCLS) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:31:25

Generated On: 20 Jul 2016 16:51:47

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	1181
----------------------	------

Subject Sex	M
-------------	---

Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	DAY6
------------	------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	V946041
--------------	---------

Actual Collection Date	2014 03 06
------------------------	------------

Actual Collection Time	06:32
------------------------	-------

Specimen Condition	
--------------------	--

Battery ID	IM2293
------------	--------

Battery Name	SICAM-1
--------------	---------

Lab Test ID	IMT1768
-------------	---------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 6

Form: Risk Markers(CCLS) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:31:25

Generated On: 20 Jul 2016 16:51:47

Lab Test Name	SICAM-1-RUO
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	99.1
Reported Numeric Result	99.1
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: 1181**

Folder: Day 6

Form: Risk Markers(CCLS) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:31:25

Generated On: 20 Jul 2016 16:51:47

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 6

Form: Biomarker-Plasma (Nic, Cot, tHCot)

Generated On: 20 Jul 2016 16:51:47

Sample type

PLASMA

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 6

Form: Biomarker-Plasma (Nic, Cot, tHCot) (1)

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05112430001915
----------------	----------------

Analyte	COT
---------	-----

Sample type	PLASMA
-------------	--------

Result	115
--------	-----

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-MAR-06
--------------------	-------------

Timepoint-minutes	0
-------------------	---

Urine Start Day	
-----------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 6

Form: Biomarker-Plasma (Nic, Cot, tHCot) (1)

Generated On: 20 Jul 2016 16:51:47

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 6

Form: Biomarker-Plasma (Nic, Cot, tHCot) (2)

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05112430001915
----------------	----------------

Analyte	NIC
---------	-----

Sample type	PLASMA
-------------	--------

Result	3.00
--------	------

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-MAR-06
--------------------	-------------

Timepoint-minutes	0
-------------------	---

Urine Start Day	
-----------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 6

Form: Biomarker-Plasma (Nic, Cot, tHCot) (2)

Generated On: 20 Jul 2016 16:51:47

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 6

Form: Biomarker-Plasma (Nic, Cot, tHCot) (3)

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05112430001916
----------------	----------------

Analyte	COT
---------	-----

Sample type	PLASMA
-------------	--------

Result	111
--------	-----

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-MAR-06
--------------------	-------------

Timepoint-minutes	0
-------------------	---

Urine Start Day	
-----------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 6

Form: Biomarker-Plasma (Nic, Cot, tHCot) (3)

Generated On: 20 Jul 2016 16:51:47

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 6

Form: Biomarker-Plasma (Nic, Cot, tHCot) (4)

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05112430001916
----------------	----------------

Analyte	NIC
---------	-----

Sample type	PLASMA
-------------	--------

Result	1.10
--------	------

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-MAR-06
--------------------	-------------

Timepoint-minutes	0
-------------------	---

Urine Start Day	
-----------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 6

Form: Biomarker-Plasma (Nic, Cot, tHCot) (4)

Generated On: 20 Jul 2016 16:51:47

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 6

Form: Biomarker-Plasma (Nic, Cot, tHCot) (5)

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05112520000335
----------------	----------------

Analyte	COT
---------	-----

Sample type	PLASMA
-------------	--------

Result	110
--------	-----

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-MAR-06
--------------------	-------------

Timepoint-minutes	0
-------------------	---

Urine Start Day	
-----------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 6

Form: Biomarker-Plasma (Nic, Cot, tHCot) (5)

Generated On: 20 Jul 2016 16:51:47

Urine End Day

6

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 6

Form: Biomarker-Plasma (Nic, Cot, tHCot) (6)

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05112520000335
----------------	----------------

Analyte	THCOT
---------	-------

Sample type	PLASMA
-------------	--------

Result	26.9
--------	------

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	6
--------------	---

Celerion Study Number	AA99128-10
-----------------------	------------

Date of Collection	2014-MAR-06
--------------------	-------------

Timepoint-minutes	0
-------------------	---

Urine Start Day	
-----------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 6

Form: Biomarker-Plasma (Nic, Cot, tHCot) (6)

Generated On: 20 Jul 2016 16:51:47

Urine End Day

6

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Discharge (Confinement)

Form: Date of Discharge

Data signed: (hfarmer1) 27 Mar 2015 14:31:28

Generated On: 20 Jul 2016 16:51:47

Date of Visit	06 MAR 2014 DD/MMM/YYYY
---------------	----------------------------

Discharge Time	10:46 hour:min 24-hour clock
----------------	---------------------------------

Is the subject continuing in the ambulatory period?	Yes <input type="radio"/>
---	---------------------------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Discharge (Confinement)

Form: Vital Signs

Data signed: (hfarmer1) 27 Mar 2015 14:31:28

Generated On: 20 Jul 2016 16:51:47

Were Vitals Signs assessed? Yes ☒

If No, please specify the reason: _____

Has the subject smoked within 15 minutes prior to assessment No ☒

Time of assessment 08:51
hour:min 24-hour clock

Pulse rate 68
beats per minute

Respiratory rate 16
breaths per minute

Blood Pressure (systolic) 135
mmHg

Blood Pressure (diastolic) 76
mmHg

Vital Signs Position of Subject Supine ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Discharge (Confinement)

Form: Advice on the risk of smoking and debriefing

Data signed: (hfarmer1) 27 Mar 2015 14:31:28

Generated On: 20 Jul 2016 16:51:47

Has the subject received advices on the risks of
smoking?

Yes ☒

Has a debriefing been performed about THS 2.2?

Yes ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Discharge (Confinement)

Form: Physical Examination

Data signed: (hfarmer1) 27 Mar 2015 14:31:26

Generated On: 20 Jul 2016 16:51:47

Was the physical examination performed?

Yes ☒

If No, please specify the reason:

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Discharge (Confinement)

Form: Physical Examination (1)

Data signed: (hfarmer1) 27 Mar 2015 14:31:26

Generated On: 20 Jul 2016 16:51:47

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

System General Appearance ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Discharge (Confinement)

Form: Physical Examination (2)

Data signed: (hfarmer1) 27 Mar 2015 14:31:26

Generated On: 20 Jul 2016 16:51:47

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

System HEENT ☒
(head, eyes, ears, nose, throat)

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Discharge (Confinement)

Form: Physical Examination (3)

Data signed: (hfarmer1) 27 Mar 2015 14:31:26

Generated On: 20 Jul 2016 16:51:47

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

System Thyroid Gland ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Discharge (Confinement)

Form: Physical Examination (4)

Data signed: (hfarmer1) 27 Mar 2015 14:31:26

Generated On: 20 Jul 2016 16:51:47

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

System Heart ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Discharge (Confinement)

Form: Physical Examination (5)

Data signed: (hfarmer1) 27 Mar 2015 14:31:26

Generated On: 20 Jul 2016 16:51:47

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

System Chest ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Discharge (Confinement)

Form: Physical Examination (6)

Data signed: (hfarmer1) 27 Mar 2015 14:31:26

Generated On: 20 Jul 2016 16:51:47

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

System Lungs ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Discharge (Confinement)

Form: Physical Examination (7)

Data signed: (hfarmer1) 27 Mar 2015 14:31:26

Generated On: 20 Jul 2016 16:51:47

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

System Gastrointestinal ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Discharge (Confinement)

Form: Physical Examination (8)

Data signed: (hfarmer1) 27 Mar 2015 14:31:26

Generated On: 20 Jul 2016 16:51:47

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

System Cardiovascular System ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Discharge (Confinement)

Form: Physical Examination (9)

Data signed: (hfarmer1) 27 Mar 2015 14:31:26

Generated On: 20 Jul 2016 16:51:47

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

System Neurologic ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Discharge (Confinement)

Form: Physical Examination (10)

Data signed: (hfarmer1) 27 Mar 2015 14:31:26

Generated On: 20 Jul 2016 16:51:47

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

System Skin ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Discharge (Confinement)

Form: Physical Examination (11)

Data signed: (hfarmer1) 27 Mar 2015 14:31:26

Generated On: 20 Jul 2016 16:51:47

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

System Back ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Discharge (Confinement)

Form: Physical Examination (12)

Data signed: (hfarmer1) 27 Mar 2015 14:31:26

Generated On: 20 Jul 2016 16:51:47

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

System Musculoskeletal ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Discharge (Confinement)

Form: Physical Examination (13)

Data signed: (hfarmer1) 27 Mar 2015 14:31:26

Generated On: 20 Jul 2016 16:51:47

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

System Abdomen ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Discharge (Confinement)

Form: Physical Examination (14)

Data signed: (hfarmer1) 27 Mar 2015 14:31:26

Generated On: 20 Jul 2016 16:51:47

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: 1181**

Folder: Discharge (Confinement)

Form: Physical Examination (15)

Data signed: (hfarmer1) 27 Mar 2015 14:31:26

Generated On: 20 Jul 2016 16:51:47

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

System

Other ☒

Other, Specify _____

Outcome _____

Abnormal, please specify _____

Clinically significant _____

Not Done

True

Not Done; please specify the reason: _____

NOT EXAMINED

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Discharge (Confinement)

Form: Physical Examination (16)

Data signed: (hfarmer1) 27 Mar 2015 14:31:26

Generated On: 20 Jul 2016 16:51:47

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

System

Other ☒

Other, Specify _____

Outcome _____

Abnormal, please specify _____

Clinically significant _____

Not Done

True

Not Done; please specify the reason: _____

NOT EXAMINED

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Discharge (Confinement)

Form: Physical Examination (17)

Data signed: (hfarmer1) 27 Mar 2015 14:31:26

Generated On: 20 Jul 2016 16:51:47

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

System

Other ☒

Other, Specify _____

Outcome _____

Abnormal, please specify _____

Clinically significant _____

Not Done

True

Not Done; please specify the reason: _____

NOT EXAMINED

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Discharge (Confinement)

Form: Physical Examination (18)

Data signed: (hfarmer1) 27 Mar 2015 14:31:26

Generated On: 20 Jul 2016 16:51:47

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

System Other ☒

Other, Specify _____

Outcome _____

Abnormal, please specify _____

Clinically significant _____

Not Done True

Not Done; please specify the reason: NOT EXAMINED

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Discharge (Confinement)

Form: Physical Examination (19)

Data signed: (hfarmer1) 27 Mar 2015 14:31:26

Generated On: 20 Jul 2016 16:51:47

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

System

Other ☒

Other, Specify _____

Outcome _____

Abnormal, please specify _____

Clinically significant _____

Not Done

True

Not Done; please specify the reason: _____

NOT EXAMINED

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Discharge (Confinement)

Form: Weight

Data signed: (hfarmer1) 27 Mar 2015 14:31:28

Generated On: 20 Jul 2016 16:51:47

Measurement(s) assessed?

Yes ☒

If No, please specify the reason: _____

Date of Assessment

06 MAR 2014
DD/MMM/YYYY

Time of assessment

09:53
hour:min 24-hour clock

Weight

61.9
kg

BMI

23.9

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Discharge (Confinement)

Form: ECG (12-Lead Standard)

Data signed: (hfarmer1) 27 Mar 2015 14:31:26

Generated On: 20 Jul 2016 16:51:47

Was the ECG performed? Yes ☒

If No, please specify the reason: _____

Position Supine ☒

Heart Rate 65
beats per minute

QRS Interval 117
msec

QT Interval 414
msec

QTcB Interval 433
msec

PR Interval 137
msec

QTcF Interval 426
msec

Interpretation Normal ☒

If Abnormal, Clinical Significance _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Discharge (Confinement)

Form: ECG (12-Lead Standard)

Data signed: (hfarmer1) 27 Mar 2015 14:31:26

Generated On: 20 Jul 2016 16:51:47

If Not Clinically significant or clinically Significant, Please
specify the finding(s)

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Discharge (Confinement)

Form: Gas Transfer

Data signed: (hfarmer1) 27 Mar 2015 14:31:27

Generated On: 20 Jul 2016 16:51:47

Was the Gas Transfer performed?

Yes ☒

If No, please specify the reason: _____

Category _____

Position

SITTING

Date of assessment
DD/MMM/YYYY

06 MAR 2014

Time of assessment

06:54

DLCO value

25.61
ml/min/mmHg

KCO value

1.40
mmol/min/kPa/L

DLCO/VA value

4.16
mL/min/mmHg/L

Interpretation

Normal ☒

If Abnormal, Clinical Significance _____

If Not Clinically Significant or Clinically Significant, Please
specify the finding(s) _____

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Discharge (Confinement)

Form: Lung Volume Measurements

Data signed: (hfarmer1) 27 Mar 2015 14:31:27

Generated On: 20 Jul 2016 16:51:47

Were the Lung Volume Measurements performed? Yes ☒

If No, please specify the reason: _____

Category _____

Position SITTING

Date of assessment DD/MMM/YYYY 06 MAR 2014

Time of assessment 07:06

VC value 4.48
L

TLC value 5.87
L

IC value 2.47
L

FRC value 3.40
L

Interpretation Abnormal ☒

If Abnormal, Clinical Significance Not clinically significant ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Discharge (Confinement)

Form: Lung Volume Measurements

Data signed: (hfarmer1) 27 Mar 2015 14:31:27

Generated On: 20 Jul 2016 16:51:47

If Not Clinically Significant or Clinically Significant, Please MILD HYPERINFLATION
specify the finding(s)

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Discharge (Confinement)

Form: Spirometry with a short-acting bronchodilator

Data signed: (hcoleman1) 18 Jun 2015 21:06:54

Generated On: 20 Jul 2016 16:51:47

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

06 MAR 2014

Time of assessment

07:35

Name of bronchodilator

ALBUTEROL SULFATE

Dose

180 MCG

Predicted FVC value

4.49
L

Best measured FVC value

4.37
L

Percent of predicted FVC value

97
%

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Discharge (Confinement)

Form: Spirometry with a short-acting bronchodilator

Data signed: (hcoleman1) 18 Jun 2015 21:06:54

Generated On: 20 Jul 2016 16:51:47

Best measured FEV1 value	3.30 L
--------------------------	-----------

Predicted FEV1 value	3.78 L
----------------------	-----------

Percent of predicted FEV1 value	87 %
---------------------------------	---------

Calculated ratio between FEV1/FVC	_____
-----------------------------------	-------

MEF 25/75 value	2.64 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: 1181**

Folder: Discharge (Confinement)

Form: Haematology

Data signed: (hfarmer1) 27 Mar 2015 14:31:26

Generated On: 20 Jul 2016 16:51:47

Were samples collected?

Yes ☒

If No, please specify the reason: _____

Was the subject fasting for at least 10 hours at time of
sample collection?

Yes ☒

Please document clinically relevant abnormalities in the AE form

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Discharge (Confinement)

Form: Clinical Chemistry

Data signed: (hfarmer1) 27 Mar 2015 14:31:26

Generated On: 20 Jul 2016 16:51:47

Were samples collected?

Yes ☒

If No, please specify the reason: _____

Was the subject fasting for at least 10 hours at time of
sample collection?

Yes ☒

Please document clinically relevant abnormalities in the AE form

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Discharge (Confinement)

Form: Urine analysis

Data signed: (hfarmer1) 27 Mar 2015 14:31:26

Generated On: 20 Jul 2016 16:51:47

Were samples collected?

Yes ☒

If No, please specify the reason: _____

Please document clinically relevant abnormalities in the AE form

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Discharge (Confinement)

Form: CO Breath Test

Data signed: (hfarmer1) 27 Mar 2015 14:31:25

Generated On: 20 Jul 2016 16:51:47

Assessment not done	False
---------------------	-------

If Not Done, please specify the reason: _____

Actual Time of Assessment	09:15
	hour:min 24-hour clock

Result	9
	ppm

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (1)

Data signed: (hfarmer1) 27 Mar 2015 14:31:28

Generated On: 20 Jul 2016 16:51:47

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	<hr/>
----------------------	-------

Subject Sex	M
-------------	---

Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	V946041
--------------	---------

Actual Collection Date	2014 03 06
------------------------	------------

Actual Collection Time	06:32
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	RC1029
------------	--------

Battery Name	TRIGLYCERIDES
--------------	---------------

Lab Test ID	RCT19
-------------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (1)

Data signed: (hfarmer1) 27 Mar 2015 14:31:28

Generated On: 20 Jul 2016 16:51:47

Lab Test Name	TRIGLYCERIDES (GPO)
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	160
Reported Numeric Result	160
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: 1181**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (1)

Data signed: (hfarmer1) 27 Mar 2015 14:31:28

Generated On: 20 Jul 2016 16:51:47

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (2)

Data signed: (hfarmer1) 27 Mar 2015 14:31:28

Generated On: 20 Jul 2016 16:51:47

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6)

Visit Name _____

Visit Type Scheduled ☒

Accession ID V946041

Actual Collection Date 2014 03 06

Actual Collection Time 06:32

Specimen Condition _____

Battery ID RC1092

Battery Name FASTING GLUCOSE

Lab Test ID RCT142

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (2)

Data signed: (hfarmer1) 27 Mar 2015 14:31:28

Generated On: 20 Jul 2016 16:51:47

Lab Test Name	FASTING GLUCOSE
Test ID	
Test Status	Done <input checked="" 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: 1181**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (2)

Data signed: (hfarmer1) 27 Mar 2015 14:31:28

Generated On: 20 Jul 2016 16:51:47

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (3)

Data signed: (hfarmer1) 27 Mar 2015 14:31:28

Generated On: 20 Jul 2016 16:51:47

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	V946041
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Actual Collection Date	2014 03 06
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Actual Collection Time	06:32
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Specimen Condition	<hr/>
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Battery ID	RC272
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Battery Name	TOTAL CHOLESTEROL
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Lab Test ID	RCT20
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (3)

Data signed: (hfarmer1) 27 Mar 2015 14:31:28

Generated On: 20 Jul 2016 16:51:47

Lab Test Name	CHOLESTEROL (HIGH PERFORMANCE)
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	166
Reported Numeric Result	166
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: 1181**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (3)

Data signed: (hfarmer1) 27 Mar 2015 14:31:28

Generated On: 20 Jul 2016 16:51:47

SI Text Result

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (4)

Data signed: (hfarmer1) 27 Mar 2015 14:31:28

Generated On: 20 Jul 2016 16:51:47

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	V946041
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Actual Collection Date	2014 03 06
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Actual Collection Time	06:32
------------------------	-------

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	RCT1
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (4)

Data signed: (hfarmer1) 27 Mar 2015 14:31:28

Generated On: 20 Jul 2016 16:51:47

Lab Test Name	TOTAL BILIRUBIN
Test ID	
Test Status	Done <input checked="" type="checkbox"/>
Reported Text Result	0.5
Reported Numeric Result	0.5
Reference Range low	0.2
Reference Range high	1.2
Range Units	MG/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (4)

Data signed: (hfarmer1) 27 Mar 2015 14:31:28

Generated On: 20 Jul 2016 16:51:47

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (5)

Data signed: (hfarmer1) 27 Mar 2015 14:31:28

Generated On: 20 Jul 2016 16:51:47

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	V946041
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Actual Collection Date	2014 03 06
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Actual Collection Time	06:32
------------------------	-------

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: 1181

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (5)

Data signed: (hfarmer1) 27 Mar 2015 14:31:28

Generated On: 20 Jul 2016 16:51:47

Lab Test Name	TOTAL PROTEIN
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	7.4
Reported Numeric Result	7.4
Reference Range low	6.1
Reference Range high	8.4
Range Units	G/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (5)

Data signed: (hfarmer1) 27 Mar 2015 14:31:28

Generated On: 20 Jul 2016 16:51:47

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (6)

Data signed: (hfarmer1) 27 Mar 2015 14:31:28

Generated On: 20 Jul 2016 16:51:47

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	V946041
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Actual Collection Date	2014 03 06
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Actual Collection Time	06:32
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Specimen Condition	<hr/>
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Battery ID	RC9255
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Battery Name	CHEMISTRY PANEL
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Lab Test ID	RCT13
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (6)

Data signed: (hfarmer1) 27 Mar 2015 14:31:28

Generated On: 20 Jul 2016 16:51:47

Lab Test Name	ALBUMIN
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	4.6
Reported Numeric Result	4.6
Reference Range low	3.3
Reference Range high	4.9
Range Units	G/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (6)

Data signed: (hfarmer1) 27 Mar 2015 14:31:28

Generated On: 20 Jul 2016 16:51:47

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (7)

Data signed: (hfarmer1) 27 Mar 2015 14:31:28

Generated On: 20 Jul 2016 16:51:47

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6)

Visit Name _____

Visit Type Scheduled ☒

Accession ID V946041

Actual Collection Date 2014 03 06

Actual Collection Time 06:32

Specimen Condition _____

Battery ID RC9255

Battery Name CHEMISTRY PANEL

Lab Test ID RCT1407

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (7)

Data signed: (hfarmer1) 27 Mar 2015 14:31:28

Generated On: 20 Jul 2016 16:51:47

Lab Test Name	ALKALINE PHOSPHATASE
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	49
Reported Numeric Result	49
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: 1181**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (7)

Data signed: (hfarmer1) 27 Mar 2015 14:31:28

Generated On: 20 Jul 2016 16:51:47

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (8)

Data signed: (hfarmer1) 27 Mar 2015 14:31:28

Generated On: 20 Jul 2016 16:51:47

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	V946041
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Actual Collection Date	2014 03 06
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Actual Collection Time	06:32
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Specimen Condition	<hr/>
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Battery ID	RC9255
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Battery Name	CHEMISTRY PANEL
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Lab Test ID	RCT1408
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (8)

Data signed: (hfarmer1) 27 Mar 2015 14:31:28

Generated On: 20 Jul 2016 16:51:47

Lab Test Name	LDH
Test ID	
Test Status	Done <input type="checkbox"/>
Reported Text Result	118
Reported Numeric Result	118
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: 1181**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (8)

Data signed: (hfarmer1) 27 Mar 2015 14:31:28

Generated On: 20 Jul 2016 16:51:47

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (9)

Data signed: (hfarmer1) 27 Mar 2015 14:31:28

Generated On: 20 Jul 2016 16:51:47

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	V946041
--------------	---------

Actual Collection Date	2014 03 06
------------------------	------------

Actual Collection Time	06:32
------------------------	-------

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: 1181

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (9)

Data signed: (hfarmer1) 27 Mar 2015 14:31:28

Generated On: 20 Jul 2016 16:51:47

Lab Test Name	SERUM SODIUM
Test ID	
Test Status	Done <input checked="" type="checkbox"/>
Reported Text Result	141
Reported Numeric Result	141
Reference Range low	132
Reference Range high	147
Range Units	MEQ/L
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (9)

Data signed: (hfarmer1) 27 Mar 2015 14:31:28

Generated On: 20 Jul 2016 16:51:47

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (10)

Data signed: (hfarmer1) 27 Mar 2015 14:31:28

Generated On: 20 Jul 2016 16:51:47

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	V946041
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Actual Collection Date	2014 03 06
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Actual Collection Time	06:32
------------------------	-------

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: 1181

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (10)

Data signed: (hfarmer1) 27 Mar 2015 14:31:28

Generated On: 20 Jul 2016 16:51:47

Lab Test Name	SERUM POTASSIUM
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	4.7
Reported Numeric Result	4.7
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: 1181**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (10)

Data signed: (hfarmer1) 27 Mar 2015 14:31:28

Generated On: 20 Jul 2016 16:51:47

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (11)

Data signed: (hfarmer1) 27 Mar 2015 14:31:28

Generated On: 20 Jul 2016 16:51:47

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	V946041
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Actual Collection Date	2014 03 06
------------------------	------------

Actual Collection Time	06:32
------------------------	-------

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: 1181

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (11)

Data signed: (hfarmer1) 27 Mar 2015 14:31:28

Generated On: 20 Jul 2016 16:51:47

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: 1181**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (11)

Data signed: (hfarmer1) 27 Mar 2015 14:31:28

Generated On: 20 Jul 2016 16:51:47

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (12)

Data signed: (hfarmer1) 27 Mar 2015 14:31:28

Generated On: 20 Jul 2016 16:51:47

Transmission Type	Cumulative <input checked="" type="radio"/>
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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"/>
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Accession ID	V946041
--------------	---------

Actual Collection Date	2014 03 06
------------------------	------------

Actual Collection Time	06:32
------------------------	-------

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: 1181

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (12)

Data signed: (hfarmer1) 27 Mar 2015 14:31:28

Generated On: 20 Jul 2016 16:51:47

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: 1181**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (12)

Data signed: (hfarmer1) 27 Mar 2015 14:31:28

Generated On: 20 Jul 2016 16:51:47

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (13)

Data signed: (hfarmer1) 27 Mar 2015 14:31:28

Generated On: 20 Jul 2016 16:51:47

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	V946041
--------------	---------

Actual Collection Date	2014 03 06
------------------------	------------

Actual Collection Time	06:32
------------------------	-------

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: 1181

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (13)

Data signed: (hfarmer1) 27 Mar 2015 14:31:28

Generated On: 20 Jul 2016 16:51:47

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	0.9
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Reported Numeric Result	0.9
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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/>
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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: 1181**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (13)

Data signed: (hfarmer1) 27 Mar 2015 14:31:28

Generated On: 20 Jul 2016 16:51:47

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (14)

Data signed: (hfarmer1) 27 Mar 2015 14:31:28

Generated On: 20 Jul 2016 16:51:47

Transmission Type Cumulative ☒

Subject ID or Number

Subject Sex M

Subject Date of Birth (b) (6)

Visit Name

Visit Type Scheduled ☒

Accession ID V946041

Actual Collection Date 2014 03 06

Actual Collection Time 06:32

Specimen Condition

Battery ID RC9255

Battery Name CHEMISTRY PANEL

Lab Test ID RCT4

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (14)

Data signed: (hfarmer1) 27 Mar 2015 14:31:28

Generated On: 20 Jul 2016 16:51:47

Lab Test Name	ALT (SGPT)
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	13
Reported Numeric Result	13
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: 1181**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (14)

Data signed: (hfarmer1) 27 Mar 2015 14:31:28

Generated On: 20 Jul 2016 16:51:47

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (15)

Data signed: (hfarmer1) 27 Mar 2015 14:31:28

Generated On: 20 Jul 2016 16:51:47

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	V946041
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Actual Collection Date	2014 03 06
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Actual Collection Time	06:32
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Specimen Condition	<hr/>
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Battery ID	RC9255
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Battery Name	CHEMISTRY PANEL
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Lab Test ID	RCT5
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (15)

Data signed: (hfarmer1) 27 Mar 2015 14:31:28

Generated On: 20 Jul 2016 16:51:47

Lab Test Name	AST (SGOT)
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	16
Reported Numeric Result	16
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: 1181**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (15)

Data signed: (hfarmer1) 27 Mar 2015 14:31:28

Generated On: 20 Jul 2016 16:51:47

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (16)

Data signed: (hfarmer1) 27 Mar 2015 14:31:28

Generated On: 20 Jul 2016 16:51:47

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	V946041
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Actual Collection Date	2014 03 06
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Actual Collection Time	06:32
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Specimen Condition	<hr/>
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Battery ID	RC9255
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Battery Name	CHEMISTRY PANEL
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Lab Test ID	RCT6
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (16)

Data signed: (hfarmer1) 27 Mar 2015 14:31:28

Generated On: 20 Jul 2016 16:51:47

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: 1181**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (16)

Data signed: (hfarmer1) 27 Mar 2015 14:31:28

Generated On: 20 Jul 2016 16:51:47

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (17)

Data signed: (hfarmer1) 27 Mar 2015 14:31:28

Generated On: 20 Jul 2016 16:51:47

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	
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Subject Sex	M
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Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	
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Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	V946041
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Actual Collection Date	2014 03 06
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Actual Collection Time	06:32
------------------------	-------

Specimen Condition	
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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: 1181

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (17)

Data signed: (hfarmer1) 27 Mar 2015 14:31:28

Generated On: 20 Jul 2016 16:51:47

Lab Test Name	MONOCYTES
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	0.28
Reported Numeric Result	0.28
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: 1181**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (17)

Data signed: (hfarmer1) 27 Mar 2015 14:31:28

Generated On: 20 Jul 2016 16:51:47

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (18)

Data signed: (hfarmer1) 27 Mar 2015 14:31:28

Generated On: 20 Jul 2016 16:51:47

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	V946041
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Actual Collection Date	2014 03 06
------------------------	------------

Actual Collection Time	06:32
------------------------	-------

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: 1181

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (18)

Data signed: (hfarmer1) 27 Mar 2015 14:31:28

Generated On: 20 Jul 2016 16:51:47

Lab Test Name	MCH
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	28
Reported Numeric Result	28
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: 1181**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (18)

Data signed: (hfarmer1) 27 Mar 2015 14:31:28

Generated On: 20 Jul 2016 16:51:47

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (19)

Data signed: (hfarmer1) 27 Mar 2015 14:31:28

Generated On: 20 Jul 2016 16:51:47

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	V946041
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Actual Collection Date	2014 03 06
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Actual Collection Time	06:32
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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: 1181

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (19)

Data signed: (hfarmer1) 27 Mar 2015 14:31:28

Generated On: 20 Jul 2016 16:51:47

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: 1181**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (19)

Data signed: (hfarmer1) 27 Mar 2015 14:31:28

Generated On: 20 Jul 2016 16:51:47

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (20)

Data signed: (hfarmer1) 27 Mar 2015 14:31:28

Generated On: 20 Jul 2016 16:51:47

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6)

Visit Name _____

Visit Type Scheduled ☒

Accession ID V946041

Actual Collection Date 2014 03 06

Actual Collection Time 06:32

Specimen Condition _____

Battery ID HM1604

Battery Name HEMATOLOGY
&DIFFERENTIAL PANEL

Lab Test ID HMT11

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (20)

Data signed: (hfarmer1) 27 Mar 2015 14:31:28

Generated On: 20 Jul 2016 16:51:47

Lab Test Name	EOSINOPHILS
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	0.12
Reported Numeric Result	0.12
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: 1181**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (20)

Data signed: (hfarmer1) 27 Mar 2015 14:31:28

Generated On: 20 Jul 2016 16:51:47

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (21)

Data signed: (hfarmer1) 27 Mar 2015 14:31:28

Generated On: 20 Jul 2016 16:51:47

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	V946041
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Actual Collection Date	2014 03 06
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Actual Collection Time	06:32
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Specimen Condition	<hr/>
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Battery ID	HM1604
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Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
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Lab Test ID	HMT12
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (21)

Data signed: (hfarmer1) 27 Mar 2015 14:31:28

Generated On: 20 Jul 2016 16:51:47

Lab Test Name	BASOPHILS
Test ID	
Test Status	Done <input checked="" type="checkbox"/>
Reported Text Result	0.04
Reported Numeric Result	0.04
Reference Range low	0.00
Reference Range high	0.20
Range Units	X10^3/UL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (21)

Data signed: (hfarmer1) 27 Mar 2015 14:31:28

Generated On: 20 Jul 2016 16:51:47

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (22)

Data signed: (hfarmer1) 27 Mar 2015 14:31:28

Generated On: 20 Jul 2016 16:51:47

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	V946041
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Actual Collection Date	2014 03 06
------------------------	------------

Actual Collection Time	06:32
------------------------	-------

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: 1181

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (22)

Data signed: (hfarmer1) 27 Mar 2015 14:31:28

Generated On: 20 Jul 2016 16:51:47

Lab Test Name	PLATELETS
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	201
Reported Numeric Result	201
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: 1181**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (22)

Data signed: (hfarmer1) 27 Mar 2015 14:31:28

Generated On: 20 Jul 2016 16:51:47

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (23)

Data signed: (hfarmer1) 27 Mar 2015 14:31:28

Generated On: 20 Jul 2016 16:51:47

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6)

Visit Name _____

Visit Type Scheduled ☒

Accession ID V946041

Actual Collection Date 2014 03 06

Actual Collection Time 06:32

Specimen Condition _____

Battery ID HM1604

Battery Name HEMATOLOGY
&DIFFERENTIAL PANEL

Lab Test ID HMT15

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (23)

Data signed: (hfarmer1) 27 Mar 2015 14:31:28

Generated On: 20 Jul 2016 16:51:47

Lab Test Name	NEUTROPHILS (%)
Test ID	
Test Status	Done <input type="checkbox"/>
Reported Text Result	51.1
Reported Numeric Result	51.1
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: 1181**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (23)

Data signed: (hfarmer1) 27 Mar 2015 14:31:28

Generated On: 20 Jul 2016 16:51:47

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (24)

Data signed: (hfarmer1) 27 Mar 2015 14:31:28

Generated On: 20 Jul 2016 16:51:47

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	
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Subject Sex	M
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Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	
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Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	V946041
--------------	---------

Actual Collection Date	2014 03 06
------------------------	------------

Actual Collection Time	06:32
------------------------	-------

Specimen Condition	
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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: 1181

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (24)

Data signed: (hfarmer1) 27 Mar 2015 14:31:28

Generated On: 20 Jul 2016 16:51:47

Lab Test Name	LYMPHOCYTES (%)
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	41.1
Reported Numeric Result	41.1
Reference Range low	15.4
Reference Range high	48.5
Range Units	%
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (24)

Data signed: (hfarmer1) 27 Mar 2015 14:31:28

Generated On: 20 Jul 2016 16:51:47

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (25)

Data signed: (hfarmer1) 27 Mar 2015 14:31:28

Generated On: 20 Jul 2016 16:51:47

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	V946041
--------------	---------

Actual Collection Date	2014 03 06
------------------------	------------

Actual Collection Time	06:32
------------------------	-------

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: 1181

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (25)

Data signed: (hfarmer1) 27 Mar 2015 14:31:28

Generated On: 20 Jul 2016 16:51:47

Lab Test Name	MONOCYTES (%)
Test ID	
Test Status	Done <input type="checkbox"/>
Reported Text Result	5.0
Reported Numeric Result	5.0
Reference Range low	2.6
Reference Range high	10.1
Range Units	%
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (25)

Data signed: (hfarmer1) 27 Mar 2015 14:31:28

Generated On: 20 Jul 2016 16:51:47

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (26)

Data signed: (hfarmer1) 27 Mar 2015 14:31:28

Generated On: 20 Jul 2016 16:51:47

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	V946041
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Actual Collection Date	2014 03 06
------------------------	------------

Actual Collection Time	06:32
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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: 1181

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (26)

Data signed: (hfarmer1) 27 Mar 2015 14:31:28

Generated On: 20 Jul 2016 16:51:47

Lab Test Name	EOSINOPHILS (%)
Test ID	
Test Status	Done <input type="checkbox"/>
Reported Text Result	2.1
Reported Numeric Result	2.1
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: 1181**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (26)

Data signed: (hfarmer1) 27 Mar 2015 14:31:28

Generated On: 20 Jul 2016 16:51:47

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (27)

Data signed: (hfarmer1) 27 Mar 2015 14:31:28

Generated On: 20 Jul 2016 16:51:47

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	V946041
--------------	---------

Actual Collection Date	2014 03 06
------------------------	------------

Actual Collection Time	06:32
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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: 1181

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (27)

Data signed: (hfarmer1) 27 Mar 2015 14:31:28

Generated On: 20 Jul 2016 16:51:47

Lab Test Name	BASOPHILS (%)
Test ID	
Test Status	Done <input type="checkbox"/>
Reported Text Result	0.7
Reported Numeric Result	0.7
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: 1181**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (27)

Data signed: (hfarmer1) 27 Mar 2015 14:31:28

Generated On: 20 Jul 2016 16:51:47

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (28)

Data signed: (hfarmer1) 27 Mar 2015 14:31:28

Generated On: 20 Jul 2016 16:51:47

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	V946041
--------------	---------

Actual Collection Date	2014 03 06
------------------------	------------

Actual Collection Time	06:32
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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: 1181

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (28)

Data signed: (hfarmer1) 27 Mar 2015 14:31:28

Generated On: 20 Jul 2016 16:51:47

Lab Test Name	HEMATOCRIT
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	46
Reported Numeric Result	46
Reference Range low	39
Reference Range high	54
Range Units	%
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (28)

Data signed: (hfarmer1) 27 Mar 2015 14:31:28

Generated On: 20 Jul 2016 16:51:47

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (29)

Data signed: (hfarmer1) 27 Mar 2015 14:31:28

Generated On: 20 Jul 2016 16:51:47

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	V946041
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Actual Collection Date	2014 03 06
------------------------	------------

Actual Collection Time	06:32
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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: 1181

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (29)

Data signed: (hfarmer1) 27 Mar 2015 14:31:28

Generated On: 20 Jul 2016 16:51:47

Lab Test Name	RBC
Test ID	
Test Status	Done <input type="checkbox"/>
Reported Text Result	5.4
Reported Numeric Result	5.4
Reference Range low	4.5
Reference Range high	6.4
Range Units	X10^6/UL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (29)

Data signed: (hfarmer1) 27 Mar 2015 14:31:28

Generated On: 20 Jul 2016 16:51:47

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (30)

Data signed: (hfarmer1) 27 Mar 2015 14:31:28

Generated On: 20 Jul 2016 16:51:47

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	V946041
--------------	---------

Actual Collection Date	2014 03 06
------------------------	------------

Actual Collection Time	06:32
------------------------	-------

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: 1181

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (30)

Data signed: (hfarmer1) 27 Mar 2015 14:31:28

Generated On: 20 Jul 2016 16:51:47

Lab Test Name	MCV
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	85
Reported Numeric Result	85
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: 1181**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (30)

Data signed: (hfarmer1) 27 Mar 2015 14:31:28

Generated On: 20 Jul 2016 16:51:47

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (31)

Data signed: (hfarmer1) 27 Mar 2015 14:31:28

Generated On: 20 Jul 2016 16:51:47

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	V946041
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Actual Collection Date	2014 03 06
------------------------	------------

Actual Collection Time	06:32
------------------------	-------

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: 1181

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (31)

Data signed: (hfarmer1) 27 Mar 2015 14:31:28

Generated On: 20 Jul 2016 16:51:47

Lab Test Name	HEMOGLOBIN
Test ID	
Test Status	Done <input checked="" type="checkbox"/>
Reported Text Result	15.3
Reported Numeric Result	15.3
Reference Range low	12.7
Reference Range high	18.1
Range Units	G/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (31)

Data signed: (hfarmer1) 27 Mar 2015 14:31:28

Generated On: 20 Jul 2016 16:51:47

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (32)

Data signed: (hfarmer1) 27 Mar 2015 14:31:28

Generated On: 20 Jul 2016 16:51:47

Transmission Type Cumulative ☒

Subject ID or Number

Subject Sex M

Subject Date of Birth (b) (6)

Visit Name

Visit Type Scheduled ☒

Accession ID V946041

Actual Collection Date 2014 03 06

Actual Collection Time 06:32

Specimen Condition

Battery ID HM1604

Battery Name HEMATOLOGY
&DIFFERENTIAL PANEL

Lab Test ID HMT7

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (32)

Data signed: (hfarmer1) 27 Mar 2015 14:31:28

Generated On: 20 Jul 2016 16:51:47

Lab Test Name	WBC
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	5.54
Reported Numeric Result	5.54
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: 1181**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (32)

Data signed: (hfarmer1) 27 Mar 2015 14:31:28

Generated On: 20 Jul 2016 16:51:47

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (33)

Data signed: (hfarmer1) 27 Mar 2015 14:31:28

Generated On: 20 Jul 2016 16:51:47

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	V946041
--------------	---------

Actual Collection Date	2014 03 06
------------------------	------------

Actual Collection Time	06:32
------------------------	-------

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: 1181

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (33)

Data signed: (hfarmer1) 27 Mar 2015 14:31:28

Generated On: 20 Jul 2016 16:51:47

Lab Test Name

RBC MORPHOLOGY 1

Test ID

Test Status

Done 

Reported Text Result

NORMOCYTIC

Reported Numeric Result

Reference Range low

Reference Range high

Range Units

Conventional Text Result

Conventional Numeric Result

Conventional Reference Range Low

Conventional Reference Range High

Conventional Units

SI Text Result

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (33)

Data signed: (hfarmer1) 27 Mar 2015 14:31:28

Generated On: 20 Jul 2016 16:51:47

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (34)

Data signed: (hfarmer1) 27 Mar 2015 14:31:28

Generated On: 20 Jul 2016 16:51:47

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	V946041
--------------	---------

Actual Collection Date	2014 03 06
------------------------	------------

Actual Collection Time	06:32
------------------------	-------

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: 1181

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (34)

Data signed: (hfarmer1) 27 Mar 2015 14:31:28

Generated On: 20 Jul 2016 16:51:47

Lab Test Name	NEUTROPHILS
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	2.83
Reported Numeric Result	2.83
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: 1181**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (34)

Data signed: (hfarmer1) 27 Mar 2015 14:31:28

Generated On: 20 Jul 2016 16:51:47

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (35)

Data signed: (hfarmer1) 27 Mar 2015 14:31:28

Generated On: 20 Jul 2016 16:51:47

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	V946041
--------------	---------

Actual Collection Date	2014 03 06
------------------------	------------

Actual Collection Time	06:32
------------------------	-------

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: 1181**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (35)

Data signed: (hfarmer1) 27 Mar 2015 14:31:28

Generated On: 20 Jul 2016 16:51:47

Lab Test Name	LYMPHOCYTES
Test ID	
Test Status	Done <input checked="" type="checkbox"/>
Reported Text Result	2.28
Reported Numeric Result	2.28
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: 1181**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (35)

Data signed: (hfarmer1) 27 Mar 2015 14:31:28

Generated On: 20 Jul 2016 16:51:47

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (36)

Data signed: (hfarmer1) 27 Mar 2015 14:31:28

Generated On: 20 Jul 2016 16:51:47

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	V946041
--------------	---------

Actual Collection Date	2014 03 06
------------------------	------------

Actual Collection Time	06:32
------------------------	-------

Specimen Condition	<hr/>
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Battery ID	UA1538
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Battery Name	URINE MACRO PANEL
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Lab Test ID	UAT10
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (36)

Data signed: (hfarmer1) 27 Mar 2015 14:31:28


Generated On: 20 Jul 2016 16:51:47

Lab Test Name

UR NITRITE

Test ID

Test Status

Done 

Reported Text Result

NEGATIVE

Reported Numeric Result

Reference Range low

Reference Range high

Range Units

Conventional Text Result

Conventional Numeric Result

Conventional Reference Range Low

Conventional Reference Range High

Conventional Units

SI Text Result

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (36)

Data signed: (hfarmer1) 27 Mar 2015 14:31:28

Generated On: 20 Jul 2016 16:51:47

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (37)

Data signed: (hfarmer1) 27 Mar 2015 14:31:28

Generated On: 20 Jul 2016 16:51:47

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	V946041
--------------	---------

Actual Collection Date	2014 03 06
------------------------	------------

Actual Collection Time	06:32
------------------------	-------

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: 1181

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (37)

Data signed: (hfarmer1) 27 Mar 2015 14:31:28

Generated On: 20 Jul 2016 16:51:47

Lab Test Name	UR SPECIFIC GRAVITY
Test ID	
Test Status	Done <input type="checkbox"/>
Reported Text Result	1.009
Reported Numeric Result	1.009
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: 1181**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (37)

Data signed: (hfarmer1) 27 Mar 2015 14:31:28

Generated On: 20 Jul 2016 16:51:47

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (38)

Data signed: (hfarmer1) 27 Mar 2015 14:31:28

Generated On: 20 Jul 2016 16:51:47

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6)

Visit Name _____

Visit Type Scheduled ☒

Accession ID V946041

Actual Collection Date 2014 03 06

Actual Collection Time 06:32

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: 1181

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (38)

Data signed: (hfarmer1) 27 Mar 2015 14:31:28

Generated On: 20 Jul 2016 16:51:47

Lab Test Name	UR PH
Test ID	
Test Status	Done <input type="checkbox"/>
Reported Text Result	5.0
Reported Numeric Result	5.0
Reference Range low	5.0
Reference Range high	8.0
Range Units	
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (38)

Data signed: (hfarmer1) 27 Mar 2015 14:31:28

Generated On: 20 Jul 2016 16:51:47

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (39)

Data signed: (hfarmer1) 27 Mar 2015 14:31:28

Generated On: 20 Jul 2016 16:51:47

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	V946041
--------------	---------

Actual Collection Date	2014 03 06
------------------------	------------

Actual Collection Time	06:32
------------------------	-------

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: 1181

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (39)

Data signed: (hfarmer1) 27 Mar 2015 14:31:28


Generated On: 20 Jul 2016 16:51:47

Lab Test Name

UR BLOOD

Test ID

Test Status

Done 

Reported Text Result

NEGATIVE

Reported Numeric Result

Reference Range low

Reference Range high

Range Units

Conventional Text Result

Conventional Numeric Result

Conventional Reference Range Low

Conventional Reference Range High

Conventional Units

SI Text Result

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (39)

Data signed: (hfarmer1) 27 Mar 2015 14:31:28

Generated On: 20 Jul 2016 16:51:47

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (40)

Data signed: (hfarmer1) 27 Mar 2015 14:31:28

Generated On: 20 Jul 2016 16:51:47

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"/>
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Accession ID	V946041
--------------	---------

Actual Collection Date	2014 03 06
------------------------	------------

Actual Collection Time	06:32
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Specimen Condition	<hr/>
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Battery ID	UA1538
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Battery Name	URINE MACRO PANEL
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Lab Test ID	UAT49
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (40)

Data signed: (hfarmer1) 27 Mar 2015 14:31:28


Generated On: 20 Jul 2016 16:51:47

Lab Test Name

UR PROTEIN

Test ID

Test Status

Done 

Reported Text Result

NEGATIVE

Reported Numeric Result

Reference Range low

Reference Range high

Range Units

Conventional Text Result

Conventional Numeric Result

Conventional Reference Range Low

Conventional Reference Range High

Conventional Units

SI Text Result

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (40)

Data signed: (hfarmer1) 27 Mar 2015 14:31:28

Generated On: 20 Jul 2016 16:51:47

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (41)

Data signed: (hfarmer1) 27 Mar 2015 14:31:28

Generated On: 20 Jul 2016 16:51:47

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	V946041
--------------	---------

Actual Collection Date	2014 03 06
------------------------	------------

Actual Collection Time	06:32
------------------------	-------

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: 1181

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (41)

Data signed: (hfarmer1) 27 Mar 2015 14:31:28

Generated On: 20 Jul 2016 16:51:47

Lab Test Name

UR GLUCOSE

Test ID

Test Status

Done 

Reported Text Result

NORMAL

Reported Numeric Result

Reference Range low

Reference Range high

Range Units

Conventional Text Result

Conventional Numeric Result

Conventional Reference Range Low

Conventional Reference Range High

Conventional Units

SI Text Result

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (41)

Data signed: (hfarmer1) 27 Mar 2015 14:31:28

Generated On: 20 Jul 2016 16:51:47

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (42)

Data signed: (hfarmer1) 27 Mar 2015 14:31:28

Generated On: 20 Jul 2016 16:51:47

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	V946041
--------------	---------

Actual Collection Date	2014 03 06
------------------------	------------

Actual Collection Time	06:32
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	UA1538
------------	--------

Battery Name	URINE MACRO PANEL
--------------	-------------------

Lab Test ID	UAT7
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (42)

Data signed: (hfarmer1) 27 Mar 2015 14:31:28


Generated On: 20 Jul 2016 16:51:47

Lab Test Name

UR BILIRUBIN

Test ID

Test Status

Done 

Reported Text Result

NEGATIVE

Reported Numeric Result

Reference Range low

Reference Range high

Range Units

Conventional Text Result

Conventional Numeric Result

Conventional Reference Range Low

Conventional Reference Range High

Conventional Units

SI Text Result

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (42)

Data signed: (hfarmer1) 27 Mar 2015 14:31:28

Generated On: 20 Jul 2016 16:51:47

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 30

Form: Date of Visit

Data signed: (hfarmer1) 27 Mar 2015 14:31:57

Generated On: 20 Jul 2016 16:51:47

Visit Not Done	False
----------------	-------

If Not Done, Specify Reason	<hr/>
-----------------------------	-------

Date of Visit	30 MAR 2014 DD/MMM/YYYY
---------------	----------------------------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 30

Form: Vital Signs

Data signed: (hfarmer1) 27 Mar 2015 14:31:58

Generated On: 20 Jul 2016 16:51:47

Were Vitals Signs assessed?

Yes ☒

If No, please specify the reason: _____

Has the subject smoked within 15 minutes prior to
assessment

No ☒

Date of assessment

30 MAR 2014
DD/MMM/YYYY

Time of assessment

14:57
hour:min 24-hour clock

Pulse rate

69
beats per minute

Respiratory rate

18
breaths per minute

Blood Pressure (systolic)

134
mmHg

Blood Pressure (diastolic)

77
mmHg

Vital Signs Position of Subject

Supine ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 30

Form: Advice on the risk of smoking and debriefing

Data signed: (hfarmer1) 27 Mar 2015 14:31:57

Generated On: 20 Jul 2016 16:51:47

Date	31 MAR 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: 1181**

Folder: Day 30

Form: Physical Examination

Data signed: (hfarmer1) 27 Mar 2015 14:31:52

Generated On: 20 Jul 2016 16:51:47

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of Assessment

30 MAR 2014
DD/MMM/YYYY

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 30

Form: Physical Examination (1)

Data signed: (hfarmer1) 27 Mar 2015 14:31:52

Generated On: 20 Jul 2016 16:51:47

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of Assessment 30 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: 1181**

Folder: Day 30

Form: Physical Examination (2)

Data signed: (hfarmer1) 27 Mar 2015 14:31:52

Generated On: 20 Jul 2016 16:51:47

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of Assessment

30 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: 1181**

Folder: Day 30

Form: Physical Examination (3)

Data signed: (hfarmer1) 27 Mar 2015 14:31:52

Generated On: 20 Jul 2016 16:51:47

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of Assessment 30 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: 1181**

Folder: Day 30

Form: Physical Examination (4)

Data signed: (hfarmer1) 27 Mar 2015 14:31:52

Generated On: 20 Jul 2016 16:51:47

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of Assessment

30 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: 1181**

Folder: Day 30

Form: Physical Examination (5)

Data signed: (hfarmer1) 27 Mar 2015 14:31:52

Generated On: 20 Jul 2016 16:51:47

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of Assessment 30 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: 1181**

Folder: Day 30

Form: Physical Examination (6)

Data signed: (hfarmer1) 27 Mar 2015 14:31:52

Generated On: 20 Jul 2016 16:51:47

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of Assessment

30 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: 1181**

Folder: Day 30

Form: Physical Examination (7)

Data signed: (hfarmer1) 27 Mar 2015 14:31:52

Generated On: 20 Jul 2016 16:51:47

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of Assessment 30 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: 1181**

Folder: Day 30

Form: Physical Examination (8)

Data signed: (hfarmer1) 27 Mar 2015 14:31:52

Generated On: 20 Jul 2016 16:51:47

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of Assessment 30 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: 1181**

Folder: Day 30

Form: Physical Examination (9)

Data signed: (hfarmer1) 27 Mar 2015 14:31:52

Generated On: 20 Jul 2016 16:51:47

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of Assessment

30 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: 1181**

Folder: Day 30

Form: Physical Examination (10)

Data signed: (hfarmer1) 27 Mar 2015 14:31:52

Generated On: 20 Jul 2016 16:51:47

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of Assessment 30 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: 1181**

Folder: Day 30

Form: Physical Examination (11)

Data signed: (hfarmer1) 27 Mar 2015 14:31:52

Generated On: 20 Jul 2016 16:51:47

Was the physical examination performed? Yes ☐

If No, please specify the reason: _____

Date of Assessment 30 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: 1181**

Folder: Day 30

Form: Physical Examination (12)

Data signed: (hfarmer1) 27 Mar 2015 14:31:52

Generated On: 20 Jul 2016 16:51:47

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of Assessment 30 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: 1181**

Folder: Day 30

Form: Physical Examination (13)

Data signed: (hfarmer1) 27 Mar 2015 14:31:52

Generated On: 20 Jul 2016 16:51:47

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of Assessment 30 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: 1181**

Folder: Day 30

Form: Physical Examination (14)

Data signed: (hfarmer1) 27 Mar 2015 14:31:52

Generated On: 20 Jul 2016 16:51:47

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of Assessment 30 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: 1181**

Folder: Day 30

Form: Physical Examination (15)

Data signed: (hfarmer1) 27 Mar 2015 14:31:52

Generated On: 20 Jul 2016 16:51:47

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of Assessment

30 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: 1181**

Folder: Day 30

Form: Physical Examination (16)

Data signed: (hfarmer1) 27 Mar 2015 14:31:52

Generated On: 20 Jul 2016 16:51:47

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of Assessment

30 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: 1181**

Folder: Day 30

Form: Physical Examination (17)

Data signed: (hfarmer1) 27 Mar 2015 14:31:52

Generated On: 20 Jul 2016 16:51:47

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of Assessment

30 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: 1181**

Folder: Day 30

Form: Physical Examination (18)

Data signed: (hfarmer1) 27 Mar 2015 14:31:52

Generated On: 20 Jul 2016 16:51:47

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of Assessment

30 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: 1181**

Folder: Day 30

Form: Physical Examination (19)

Data signed: (hfarmer1) 27 Mar 2015 14:31:52

Generated On: 20 Jul 2016 16:51:47

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of Assessment

30 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: 1181**

Folder: Day 30

Form: Weight

Data signed: (hfarmer1) 27 Mar 2015 14:31:58

Generated On: 20 Jul 2016 16:51:47

Measurement(s) assessed?

Yes ☒

If No, please specify the reason: _____

Date of Assessment

30 MAR 2014
DD/MMM/YYYY

Time of assessment

15:15
hour:min 24-hour clock

Weight

59.4
kg

BMI

22.9

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 30

Form: ECG (12-Lead Standard)

Data signed: (hfarmer1) 27 Mar 2015 14:31:51

Generated On: 20 Jul 2016 16:51:47

Was the ECG performed?

Yes ☒

If No, please specify the reason: _____

Date of Assessment

30 MAR 2014
DD/MMM/YYYY

Position

Supine ☒

Heart Rate

70
beats per minute

QRS Interval

116
msec

QT Interval

399
msec

QTcB Interval

431
msec

PR Interval

124
msec

QTcF Interval

420
msec

Interpretation

Normal ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 30

Form: ECG (12-Lead Standard)

Data signed: (hfarmer1) 27 Mar 2015 14:31:51

Generated On: 20 Jul 2016 16:51:47

If Abnormal, Clinical Significance _____

If Not Clinically significant or clinically Significant, Please
specify the finding(s) _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 30

Form: Haematology

Data signed: (hfarmer1) 27 Mar 2015 14:31:51

Generated On: 20 Jul 2016 16:51:47

Were samples collected?

Yes ☒

If No, please specify the reason: _____

Was the subject fasting for at least 10 hours at time of
sample collection?

Yes ☒

Please document clinically relevant abnormalities in the AE form

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 30

Form: Clinical Chemistry

Data signed: (hfarmer1) 27 Mar 2015 14:31:51

Generated On: 20 Jul 2016 16:51:47

Were samples collected?

Yes ☒

If No, please specify the reason: _____

Was the subject fasting for at least 10 hours at time of
sample collection?

Yes ☒

Please document clinically relevant abnormalities in the AE form

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 30

Form: Urine analysis

Data signed: (hfarmer1) 27 Mar 2015 14:31:51

Generated On: 20 Jul 2016 16:51:47

Were samples collected?

Yes ☒

If No, please specify the reason: _____

Please document clinically relevant abnormalities in the AE form

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 30

Form: Plasma Nicotine Sample

Data signed: (hfarmer1) 27 Mar 2015 14:31:51

Generated On: 20 Jul 2016 16:51:47

Not Done	False
----------	-------

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	30 MAR 2014
---------------------	-------------

Time hour:min 24-hour clock	10:20
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 30

Form: Plasma Cotinine Sample

Data signed: (hfarmer1) 27 Mar 2015 14:31:51

Generated On: 20 Jul 2016 16:51:47

Not Done	False
----------	-------

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	30 MAR 2014
---------------------	-------------

Time hour:min 24-hour clock	10:20
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 30

Form: CoHb Blood Sample <D30_D60>

Data signed: (hfarmer1) 27 Mar 2015 14:31:51

Generated On: 20 Jul 2016 16:51:47

Not Done	False
----------	-------

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	30 MAR 2014
---------------------	-------------

Timepoint	10:00 - 11:30 <input checked="" type="radio"/>
-----------	--

Time hour:min 24-hour clock	10:20
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 30

Form: CO Breath Test

Data signed: (hfarmer1) 27 Mar 2015 14:31:51

Generated On: 20 Jul 2016 16:51:47

Assessment not done	False
---------------------	-------

If Not Done, please specify the reason: _____

Actual Date of Assessment	30 MAR 2014 DD/MMM/YYYY
---------------------------	----------------------------

Actual Time of Assessment	10:09 hour:min 24-hour clock
---------------------------	---------------------------------

Result	4 ppm
--------	----------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 30

Form: Risk markers: hs-CRP, fibrinogen, homocysteine, LDL, HDL, sICAM-1

Data signed: (hfarmer1) 27 Mar 2015 14:31:51

Generated On: 20 Jul 2016 16:51:47

Not Done	False
----------	-------

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	31 MAR 2014
---------------------	-------------

Time hour:min 24-hour clock	06:23
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 30

Form: 24 hour urine collections

Data signed: (hfarmer1) 27 Mar 2015 14:31:57

Generated On: 20 Jul 2016 16:51:47

Start Date	30 MAR 2014 DD/MMM/YYYY
------------	----------------------------

Start Time	09:12 hour:min 24-hour clock
------------	---------------------------------

End Date	31 MAR 2014 DD/MMM/YYYY
----------	----------------------------

End Time	08:51 hour:min 24-hour clock
----------	---------------------------------

Volume	2190 mL
--------	------------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 30

Form: Sample Urine Collection

Data signed: (hfarmer1) 27 Mar 2015 14:31:57

Generated On: 20 Jul 2016 16:51:47

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: 1181**

Folder: Day 30

Form: Lab_BU_CCLS (1)

Data signed: (hfarmer1) 27 Mar 2015 14:32:01

Generated On: 20 Jul 2016 16:51:47

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	<hr/>
----------------------	-------

Subject Sex	M
-------------	---

Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	V969094
--------------	---------

Actual Collection Date	2014 03 31
------------------------	------------

Actual Collection Time	06:23
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	RC1029
------------	--------

Battery Name	TRIGLYCERIDES
--------------	---------------

Lab Test ID	RCT19
-------------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Day 30

Form: Lab_BU_CCLS (1)

Data signed: (hfarmer1) 27 Mar 2015 14:32:01

Generated On: 20 Jul 2016 16:51:47

Lab Test Name	TRIGLYCERIDES (GPO)
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	112
Reported Numeric Result	112
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: 1181**

Folder: Day 30

Form: Lab_BU_CCLS (1)

Data signed: (hfarmer1) 27 Mar 2015 14:32:01

Generated On: 20 Jul 2016 16:51:47

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 30

Form: Lab_BU_CCLS (2)

Data signed: (hfarmer1) 27 Mar 2015 14:32:01

Generated On: 20 Jul 2016 16:51:47

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	<hr/>
----------------------	-------

Subject Sex	M
-------------	---

Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	V969094
--------------	---------

Actual Collection Date	2014 03 31
------------------------	------------

Actual Collection Time	06:23
------------------------	-------

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: 1181**

Folder: Day 30

Form: Lab_BU_CCLS (2)

Data signed: (hfarmer1) 27 Mar 2015 14:32:01

Generated On: 20 Jul 2016 16:51:47

Lab Test Name	FASTING GLUCOSE
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	97
Reported Numeric Result	97
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: 1181**

Folder: Day 30

Form: Lab_BU_CCLS (2)

Data signed: (hfarmer1) 27 Mar 2015 14:32:01

Generated On: 20 Jul 2016 16:51:47

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 30

Form: Lab_BU_CCLS (3)

Data signed: (hfarmer1) 27 Mar 2015 14:32:01

Generated On: 20 Jul 2016 16:51:47

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	<hr/>
----------------------	-------

Subject Sex	M
-------------	---

Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	V969094
--------------	---------

Actual Collection Date	2014 03 31
------------------------	------------

Actual Collection Time	06:23
------------------------	-------

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: 1181**

Folder: Day 30

Form: Lab_BU_CCLS (3)

Data signed: (hfarmer1) 27 Mar 2015 14:32:01

Generated On: 20 Jul 2016 16:51:47

Lab Test Name	CHOLESTEROL (HIGH PERFORMANCE)
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	172
Reported Numeric Result	172
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: 1181**

Folder: Day 30

Form: Lab_BU_CCLS (3)

Data signed: (hfarmer1) 27 Mar 2015 14:32:01

Generated On: 20 Jul 2016 16:51:47

SI Text Result

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 30

Form: Lab_BU_CCLS (4)

Data signed: (hfarmer1) 27 Mar 2015 14:32:01

Generated On: 20 Jul 2016 16:51:47

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	<hr/>
----------------------	-------

Subject Sex	M
-------------	---

Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	V969094
--------------	---------

Actual Collection Date	2014 03 31
------------------------	------------

Actual Collection Time	06:23
------------------------	-------

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: 1181**

Folder: Day 30

Form: Lab_BU_CCLS (4)

Data signed: (hfarmer1) 27 Mar 2015 14:32:01

Generated On: 20 Jul 2016 16:51:47

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: 1181**

Folder: Day 30

Form: Lab_BU_CCLS (4)

Data signed: (hfarmer1) 27 Mar 2015 14:32:01

Generated On: 20 Jul 2016 16:51:47

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 30

Form: Lab_BU_CCLS (5)

Data signed: (hfarmer1) 27 Mar 2015 14:32:01

Generated On: 20 Jul 2016 16:51:47

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	V969094
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Actual Collection Date	2014 03 31
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Actual Collection Time	06:23
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Specimen Condition	<hr/>
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Battery ID	RC9255
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Battery Name	CHEMISTRY PANEL
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Lab Test ID	RCT12
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 30

Form: Lab_BU_CCLS (5)

Data signed: (hfarmer1) 27 Mar 2015 14:32:01

Generated On: 20 Jul 2016 16:51:47

Lab Test Name	TOTAL PROTEIN
Test ID	
Test Status	Done <input type="checkbox"/>
Reported Text Result	7.4
Reported Numeric Result	7.4
Reference Range low	6.1
Reference Range high	8.4
Range Units	G/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 30

Form: Lab_BU_CCLS (5)

Data signed: (hfarmer1) 27 Mar 2015 14:32:01

Generated On: 20 Jul 2016 16:51:47

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 30

Form: Lab_BU_CCLS (6)

Data signed: (hfarmer1) 27 Mar 2015 14:32:01

Generated On: 20 Jul 2016 16:51:47

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	V969094
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Actual Collection Date	2014 03 31
------------------------	------------

Actual Collection Time	06:23
------------------------	-------

Specimen Condition	<hr/>
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Battery ID	RC9255
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Battery Name	CHEMISTRY PANEL
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Lab Test ID	RCT13
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 30

Form: Lab_BU_CCLS (6)

Data signed: (hfarmer1) 27 Mar 2015 14:32:01

Generated On: 20 Jul 2016 16:51:47

Lab Test Name	ALBUMIN
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	4.5
Reported Numeric Result	4.5
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: 1181**

Folder: Day 30

Form: Lab_BU_CCLS (6)

Data signed: (hfarmer1) 27 Mar 2015 14:32:01

Generated On: 20 Jul 2016 16:51:47

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 30

Form: Lab_BU_CCLS (7)

Data signed: (hfarmer1) 27 Mar 2015 14:32:01

Generated On: 20 Jul 2016 16:51:47

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	V969094
--------------	---------

Actual Collection Date	2014 03 31
------------------------	------------

Actual Collection Time	06:23
------------------------	-------

Specimen Condition	<hr/>
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Battery ID	RC9255
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Battery Name	CHEMISTRY PANEL
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Lab Test ID	RCT1407
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Day 30

Form: Lab_BU_CCLS (7)

Data signed: (hfarmer1) 27 Mar 2015 14:32:01

Generated On: 20 Jul 2016 16:51:47

Lab Test Name	ALKALINE PHOSPHATASE
Test ID	
Test Status	Done <input 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: 1181**

Folder: Day 30

Form: Lab_BU_CCLS (7)

Data signed: (hfarmer1) 27 Mar 2015 14:32:01

Generated On: 20 Jul 2016 16:51:47

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 30

Form: Lab_BU_CCLS (8)

Data signed: (hfarmer1) 27 Mar 2015 14:32:01

Generated On: 20 Jul 2016 16:51:47

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	V969094
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Actual Collection Date	2014 03 31
------------------------	------------

Actual Collection Time	06:23
------------------------	-------

Specimen Condition	<hr/>
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Battery ID	RC9255
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Battery Name	CHEMISTRY PANEL
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Lab Test ID	RCT1408
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 30

Form: Lab_BU_CCLS (8)

Data signed: (hfarmer1) 27 Mar 2015 14:32:01

Generated On: 20 Jul 2016 16:51:47

Lab Test Name	LDH
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	129
Reported Numeric Result	129
Reference Range low	53
Reference Range high	234
Range Units	U/L
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 30

Form: Lab_BU_CCLS (8)

Data signed: (hfarmer1) 27 Mar 2015 14:32:01

Generated On: 20 Jul 2016 16:51:47

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 30

Form: Lab_BU_CCLS (9)

Data signed: (hfarmer1) 27 Mar 2015 14:32:01

Generated On: 20 Jul 2016 16:51:47

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	V969094
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Actual Collection Date	2014 03 31
------------------------	------------

Actual Collection Time	06:23
------------------------	-------

Specimen Condition	<hr/>
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Battery ID	RC9255
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Battery Name	CHEMISTRY PANEL
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Lab Test ID	RCT15
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 30

Form: Lab_BU_CCLS (9)

Data signed: (hfarmer1) 27 Mar 2015 14:32:01

Generated On: 20 Jul 2016 16:51:47

Lab Test Name	SERUM SODIUM
Test ID	
Test Status	Done <input checked="" 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: 1181**

Folder: Day 30

Form: Lab_BU_CCLS (9)

Data signed: (hfarmer1) 27 Mar 2015 14:32:01

Generated On: 20 Jul 2016 16:51:47

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 30

Form: Lab_BU_CCLS (10)

Data signed: (hfarmer1) 27 Mar 2015 14:32:01

Generated On: 20 Jul 2016 16:51:47

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	V969094
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Actual Collection Date	2014 03 31
------------------------	------------

Actual Collection Time	06:23
------------------------	-------

Specimen Condition	<hr/>
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Battery ID	RC9255
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Battery Name	CHEMISTRY PANEL
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Lab Test ID	RCT16
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Day 30

Form: Lab_BU_CCLS (10)

Data signed: (hfarmer1) 27 Mar 2015 14:32:01

Generated On: 20 Jul 2016 16:51:47

Lab Test Name	SERUM POTASSIUM
Test ID	
Test Status	Done <input checked="" type="checkbox"/>
Reported Text Result	4.7
Reported Numeric Result	4.7
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: 1181**

Folder: Day 30

Form: Lab_BU_CCLS (10)

Data signed: (hfarmer1) 27 Mar 2015 14:32:01

Generated On: 20 Jul 2016 16:51:47

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 30

Form: Lab_BU_CCLS (11)

Data signed: (hfarmer1) 27 Mar 2015 14:32:01

Generated On: 20 Jul 2016 16:51:47

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	V969094
--------------	---------

Actual Collection Date	2014 03 31
------------------------	------------

Actual Collection Time	06:23
------------------------	-------

Specimen Condition	<hr/>
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Battery ID	RC9255
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Battery Name	CHEMISTRY PANEL
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Lab Test ID	RCT29
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 30

Form: Lab_BU_CCLS (11)

Data signed: (hfarmer1) 27 Mar 2015 14:32:01


Generated On: 20 Jul 2016 16:51:47

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: 1181**

Folder: Day 30

Form: Lab_BU_CCLS (11)

Data signed: (hfarmer1) 27 Mar 2015 14:32:01

Generated On: 20 Jul 2016 16:51:47

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 30

Form: Lab_BU_CCLS (12)

Data signed: (hfarmer1) 27 Mar 2015 14:32:01

Generated On: 20 Jul 2016 16:51:47

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	V969094
--------------	---------

Actual Collection Date	2014 03 31
------------------------	------------

Actual Collection Time	06:23
------------------------	-------

Specimen Condition	<hr/>
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Battery ID	RC9255
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Battery Name	CHEMISTRY PANEL
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Lab Test ID	RCT3
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Day 30

Form: Lab_BU_CCLS (12)

Data signed: (hfarmer1) 27 Mar 2015 14:32:01

Generated On: 20 Jul 2016 16:51:47

Lab Test Name	GGT
Test ID	
Test Status	Done <input type="radio"/>
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: 1181**

Folder: Day 30

Form: Lab_BU_CCLS (12)

Data signed: (hfarmer1) 27 Mar 2015 14:32:01

Generated On: 20 Jul 2016 16:51:47

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 30

Form: Lab_BU_CCLS (13)

Data signed: (hfarmer1) 27 Mar 2015 14:32:01

Generated On: 20 Jul 2016 16:51:47

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	V969094
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Actual Collection Date	2014 03 31
------------------------	------------

Actual Collection Time	06:23
------------------------	-------

Specimen Condition	<hr/>
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Battery ID	RC9255
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Battery Name	CHEMISTRY PANEL
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Lab Test ID	RCT392
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 30

Form: Lab_BU_CCLS (13)

Data signed: (hfarmer1) 27 Mar 2015 14:32:01

Generated On: 20 Jul 2016 16:51:47

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	0.9
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Reported Numeric Result	0.9
-------------------------	-----

Reference Range low	0.5
---------------------	-----

Reference Range high	1.2
----------------------	-----

Range Units	MG/DL
-------------	-------

Conventional Text Result	<hr/>
--------------------------	-------

Conventional Numeric Result	<hr/>
-----------------------------	-------

Conventional Reference Range Low	<hr/>
----------------------------------	-------

Conventional Reference Range High	<hr/>
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Conventional Units	<hr/>
--------------------	-------

SI Text Result	<hr/>
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 30

Form: Lab_BU_CCLS (13)

Data signed: (hfarmer1) 27 Mar 2015 14:32:01

Generated On: 20 Jul 2016 16:51:47

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 30

Form: Lab_BU_CCLS (14)

Data signed: (hfarmer1) 27 Mar 2015 14:32:01

Generated On: 20 Jul 2016 16:51:47

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	V969094
--------------	---------

Actual Collection Date	2014 03 31
------------------------	------------

Actual Collection Time	06:23
------------------------	-------

Specimen Condition	<hr/>
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Battery ID	RC9255
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Battery Name	CHEMISTRY PANEL
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Lab Test ID	RCT4
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 30

Form: Lab_BU_CCLS (14)

Data signed: (hfarmer1) 27 Mar 2015 14:32:01

Generated On: 20 Jul 2016 16:51:47

Lab Test Name	ALT (SGPT)
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	9
Reported Numeric Result	9
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: 1181**

Folder: Day 30

Form: Lab_BU_CCLS (14)

Data signed: (hfarmer1) 27 Mar 2015 14:32:01

Generated On: 20 Jul 2016 16:51:47

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 30

Form: Lab_BU_CCLS (15)

Data signed: (hfarmer1) 27 Mar 2015 14:32:01

Generated On: 20 Jul 2016 16:51:47

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"/>
------------	--

Accession ID	V969094
--------------	---------

Actual Collection Date	2014 03 31
------------------------	------------

Actual Collection Time	06:23
------------------------	-------

Specimen Condition	<hr/>
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Battery ID	RC9255
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Battery Name	CHEMISTRY PANEL
--------------	-----------------

Lab Test ID	RCT5
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 30

Form: Lab_BU_CCLS (15)

Data signed: (hfarmer1) 27 Mar 2015 14:32:01

Generated On: 20 Jul 2016 16:51:47

Lab Test Name	AST (SGOT)
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	15
Reported Numeric Result	15
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: 1181**

Folder: Day 30

Form: Lab_BU_CCLS (15)

Data signed: (hfarmer1) 27 Mar 2015 14:32:01

Generated On: 20 Jul 2016 16:51:47

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 30

Form: Lab_BU_CCLS (16)

Data signed: (hfarmer1) 27 Mar 2015 14:32:01

Generated On: 20 Jul 2016 16:51:47

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	V969094
--------------	---------

Actual Collection Date	2014 03 31
------------------------	------------

Actual Collection Time	06:23
------------------------	-------

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: 1181

Folder: Day 30

Form: Lab_BU_CCLS (16)

Data signed: (hfarmer1) 27 Mar 2015 14:32:01

Generated On: 20 Jul 2016 16:51:47

Lab Test Name	UREA NITROGEN
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	11
Reported Numeric Result	11
Reference Range low	4
Reference Range high	24
Range Units	MG/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 30

Form: Lab_BU_CCLS (16)

Data signed: (hfarmer1) 27 Mar 2015 14:32:01

Generated On: 20 Jul 2016 16:51:47

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 30

Form: Lab_BU_CCLS (17)

Data signed: (hfarmer1) 27 Mar 2015 14:32:01

Generated On: 20 Jul 2016 16:51:47

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	V969094
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Actual Collection Date	2014 03 31
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Actual Collection Time	06:23
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Specimen Condition	<hr/>
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Battery ID	HM1604
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Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
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Lab Test ID	HMT10
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 30

Form: Lab_BU_CCLS (17)

Data signed: (hfarmer1) 27 Mar 2015 14:32:01

Generated On: 20 Jul 2016 16:51:47

Lab Test Name	MONOCYTES
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	0.34
Reported Numeric Result	0.34
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: 1181**

Folder: Day 30

Form: Lab_BU_CCLS (17)

Data signed: (hfarmer1) 27 Mar 2015 14:32:01

Generated On: 20 Jul 2016 16:51:47

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 30

Form: Lab_BU_CCLS (18)

Data signed: (hfarmer1) 27 Mar 2015 14:32:01

Generated On: 20 Jul 2016 16:51:47

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	V969094
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Actual Collection Date	2014 03 31
------------------------	------------

Actual Collection Time	06:23
------------------------	-------

Specimen Condition	<hr/>
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Battery ID	HM1604
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Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
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Lab Test ID	HMT100
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 30

Form: Lab_BU_CCLS (18)

Data signed: (hfarmer1) 27 Mar 2015 14:32:01

Generated On: 20 Jul 2016 16:51:47

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: 1181**

Folder: Day 30

Form: Lab_BU_CCLS (18)

Data signed: (hfarmer1) 27 Mar 2015 14:32:01

Generated On: 20 Jul 2016 16:51:47

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 30

Form: Lab_BU_CCLS (19)

Data signed: (hfarmer1) 27 Mar 2015 14:32:01

Generated On: 20 Jul 2016 16:51:47

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	V969094
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Actual Collection Date	2014 03 31
------------------------	------------

Actual Collection Time	06:23
------------------------	-------

Specimen Condition	<hr/>
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Battery ID	HM1604
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Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
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Lab Test ID	HMT102
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 30

Form: Lab_BU_CCLS (19)

Data signed: (hfarmer1) 27 Mar 2015 14:32:01

Generated On: 20 Jul 2016 16:51:47

Lab Test Name	MCHC
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	34
Reported Numeric Result	34
Reference Range low	31
Reference Range high	38
Range Units	G/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 30

Form: Lab_BU_CCLS (19)

Data signed: (hfarmer1) 27 Mar 2015 14:32:01

Generated On: 20 Jul 2016 16:51:47

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 30

Form: Lab_BU_CCLS (20)

Data signed: (hfarmer1) 27 Mar 2015 14:32:01

Generated On: 20 Jul 2016 16:51:47

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	V969094
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Actual Collection Date	2014 03 31
------------------------	------------

Actual Collection Time	06:23
------------------------	-------

Specimen Condition	<hr/>
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Battery ID	HM1604
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Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
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Lab Test ID	HMT11
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 30

Form: Lab_BU_CCLS (20)

Data signed: (hfarmer1) 27 Mar 2015 14:32:01

Generated On: 20 Jul 2016 16:51:47

Lab Test Name	EOSINOPHILS
Test ID	
Test Status	Done <input checked="" type="checkbox"/>
Reported Text Result	0.15
Reported Numeric Result	0.15
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: 1181**

Folder: Day 30

Form: Lab_BU_CCLS (20)

Data signed: (hfarmer1) 27 Mar 2015 14:32:01

Generated On: 20 Jul 2016 16:51:47

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 30

Form: Lab_BU_CCLS (21)

Data signed: (hfarmer1) 27 Mar 2015 14:32:01

Generated On: 20 Jul 2016 16:51:47

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	V969094
--------------	---------

Actual Collection Date	2014 03 31
------------------------	------------

Actual Collection Time	06:23
------------------------	-------

Specimen Condition	<hr/>
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Battery ID	HM1604
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Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
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Lab Test ID	HMT12
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 30

Form: Lab_BU_CCLS (21)

Data signed: (hfarmer1) 27 Mar 2015 14:32:01

Generated On: 20 Jul 2016 16:51:47

Lab Test Name	BASOPHILS
Test ID	
Test Status	Done <input type="checkbox"/>
Reported Text Result	0.05
Reported Numeric Result	0.05
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: 1181**

Folder: Day 30

Form: Lab_BU_CCLS (21)

Data signed: (hfarmer1) 27 Mar 2015 14:32:01

Generated On: 20 Jul 2016 16:51:47

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 30

Form: Lab_BU_CCLS (22)

Data signed: (hfarmer1) 27 Mar 2015 14:32:01

Generated On: 20 Jul 2016 16:51:47

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	V969094
--------------	---------

Actual Collection Date	2014 03 31
------------------------	------------

Actual Collection Time	06:23
------------------------	-------

Specimen Condition	<hr/>
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Battery ID	HM1604
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Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
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Lab Test ID	HMT13
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 30

Form: Lab_BU_CCLS (22)

Data signed: (hfarmer1) 27 Mar 2015 14:32:01

Generated On: 20 Jul 2016 16:51:47

Lab Test Name	PLATELETS
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	201
Reported Numeric Result	201
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: 1181**

Folder: Day 30

Form: Lab_BU_CCLS (22)

Data signed: (hfarmer1) 27 Mar 2015 14:32:01

Generated On: 20 Jul 2016 16:51:47

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 30

Form: Lab_BU_CCLS (23)

Data signed: (hfarmer1) 27 Mar 2015 14:32:01

Generated On: 20 Jul 2016 16:51:47

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	V969094
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Actual Collection Date	2014 03 31
------------------------	------------

Actual Collection Time	06:23
------------------------	-------

Specimen Condition	<hr/>
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Battery ID	HM1604
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Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
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Lab Test ID	HMT15
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 30

Form: Lab_BU_CCLS (23)

Data signed: (hfarmer1) 27 Mar 2015 14:32:01

Generated On: 20 Jul 2016 16:51:47

Lab Test Name	NEUTROPHILS (%)
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	46.7
Reported Numeric Result	46.7
Reference Range low	40.5
Reference Range high	75.0
Range Units	%
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 30

Form: Lab_BU_CCLS (23)

Data signed: (hfarmer1) 27 Mar 2015 14:32:01

Generated On: 20 Jul 2016 16:51:47

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 30

Form: Lab_BU_CCLS (24)

Data signed: (hfarmer1) 27 Mar 2015 14:32:01

Generated On: 20 Jul 2016 16:51:47

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	V969094
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Actual Collection Date	2014 03 31
------------------------	------------

Actual Collection Time	06:23
------------------------	-------

Specimen Condition	<hr/>
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Battery ID	HM1604
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Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
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Lab Test ID	HMT16
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Day 30

Form: Lab_BU_CCLS (24)

Data signed: (hfarmer1) 27 Mar 2015 14:32:01

Generated On: 20 Jul 2016 16:51:47

Lab Test Name	LYMPHOCYTES (%)
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	45.0
Reported Numeric Result	45.0
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: 1181**

Folder: Day 30

Form: Lab_BU_CCLS (24)

Data signed: (hfarmer1) 27 Mar 2015 14:32:01

Generated On: 20 Jul 2016 16:51:47

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 30

Form: Lab_BU_CCLS (25)

Data signed: (hfarmer1) 27 Mar 2015 14:32:01

Generated On: 20 Jul 2016 16:51:47

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	V969094
--------------	---------

Actual Collection Date	2014 03 31
------------------------	------------

Actual Collection Time	06:23
------------------------	-------

Specimen Condition	<hr/>
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Battery ID	HM1604
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Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
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Lab Test ID	HMT17
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 30

Form: Lab_BU_CCLS (25)

Data signed: (hfarmer1) 27 Mar 2015 14:32:01

Generated On: 20 Jul 2016 16:51:47

Lab Test Name	MONOCYTES (%)
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	5.2
Reported Numeric Result	5.2
Reference Range low	2.6
Reference Range high	10.1
Range Units	%
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 30

Form: Lab_BU_CCLS (25)

Data signed: (hfarmer1) 27 Mar 2015 14:32:01

Generated On: 20 Jul 2016 16:51:47

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 30

Form: Lab_BU_CCLS (26)

Data signed: (hfarmer1) 27 Mar 2015 14:32:01

Generated On: 20 Jul 2016 16:51:47

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	V969094
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Actual Collection Date	2014 03 31
------------------------	------------

Actual Collection Time	06:23
------------------------	-------

Specimen Condition	<hr/>
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Battery ID	HM1604
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Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
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Lab Test ID	HMT18
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Day 30

Form: Lab_BU_CCLS (26)

Data signed: (hfarmer1) 27 Mar 2015 14:32:01

Generated On: 20 Jul 2016 16:51:47

Lab Test Name	EOSINOPHILS (%)
Test ID	
Test Status	Done <input checked="" type="checkbox"/>
Reported Text Result	2.3
Reported Numeric Result	2.3
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: 1181**

Folder: Day 30

Form: Lab_BU_CCLS (26)

Data signed: (hfarmer1) 27 Mar 2015 14:32:01

Generated On: 20 Jul 2016 16:51:47

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 30

Form: Lab_BU_CCLS (27)

Data signed: (hfarmer1) 27 Mar 2015 14:32:01

Generated On: 20 Jul 2016 16:51:47

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	V969094
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Actual Collection Date	2014 03 31
------------------------	------------

Actual Collection Time	06:23
------------------------	-------

Specimen Condition	<hr/>
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Battery ID	HM1604
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Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
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Lab Test ID	HMT19
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 30

Form: Lab_BU_CCLS (27)

Data signed: (hfarmer1) 27 Mar 2015 14:32:01

Generated On: 20 Jul 2016 16:51:47

Lab Test Name	BASOPHILS (%)
Test ID	
Test Status	Done <input checked="" type="radio"/>
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: 1181**

Folder: Day 30

Form: Lab_BU_CCLS (27)

Data signed: (hfarmer1) 27 Mar 2015 14:32:01

Generated On: 20 Jul 2016 16:51:47

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 30

Form: Lab_BU_CCLS (28)

Data signed: (hfarmer1) 27 Mar 2015 14:32:01

Generated On: 20 Jul 2016 16:51:47

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	V969094
--------------	---------

Actual Collection Date	2014 03 31
------------------------	------------

Actual Collection Time	06:23
------------------------	-------

Specimen Condition	<hr/>
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Battery ID	HM1604
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Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
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Lab Test ID	HMT2
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Day 30

Form: Lab_BU_CCLS (28)

Data signed: (hfarmer1) 27 Mar 2015 14:32:01

Generated On: 20 Jul 2016 16:51:47

Lab Test Name	HEMATOCRIT
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	46
Reported Numeric Result	46
Reference Range low	39
Reference Range high	54
Range Units	%
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 30

Form: Lab_BU_CCLS (28)

Data signed: (hfarmer1) 27 Mar 2015 14:32:01

Generated On: 20 Jul 2016 16:51:47

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 30

Form: Lab_BU_CCLS (29)

Data signed: (hfarmer1) 27 Mar 2015 14:32:01

Generated On: 20 Jul 2016 16:51:47

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	V969094
--------------	---------

Actual Collection Date	2014 03 31
------------------------	------------

Actual Collection Time	06:23
------------------------	-------

Specimen Condition	<hr/>
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Battery ID	HM1604
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Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
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Lab Test ID	HMT3
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 30

Form: Lab_BU_CCLS (29)

Data signed: (hfarmer1) 27 Mar 2015 14:32:01

Generated On: 20 Jul 2016 16:51:47

Lab Test Name	RBC
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	5.4
Reported Numeric Result	5.4
Reference Range low	4.5
Reference Range high	6.4
Range Units	X10^6/UL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 30

Form: Lab_BU_CCLS (29)

Data signed: (hfarmer1) 27 Mar 2015 14:32:01

Generated On: 20 Jul 2016 16:51:47

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 30

Form: Lab_BU_CCLS (30)

Data signed: (hfarmer1) 27 Mar 2015 14:32:01

Generated On: 20 Jul 2016 16:51:47

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	V969094
--------------	---------

Actual Collection Date	2014 03 31
------------------------	------------

Actual Collection Time	06:23
------------------------	-------

Specimen Condition	<hr/>
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Battery ID	HM1604
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Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
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Lab Test ID	HMT4
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Day 30

Form: Lab_BU_CCLS (30)

Data signed: (hfarmer1) 27 Mar 2015 14:32:01

Generated On: 20 Jul 2016 16:51:47

Lab Test Name	MCV
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	86
Reported Numeric Result	86
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: 1181**

Folder: Day 30

Form: Lab_BU_CCLS (30)

Data signed: (hfarmer1) 27 Mar 2015 14:32:01

Generated On: 20 Jul 2016 16:51:47

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 30

Form: Lab_BU_CCLS (31)

Data signed: (hfarmer1) 27 Mar 2015 14:32:01

Generated On: 20 Jul 2016 16:51:47

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	V969094
--------------	---------

Actual Collection Date	2014 03 31
------------------------	------------

Actual Collection Time	06:23
------------------------	-------

Specimen Condition	<hr/>
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Battery ID	HM1604
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Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
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Lab Test ID	HMT40
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 30

Form: Lab_BU_CCLS (31)

Data signed: (hfarmer1) 27 Mar 2015 14:32:01

Generated On: 20 Jul 2016 16:51:47

Lab Test Name	HEMOGLOBIN
Test ID	
Test Status	Done <input checked="" type="checkbox"/>
Reported Text Result	15.5
Reported Numeric Result	15.5
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: 1181**

Folder: Day 30

Form: Lab_BU_CCLS (31)

Data signed: (hfarmer1) 27 Mar 2015 14:32:01

Generated On: 20 Jul 2016 16:51:47

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 30

Form: Lab_BU_CCLS (32)

Data signed: (hfarmer1) 27 Mar 2015 14:32:01

Generated On: 20 Jul 2016 16:51:47

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	V969094
--------------	---------

Actual Collection Date	2014 03 31
------------------------	------------

Actual Collection Time	06:23
------------------------	-------

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: 1181**

Folder: Day 30

Form: Lab_BU_CCLS (32)

Data signed: (hfarmer1) 27 Mar 2015 14:32:01

Generated On: 20 Jul 2016 16:51:47

Lab Test Name	WBC
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	6.45
Reported Numeric Result	6.45
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: 1181**

Folder: Day 30

Form: Lab_BU_CCLS (32)

Data signed: (hfarmer1) 27 Mar 2015 14:32:01

Generated On: 20 Jul 2016 16:51:47

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 30

Form: Lab_BU_CCLS (33)

Data signed: (hfarmer1) 27 Mar 2015 14:32:01

Generated On: 20 Jul 2016 16:51:47

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"/>
------------	--

Accession ID	V969094
--------------	---------

Actual Collection Date	2014 03 31
------------------------	------------

Actual Collection Time	06:23
------------------------	-------

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: 1181**

Folder: Day 30

Form: Lab_BU_CCLS (33)

Data signed: (hfarmer1) 27 Mar 2015 14:32:01


Generated On: 20 Jul 2016 16:51:47

Lab Test Name

RBC MORPHOLOGY 1

Test ID

Test Status

Done 

Reported Text Result

NORMOCYTIC

Reported Numeric Result

Reference Range low

Reference Range high

Range Units

Conventional Text Result

Conventional Numeric Result

Conventional Reference Range Low

Conventional Reference Range High

Conventional Units

SI Text Result

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 30

Form: Lab_BU_CCLS (33)

Data signed: (hfarmer1) 27 Mar 2015 14:32:01

Generated On: 20 Jul 2016 16:51:47

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 30

Form: Lab_BU_CCLS (34)

Data signed: (hfarmer1) 27 Mar 2015 14:32:01

Generated On: 20 Jul 2016 16:51:47

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	V969094
--------------	---------

Actual Collection Date	2014 03 31
------------------------	------------

Actual Collection Time	06:23
------------------------	-------

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: 1181

Folder: Day 30

Form: Lab_BU_CCLS (34)

Data signed: (hfarmer1) 27 Mar 2015 14:32:01

Generated On: 20 Jul 2016 16:51:47

Lab Test Name	NEUTROPHILS
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	3.01
Reported Numeric Result	3.01
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: 1181**

Folder: Day 30

Form: Lab_BU_CCLS (34)

Data signed: (hfarmer1) 27 Mar 2015 14:32:01

Generated On: 20 Jul 2016 16:51:47

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 30

Form: Lab_BU_CCLS (35)

Data signed: (hfarmer1) 27 Mar 2015 14:32:01

Generated On: 20 Jul 2016 16:51:47

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	V969094
--------------	---------

Actual Collection Date	2014 03 31
------------------------	------------

Actual Collection Time	06:23
------------------------	-------

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: 1181**

Folder: Day 30

Form: Lab_BU_CCLS (35)

Data signed: (hfarmer1) 27 Mar 2015 14:32:01

Generated On: 20 Jul 2016 16:51:47

Lab Test Name	LYMPHOCYTES
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	2.90
Reported Numeric Result	2.90
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: 1181**

Folder: Day 30

Form: Lab_BU_CCLS (35)

Data signed: (hfarmer1) 27 Mar 2015 14:32:01

Generated On: 20 Jul 2016 16:51:47

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 30

Form: Lab_BU_CCLS (36)

Data signed: (hfarmer1) 27 Mar 2015 14:32:01

Generated On: 20 Jul 2016 16:51:47

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	V969094
--------------	---------

Actual Collection Date	2014 03 31
------------------------	------------

Actual Collection Time	06:23
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

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: 1181**

Folder: Day 30

Form: Lab_BU_CCLS (36)

Data signed: (hfarmer1) 27 Mar 2015 14:32:01


Generated On: 20 Jul 2016 16:51:47

Lab Test Name

UR NITRITE

Test ID

Test Status

Done 

Reported Text Result

NEGATIVE

Reported Numeric Result

Reference Range low

Reference Range high

Range Units

Conventional Text Result

Conventional Numeric Result

Conventional Reference Range Low

Conventional Reference Range High

Conventional Units

SI Text Result

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 30

Form: Lab_BU_CCLS (36)

Data signed: (hfarmer1) 27 Mar 2015 14:32:01

Generated On: 20 Jul 2016 16:51:47

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 30

Form: Lab_BU_CCLS (37)

Data signed: (hfarmer1) 27 Mar 2015 14:32:01

Generated On: 20 Jul 2016 16:51:47

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	<hr/>
----------------------	-------

Subject Sex	M
-------------	---

Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	V969094
--------------	---------

Actual Collection Date	2014 03 31
------------------------	------------

Actual Collection Time	06:23
------------------------	-------

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: 1181**

Folder: Day 30

Form: Lab_BU_CCLS (37)

Data signed: (hfarmer1) 27 Mar 2015 14:32:01

Generated On: 20 Jul 2016 16:51:47

Lab Test Name	UR SPECIFIC GRAVITY
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	1.014
Reported Numeric Result	1.014
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: 1181**

Folder: Day 30

Form: Lab_BU_CCLS (37)

Data signed: (hfarmer1) 27 Mar 2015 14:32:01

Generated On: 20 Jul 2016 16:51:47

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 30

Form: Lab_BU_CCLS (38)

Data signed: (hfarmer1) 27 Mar 2015 14:32:01

Generated On: 20 Jul 2016 16:51:47

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	V969094
--------------	---------

Actual Collection Date	2014 03 31
------------------------	------------

Actual Collection Time	06:23
------------------------	-------

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: 1181**

Folder: Day 30

Form: Lab_BU_CCLS (38)

Data signed: (hfarmer1) 27 Mar 2015 14:32:01

Generated On: 20 Jul 2016 16:51:47

Lab Test Name	UR PH
Test ID	
Test Status	Done <input type="checkbox"/>
Reported Text Result	5.5
Reported Numeric Result	5.5
Reference Range low	5.0
Reference Range high	8.0
Range Units	
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 30

Form: Lab_BU_CCLS (38)

Data signed: (hfarmer1) 27 Mar 2015 14:32:01

Generated On: 20 Jul 2016 16:51:47

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 30

Form: Lab_BU_CCLS (39)

Data signed: (hfarmer1) 27 Mar 2015 14:32:01

Generated On: 20 Jul 2016 16:51:47

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	V969094
--------------	---------

Actual Collection Date	2014 03 31
------------------------	------------

Actual Collection Time	06:23
------------------------	-------

Specimen Condition	<hr/>
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Battery ID	UA1538
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Battery Name	URINE MACRO PANEL
--------------	-------------------

Lab Test ID	UAT43
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 30

Form: Lab_BU_CCLS (39)

Data signed: (hfarmer1) 27 Mar 2015 14:32:01


Generated On: 20 Jul 2016 16:51:47

Lab Test Name

UR BLOOD

Test ID

Test Status

Done 

Reported Text Result

NEGATIVE

Reported Numeric Result

Reference Range low

Reference Range high

Range Units

Conventional Text Result

Conventional Numeric Result

Conventional Reference Range Low

Conventional Reference Range High

Conventional Units

SI Text Result

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 30

Form: Lab_BU_CCLS (39)

Data signed: (hfarmer1) 27 Mar 2015 14:32:01

Generated On: 20 Jul 2016 16:51:47

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 30

Form: Lab_BU_CCLS (40)

Data signed: (hfarmer1) 27 Mar 2015 14:32:01

Generated On: 20 Jul 2016 16:51:47

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	V969094
--------------	---------

Actual Collection Date	2014 03 31
------------------------	------------

Actual Collection Time	06:23
------------------------	-------

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: 1181**

Folder: Day 30

Form: Lab_BU_CCLS (40)

Data signed: (hfarmer1) 27 Mar 2015 14:32:01


Generated On: 20 Jul 2016 16:51:47

Lab Test Name

UR PROTEIN

Test ID

Test Status

Done 

Reported Text Result

NEGATIVE

Reported Numeric Result

Reference Range low

Reference Range high

Range Units

Conventional Text Result

Conventional Numeric Result

Conventional Reference Range Low

Conventional Reference Range High

Conventional Units

SI Text Result

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 30

Form: Lab_BU_CCLS (40)

Data signed: (hfarmer1) 27 Mar 2015 14:32:01

Generated On: 20 Jul 2016 16:51:47

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 30

Form: Lab_BU_CCLS (41)

Data signed: (hfarmer1) 27 Mar 2015 14:32:01

Generated On: 20 Jul 2016 16:51:47

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	<hr/>
----------------------	-------

Subject Sex	M
-------------	---

Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	V969094
--------------	---------

Actual Collection Date	2014 03 31
------------------------	------------

Actual Collection Time	06:23
------------------------	-------

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: 1181**

Folder: Day 30

Form: Lab_BU_CCLS (41)

Data signed: (hfarmer1) 27 Mar 2015 14:32:01


Generated On: 20 Jul 2016 16:51:47

Lab Test Name

UR GLUCOSE

Test ID

Test Status

Done 

Reported Text Result

NORMAL

Reported Numeric Result

Reference Range low

Reference Range high

Range Units

Conventional Text Result

Conventional Numeric Result

Conventional Reference Range Low

Conventional Reference Range High

Conventional Units

SI Text Result

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 30

Form: Lab_BU_CCLS (41)

Data signed: (hfarmer1) 27 Mar 2015 14:32:01

Generated On: 20 Jul 2016 16:51:47

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 30

Form: Lab_BU_CCLS (42)

Data signed: (hfarmer1) 27 Mar 2015 14:32:01

Generated On: 20 Jul 2016 16:51:47

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	<hr/>
----------------------	-------

Subject Sex	M
-------------	---

Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	V969094
--------------	---------

Actual Collection Date	2014 03 31
------------------------	------------

Actual Collection Time	06:23
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	UA1538
------------	--------

Battery Name	URINE MACRO PANEL
--------------	-------------------

Lab Test ID	UAT7
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 30

Form: Lab_BU_CCLS (42)

Data signed: (hfarmer1) 27 Mar 2015 14:32:01


Generated On: 20 Jul 2016 16:51:47

Lab Test Name

UR BILIRUBIN

Test ID

Test Status

Done 

Reported Text Result

NEGATIVE

Reported Numeric Result

Reference Range low

Reference Range high

Range Units

Conventional Text Result

Conventional Numeric Result

Conventional Reference Range Low

Conventional Reference Range High

Conventional Units

SI Text Result

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 30

Form: Lab_BU_CCLS (42)

Data signed: (hfarmer1) 27 Mar 2015 14:32:01

Generated On: 20 Jul 2016 16:51:47

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 30

Form: Lab_BU_COHB (1)

Data signed: (hfarmer1) 27 Mar 2015 14:32:14

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05115150001181
Analyte	CARBOXYHEMOGLOBIN
Sample type	BLOOD
Result	2.40
Result Unit	%
Lab Status	OK
Sample comment	.
Detection method	SPECTROPHOTOMETRIC
Lower limit of quantification	0.500
Planned time point (Hour)	10
Day of Visit	30
Celerion Study Number	AA99128-16
Date of Collection	2014-MAR-30
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 30

Form: Lab_BU_COHB (1)

Data signed: (hfarmer1) 27 Mar 2015 14:32:14

Generated On: 20 Jul 2016 16:51:47

Start Day (24 hour urine only) _____

End Day (24 hour Urine Only) _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 30

Form: Cough Assessment (Paper)

Data signed: (hfarmer1) 27 Mar 2015 14:31:54

Generated On: 20 Jul 2016 16:51:47

Was paper questionnaire used? Yes ☐

Reason not done _____

Date of assessment 31 MAR 2014
DD/MMM/YYYY DD/MMM/YYYY

Time of assessment 06:19
hour:min 24-hour clock

Have you experienced a regular need to cough e.g. No ☐
coughing several times in the last 24 hrs?

If YES, please answer the following questions:

First Question: Cough Impact Scale
How much is your cough bothering you? _____

Second Question: Cough Intensity Scale:
How intense is your cough? _____

Third Question: Cough Frequency Scale:
How frequently do you normally have to cough each
day? _____

Fourth Question: Sputum Production
To what extent do you produce sputum when coughing? _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 30

Form: Cough Assessment (Paper)

Data signed: (hfarmer1) 27 Mar 2015 14:31:54

Generated On: 20 Jul 2016 16:51:47

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: 1181

Folder: Day 30

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS) (Paper)

Data signed: (hfarmer1) 27 Mar 2015 14:31:55

Generated On: 20 Jul 2016 16:51:47

Was paper questionnaire used?

Yes ☒

Reason not done

Date of assessment
DD/MMM/YYYY

31 MAR 2014
DD/MMM/YYYY

Time of assessment

06:21
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: 1181

Folder: Day 30

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS) (Paper) (3)

Data signed: (hfarmer1) 27 Mar 2015 14:31:55

Generated On: 20 Jul 2016 16:51:47

	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: 1181

Folder: Day 30

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS) (Paper) (10)

Data signed: (hfarmer1) 27 Mar 2015 14:31:55

Generated On: 20 Jul 2016 16:51:47

	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: 1181**

Folder: Day 30

**Form: Prochaska "Stage of Change" Questionnaire: Intention to Quit
Smoking**

Data signed: (hfarmer1) 27 Mar 2015 14:31:56

Generated On: 20 Jul 2016 16:51:47

Was paper questionnaire used? Yes ☒

Reason not done _____

Type PROCHASKA STAGE OF
CHANGE QUESTIONNAIRE:
INTENTION TO QUIT
SMOKING

Date of assessment 30 MAR 2014
DD/MMM/YYYY

Time of assessment 20:23
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: 1181

Folder: Day 30

Form: Human Smoking Topography Questionnaire

Data signed: (hfarmer1) 27 Mar 2015 14:31:58

Generated On: 20 Jul 2016 16:51:47

Type

HUMAN SMOKING
TOPOGRAPHY
QUESTIONNAIRE

Was paper questionnaire used?

No ☒

Reason not done

SUBJECT IS IN THE 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: 1181**

Folder: Day 30

Form: Human Smoking Topography Questionnaire

Data signed: (hfarmer1) 27 Mar 2015 14:31:58

Generated On: 20 Jul 2016 16:51:47

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: 1181**

Folder: Day 30

Form: Questionnaire on smoking urges (QSU) (Paper)

Data signed: (hfarmer1) 27 Mar 2015 14:31:57

Generated On: 20 Jul 2016 16:51:47

Type	QUESTIONNAIRE ON SMOKING URGES
------	-----------------------------------

Was paper questionnaire used?	Yes <input type="radio"/>
-------------------------------	---------------------------

Reason not done	
-----------------	--

Date of assessment	30 MAR 2014
--------------------	-------------

DD/MMM/YYYY

Time of assessment	20:22
--------------------	-------

hour:min 24-hour clock

1. I have a desire for a cigarette right now	Somewhat agree <input type="radio"/>
--	--------------------------------------

2. Nothing would be better than smoking a cigarette right now	Do not agree or disagree <input type="radio"/>
--	--

3. If it were possible I would probably smoke now	Do not agree or disagree <input type="radio"/>
---	--

4. I could control things better right now if I could smoke	Strongly disagree <input type="radio"/>
---	---

5. All I want right now is a cigarette	Strongly disagree <input type="radio"/>
--	---

6. I have an urge for a cigarette	Disagree <input type="radio"/>
-----------------------------------	--------------------------------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 30

Form: Questionnaire on smoking urges (QSU) (Paper)

Data signed: (hfarmer1) 27 Mar 2015 14:31:57

Generated On: 20 Jul 2016 16:51:47

7. A cigarette would taste good now Disagree ☐

8. I would do almost anything for a cigarette now Strongly disagree ☐

9. Smoking would make me less depressed Strongly disagree ☐

10. I am going to smoke as soon as possible Disagree ☐

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 30

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper)

Data signed: (hfarmer1) 27 Mar 2015 14:31:54

Generated On: 20 Jul 2016 16:51:47

Was paper questionnaire used?

Yes ☒

Reason not done

Date of assessment

30 MAR 2014

DD/MMM/YYYY

DD/MMM/YYYY

Time of assessment

20:20

hour:min 24-hour clock

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 30

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:31:54

Generated On: 20 Jul 2016 16:51:47

Was paper questionnaire used? Yes ☒

Reason not done _____

Date of assessment 30 MAR 2014
DD/MMM/YYYY

Time of assessment 20:20
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 Quite a lot ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 30

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper) (2)

Data signed: (hfarmer1) 27 Mar 2015 14:31:54

Generated On: 20 Jul 2016 16:51:47

Was paper questionnaire used? Yes ☒

Reason not done _____

Date of assessment 30 MAR 2014
DD/MMM/YYYY

Time of assessment 20:20
hour:min 24-hour clock

If you have smoked since you last completed this questionnaire,
please mark what best represents how smoking made you feel Did cigarettes taste good? ☒

Response Moderately ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 30

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper) (3)

Data signed: (hfarmer1) 27 Mar 2015 14:31:54

Generated On: 20 Jul 2016 16:51:47

Was paper questionnaire used? Yes ☒

Reason not done _____

Date of assessment 30 MAR 2014
DD/MMM/YYYY

Time of assessment 20:20
hour:min 24-hour clock

If you have smoked since you last completed this questionnaire,
please mark what best represents how smoking made you feel

Did you enjoy the sensation in your throat and chest? ☒

Response Moderately ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 30

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper) (4)

Data signed: (hfarmer1) 27 Mar 2015 14:31:54

Generated On: 20 Jul 2016 16:51:47

Was paper questionnaire used? Yes ☒

Reason not done _____

Date of assessment 30 MAR 2014
DD/MMM/YYYY

Time of assessment 20:20
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 A lot ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 30

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper) (5)

Data signed: (hfarmer1) 27 Mar 2015 14:31:54

Generated On: 20 Jul 2016 16:51:47

Was paper questionnaire used? Yes ☐

Reason not done _____

Date of assessment 30 MAR 2014
DD/MMM/YYYY

Time of assessment 20:20
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 Little ☐

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 30

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper) (6)

Data signed: (hfarmer1) 27 Mar 2015 14:31:54

Generated On: 20 Jul 2016 16:51:47

Was paper questionnaire used? Yes ☐

Reason not done _____

Date of assessment 30 MAR 2014
DD/MMM/YYYY

Time of assessment 20:20
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 Not at all ☐

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 30

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper) (7)

Data signed: (hfarmer1) 27 Mar 2015 14:31:54

Generated On: 20 Jul 2016 16:51:47

Was paper questionnaire used? Yes ☒

Reason not done _____

Date of assessment 30 MAR 2014
DD/MMM/YYYY

Time of assessment 20:20
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 Not at all ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 30

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper) (8)

Data signed: (hfarmer1) 27 Mar 2015 14:31:54

Generated On: 20 Jul 2016 16:51:47

Was paper questionnaire used? Yes ☐

Reason not done _____

Date of assessment 30 MAR 2014
DD/MMM/YYYY

Time of assessment 20:20
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: 1181**

Folder: Day 30

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper) (9)

Data signed: (hfarmer1) 27 Mar 2015 14:31:54

Generated On: 20 Jul 2016 16:51:47

Was paper questionnaire used? Yes ☐

Reason not done _____

Date of assessment 30 MAR 2014
DD/MMM/YYYY

Time of assessment 20:20
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 Little ☐

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 30

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper) (10)

Data signed: (hfarmer1) 27 Mar 2015 14:31:54

Generated On: 20 Jul 2016 16:51:47

Was paper questionnaire used? Yes ☐

Reason not done _____

Date of assessment 30 MAR 2014
DD/MMM/YYYY
DD/MMM/YYYY

Time of assessment 20:20
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: 1181**

Folder: Day 30

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper) (11)

Data signed: (hfarmer1) 27 Mar 2015 14:31:54

Generated On: 20 Jul 2016 16:51:47

Was paper questionnaire used? Yes ☒

Reason not done _____

Date of assessment 30 MAR 2014
DD/MMM/YYYY

Time of assessment 20:20
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 A lot ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 30

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper) (12)

Data signed: (hfarmer1) 27 Mar 2015 14:31:54

Generated On: 20 Jul 2016 16:51:47

Was paper questionnaire used? Yes ☒

Reason not done _____

Date of assessment 30 MAR 2014
DD/MMM/YYYY

Time of assessment 20:20
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 Moderately ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 30

Form: Risk Markers(CCLS) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:31:58

Generated On: 20 Jul 2016 16:51:47

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	1181
----------------------	------

Subject Sex	M
-------------	---

Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	DAY30
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	V969094
--------------	---------

Actual Collection Date	2014 03 31
------------------------	------------

Actual Collection Time	06:23
------------------------	-------

Specimen Condition	
--------------------	--

Battery ID	RC6871
------------	--------

Battery Name	HDL
--------------	-----

Lab Test ID	RCT1684
-------------	---------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Day 30

Form: Risk Markers(CCLS) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:31:58

Generated On: 20 Jul 2016 16:51:47

Lab Test Name	DIRECT HDL-C 3RD GENERATION
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	48
Reported Numeric Result	48
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: 1181**

Folder: Day 30

Form: Risk Markers(CCLS) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:31:58

Generated On: 20 Jul 2016 16:51:47

SI Text Result

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Day 30

Form: Risk Markers(CCLS) (2)

Data signed: (hfarmer1) 27 Mar 2015 14:31:58

Generated On: 20 Jul 2016 16:51:47

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	1181
----------------------	------

Subject Sex	M
-------------	---

Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	DAY30
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	V969094
--------------	---------

Actual Collection Date	2014 03 31
------------------------	------------

Actual Collection Time	06:23
------------------------	-------

Specimen Condition	
--------------------	--

Battery ID	SC3249
------------	--------

Battery Name	HS-CRP
--------------	--------

Lab Test ID	SCT1528
-------------	---------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 30


Form: Risk Markers(CCLS) (2)

Data signed: (hfarmer1) 27 Mar 2015 14:31:58

Generated On: 20 Jul 2016 16:51:47

Lab Test Name	C-REACTIVE PROTEIN (N HS)-QT
---------------	---------------------------------

Test ID	
---------	--

Test Status	Done 
-------------	--

Reported Text Result	0.204
----------------------	-------

Reported Numeric Result	0.204
-------------------------	-------

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: 1181**

Folder: Day 30

Form: Risk Markers(CCLS) (2)

Data signed: (hfarmer1) 27 Mar 2015 14:31:58

Generated On: 20 Jul 2016 16:51:47

SI Text Result

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 30

Form: Risk Markers(CCLS) (3)

Data signed: (hfarmer1) 27 Mar 2015 14:31:58

Generated On: 20 Jul 2016 16:51:47

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	1181
----------------------	------

Subject Sex	M
-------------	---

Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	DAY30
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	V969094
--------------	---------

Actual Collection Date	2014 03 31
------------------------	------------

Actual Collection Time	06:23
------------------------	-------

Specimen Condition	
--------------------	--

Battery ID	CG267
------------	-------

Battery Name	FIBRINOGEN
--------------	------------

Lab Test ID	CGT285
-------------	--------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Day 30

Form: Risk Markers(CCLS) (3)

Data signed: (hfarmer1) 27 Mar 2015 14:31:58

Generated On: 20 Jul 2016 16:51:47

Lab Test Name	FIBRINOGEN
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	321
Reported Numeric Result	321
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: 1181**

Folder: Day 30

Form: Risk Markers(CCLS) (3)

Data signed: (hfarmer1) 27 Mar 2015 14:31:58

Generated On: 20 Jul 2016 16:51:47

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 30

Form: Risk Markers(CCLS) (4)

Data signed: (hfarmer1) 27 Mar 2015 14:31:58

Generated On: 20 Jul 2016 16:51:47

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	1181
----------------------	------

Subject Sex	M
-------------	---

Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	DAY30
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	V969094
--------------	---------

Actual Collection Date	2014 03 31
------------------------	------------

Actual Collection Time	06:23
------------------------	-------

Specimen Condition	
--------------------	--

Battery ID	CN236
------------	-------

Battery Name	HOMOCYSTEINE
--------------	--------------

Lab Test ID	CNT145
-------------	--------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 30

Form: Risk Markers(CCLS) (4)

Data signed: (hfarmer1) 27 Mar 2015 14:31:58

Generated On: 20 Jul 2016 16:51:47

Lab Test Name	HOMOCYSTEINE, EDTAPL
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	8.26
Reported Numeric Result	8.26
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: 1181**

Folder: Day 30

Form: Risk Markers(CCLS) (4)

Data signed: (hfarmer1) 27 Mar 2015 14:31:58

Generated On: 20 Jul 2016 16:51:47

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Day 30

Form: Risk Markers(CCLS) (5)

Data signed: (hfarmer1) 27 Mar 2015 14:31:58

Generated On: 20 Jul 2016 16:51:47

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	1181
----------------------	------

Subject Sex	M
-------------	---

Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	DAY30
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	V969094
--------------	---------

Actual Collection Date	2014 03 31
------------------------	------------

Actual Collection Time	06:23
------------------------	-------

Specimen Condition	
--------------------	--

Battery ID	IM2293
------------	--------

Battery Name	SICAM-1
--------------	---------

Lab Test ID	IMT1768
-------------	---------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Day 30

Form: Risk Markers(CCLS) (5)

Data signed: (hfarmer1) 27 Mar 2015 14:31:58

Generated On: 20 Jul 2016 16:51:47

Lab Test Name	SICAM-1-RUO
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	99.6
Reported Numeric Result	99.6
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: 1181**

Folder: Day 30

Form: Risk Markers(CCLS) (5)

Data signed: (hfarmer1) 27 Mar 2015 14:31:58

Generated On: 20 Jul 2016 16:51:47

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 30

Form: Risk Markers(CCLS) (6)

Data signed: (hfarmer1) 27 Mar 2015 14:31:58

Generated On: 20 Jul 2016 16:51:47

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	1181
----------------------	------

Subject Sex	M
-------------	---

Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	DAY30
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	V969094
--------------	---------

Actual Collection Date	2014 03 31
------------------------	------------

Actual Collection Time	06:23
------------------------	-------

Specimen Condition	
--------------------	--

Battery ID	RC9267
------------	--------

Battery Name	LDL
--------------	-----

Lab Test ID	RCT2394
-------------	---------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 30

Form: Risk Markers(CCLS) (6)

Data signed: (hfarmer1) 27 Mar 2015 14:31:58

Generated On: 20 Jul 2016 16:51:47

Lab Test Name	DIRECT LDL-C 2ND GEN (-70)
---------------	----------------------------

Test ID	<hr/>
---------	-------

Test Status	Done 
-------------	--

Reported Text Result	110
----------------------	-----

Reported Numeric Result	110
-------------------------	-----

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: 1181**

Folder: Day 30

Form: Risk Markers(CCLS) (6)

Data signed: (hfarmer1) 27 Mar 2015 14:31:58

Generated On: 20 Jul 2016 16:51:47

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 30

Form: Biomarker-Urine (CEMA, HPMA, HBMA)

Data signed: (hfarmer1) 27 Mar 2015 14:32:15

Generated On: 20 Jul 2016 16:51:47

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 30

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:32:15

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05112450002067
Analyte	HPMA
Sample type	URINE
Result	713
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-MAR-30
Timepoint-minutes	
Urine Start Day	30

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 30

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:32:15

Generated On: 20 Jul 2016 16:51:47

Urine End Day

31

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 30

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (2)

Data signed: (hfarmer1) 27 Mar 2015 14:32:15

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05112450002067
Analyte	CEMA
Sample type	URINE
Result	67.7
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-MAR-30
Timepoint-minutes	
Urine Start Day	30

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 30

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (2)

Data signed: (hfarmer1) 27 Mar 2015 14:32:15

Generated On: 20 Jul 2016 16:51:47

Urine End Day	31
---------------	----

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 30

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (3)

Data signed: (hfarmer1) 27 Mar 2015 14:32:15

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05112450002067
Analyte	HBMA
Sample type	URINE
Result	316
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-MAR-30
Timepoint-minutes	
Urine Start Day	30

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 30

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (3)

Data signed: (hfarmer1) 27 Mar 2015 14:32:15

Generated On: 20 Jul 2016 16:51:47

Urine End Day

31

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 30

Form: Biomarker-Urine (NNN, NNAL)

Data signed: (hfarmer1) 27 Mar 2015 14:32:14

Generated On: 20 Jul 2016 16:51:47

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 30

Form: Biomarker-Urine (NNN, NNAL) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:32:14

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05112460002462
Analyte	NNAL
Sample type	URINE
Result	30.6
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	30
Celerion Study Number	AA99128-04
Date of Collection	2014-MAR-30
Timepoint-minutes	
Urine Start Day	30

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 30

Form: Biomarker-Urine (NNN, NNAL) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:32:14

Generated On: 20 Jul 2016 16:51:47

Urine End Day

31

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 30

Form: Biomarker-Urine (NNN, NNAL) (2)

Data signed: (hfarmer1) 27 Mar 2015 14:32:14

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05112460002462
Analyte	NNN
Sample type	URINE
Result	1.03
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	AA99128-04
Date of Collection	2014-MAR-30
Timepoint-minutes	
Urine Start Day	30

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 30

Form: Biomarker-Urine (NNN, NNAL) (2)

Data signed: (hfarmer1) 27 Mar 2015 14:32:14

Generated On: 20 Jul 2016 16:51:47

Urine End Day

31

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 30

Form: Biomarker-Urine (HEMA)

Data signed: (hfarmer1) 27 Mar 2015 14:32:14

Generated On: 20 Jul 2016 16:51:47

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 30

Form: Biomarker-Urine (HEMA) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:32:14

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05112470001230
Analyte	HEMA
Sample type	URINE
Result	2.88
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-MAR-30
Timepoint-minutes	
Urine Start Day	30

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 30

Form: Biomarker-Urine (HEMA) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:32:14

Generated On: 20 Jul 2016 16:51:47

Urine End Day

31

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 30

Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)

Data signed: (hfarmer1) 27 Mar 2015 14:32:15

Generated On: 20 Jul 2016 16:51:47

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 30

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(1)**

Data signed: (hfarmer1) 27 Mar 2015 14:32:15

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05112480001109
Analyte	COT
Sample type	URINE
Result	399
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-MAR-30
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 30

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(1)**

Data signed: (hfarmer1) 27 Mar 2015 14:32:15

Generated On: 20 Jul 2016 16:51:47

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: 1181**

Folder: Day 30

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(2)**

Data signed: (hfarmer1) 27 Mar 2015 14:32:15

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05112480001109
Analyte	COT-GLUC
Sample type	URINE
Result	710
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-MAR-30
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 30

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(2)**

Data signed: (hfarmer1) 27 Mar 2015 14:32:15

Generated On: 20 Jul 2016 16:51:47

Urine Start Day	30
<hr/>	
Urine End Day	31
<hr/>	

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Day 30

Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc) (3)

Data signed: (hfarmer1) 27 Mar 2015 14:32:15

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05112480001109
Analyte	NIC
Sample type	URINE
Result	59.5
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-MAR-30
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 30

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(3)**

Data signed: (hfarmer1) 27 Mar 2015 14:32:15

Generated On: 20 Jul 2016 16:51:47

Urine Start Day	30
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Urine End Day	31
<hr/>	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 30

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(4)**

Data signed: (hfarmer1) 27 Mar 2015 14:32:15

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05112480001109
Analyte	NIC-GLUC
Sample type	URINE
Result	198
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-MAR-30
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 30

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(4)**

Data signed: (hfarmer1) 27 Mar 2015 14:32:15

Generated On: 20 Jul 2016 16:51:47

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: 1181**

Folder: Day 30

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(5)**

Data signed: (hfarmer1) 27 Mar 2015 14:32:15

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05112480001109
Analyte	THCOT
Sample type	URINE
Result	552
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-MAR-30
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 30

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(5)**

Data signed: (hfarmer1) 27 Mar 2015 14:32:15

Generated On: 20 Jul 2016 16:51:47

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: 1181**

Folder: Day 30

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(6)**

Data signed: (hfarmer1) 27 Mar 2015 14:32:15

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05112480001109
Analyte	THCOT-GLUC
Sample type	URINE
Result	333
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-MAR-30
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 30

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(6)**

Data signed: (hfarmer1) 27 Mar 2015 14:32:15

Generated On: 20 Jul 2016 16:51:47

Urine Start Day	30
<hr/>	
Urine End Day	31
<hr/>	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 30

Form: Biomarker-Urine (3-OH BaP)

Data signed: (hfarmer1) 27 Mar 2015 14:32:15

Generated On: 20 Jul 2016 16:51:47

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 30

Form: Biomarker-Urine (3-OH BaP) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:32:15

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05112490001230
Analyte	3-OH BAP
Sample type	URINE
Result	36.7
Result Unit	FG/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	AA99128-07
Date of Collection	2014-MAR-30
Timepoint-minutes	
Urine Start Day	30

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 30

Form: Biomarker-Urine (3-OH BaP) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:32:15

Generated On: 20 Jul 2016 16:51:47

Urine End Day

31

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 30

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP)

Data signed: (hfarmer1) 27 Mar 2015 14:32:15

Generated On: 20 Jul 2016 16:51:47

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 30

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:32:15

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05112510001230
Analyte	1-NA
Sample type	URINE
Result	18.9
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-MAR-30
Timepoint-minutes	
Urine Start Day	30

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 30

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:32:15

Generated On: 20 Jul 2016 16:51:47

Urine End Day	31
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 30

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (2)

Data signed: (hfarmer1) 27 Mar 2015 14:32:15

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05112510001230
Analyte	2-NA
Sample type	URINE
Result	3.95
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-MAR-30
Timepoint-minutes	
Urine Start Day	30

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 30

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (2)

Data signed: (hfarmer1) 27 Mar 2015 14:32:15

Generated On: 20 Jul 2016 16:51:47

Urine End Day

31

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 30

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (3)

Data signed: (hfarmer1) 27 Mar 2015 14:32:15

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05112510001230
Analyte	4-ABP
Sample type	URINE
Result	4.34
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-MAR-30
Timepoint-minutes	
Urine Start Day	30

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 30

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (3)

Data signed: (hfarmer1) 27 Mar 2015 14:32:15

Generated On: 20 Jul 2016 16:51:47

Urine End Day

31

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 30

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (4)

Data signed: (hfarmer1) 27 Mar 2015 14:32:15

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05112510001230
Analyte	O-TOL
Sample type	URINE
Result	51.6
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	30
Celerion Study Number	AA99128-09
Date of Collection	2014-MAR-30
Timepoint-minutes	
Urine Start Day	30

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 30

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (4)

Data signed: (hfarmer1) 27 Mar 2015 14:32:15

Generated On: 20 Jul 2016 16:51:47

Urine End Day

31

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 30

Form: Biomarker-Urine (11-dTXb2)

Data signed: (hfarmer1) 27 Mar 2015 14:32:14

Generated On: 20 Jul 2016 16:51:47

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 30

Form: Biomarker-Urine (11-dTXb2) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:32:14

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05112530000397
Analyte	11-DTXB2
Sample type	URINE
Result	350
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	AA99128-11
Date of Collection	2014-MAR-30
Timepoint-minutes	
Urine Start Day	30

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 30

Form: Biomarker-Urine (11-dTXb2) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:32:14

Generated On: 20 Jul 2016 16:51:47

Urine End Day

31

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 30

Form: Biomarker-Urine (iPF2a-III)

Data signed: (hfarmer1) 27 Mar 2015 14:32:14

Generated On: 20 Jul 2016 16:51:47

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 30

Form: Biomarker-Urine (iPF2a-III) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:32:14

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05112540000397
Analyte	IPF2A-III
Sample type	URINE
Result	123
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-MAR-30
Timepoint-minutes	
Urine Start Day	30

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 30

Form: Biomarker-Urine (iPF2a-III) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:32:14

Generated On: 20 Jul 2016 16:51:47

Urine End Day

31

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 30

Form: Biomarker-Urine (1-OHP)

Data signed: (hfarmer1) 27 Mar 2015 14:32:15

Generated On: 20 Jul 2016 16:51:47

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 30

Form: Biomarker-Urine (1-OHP) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:32:15

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05115190001549
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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	30
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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	30
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 30

Form: Biomarker-Urine (1-OHP) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:32:15

Generated On: 20 Jul 2016 16:51:47

Urine End Day	31
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 30

Form: Biomarker-Urine (SPMA, SBMA)

Data signed: (hfarmer1) 27 Mar 2015 14:32:15

Generated On: 20 Jul 2016 16:51:47

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 30

Form: Biomarker-Urine (SPMA, SBMA) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:32:15

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05115170001527
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-MAR-30
Timepoint-minutes	
Urine Start Day	30

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 30

Form: Biomarker-Urine (SPMA, SBMA) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:32:15

Generated On: 20 Jul 2016 16:51:47

Urine End Day

31

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 30

Form: Biomarker-Urine (SPMA, SBMA) (2)

Data signed: (hfarmer1) 27 Mar 2015 14:32:15

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05115170001527
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-MAR-30
Timepoint-minutes	
Urine Start Day	30

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 30

Form: Biomarker-Urine (SPMA, SBMA) (2)

Data signed: (hfarmer1) 27 Mar 2015 14:32:15

Generated On: 20 Jul 2016 16:51:47

Urine End Day

31

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 30

Form: Biomarker-Urine (MHBMA)

Data signed: (hfarmer1) 27 Mar 2015 14:32:15

Generated On: 20 Jul 2016 16:51:47

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 30

Form: Biomarker-Urine (MHBMA) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:32:15

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05115180001549
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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	30
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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	30
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 30

Form: Biomarker-Urine (MHBMA) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:32:15

Generated On: 20 Jul 2016 16:51:47

Urine End Day

31

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 30

Form: Biomarker-Urine (Creatinine)

Data signed: (hfarmer1) 27 Mar 2015 14:32:15

Generated On: 20 Jul 2016 16:51:47

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 30

Form: Biomarker-Urine (Creatinine) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:32:15

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05115160001230
Analyte	CREATININE
Sample type	URINE
Result	73.9
Result Unit	MG/DL
Lab Status	OK
Sample comment	ANALYSIS NOT REQUIRED
Detection method	SPECTROPHOTOMETRIC
Planned time point (Hour)	0
Day of Visit	30
Celerion Study Number	AA99128-14
Date of Collection	2014-MAR-30
Timepoint-minutes	
Urine Start Day	30

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 30

Form: Biomarker-Urine (Creatinine) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:32:15

Generated On: 20 Jul 2016 16:51:47

Urine End Day

31

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 30

Form: Biomarker-Plasma (Nic, Cot, tHCot)

Data signed: (hfarmer1) 27 Mar 2015 14:32:15

Generated On: 20 Jul 2016 16:51:47

Sample type

PLASMA

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 30

Form: Biomarker-Plasma (Nic, Cot, tHCot) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:32:15

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05112430001917
Analyte	COT
Sample type	PLASMA
Result	69.9
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	30
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: 1181**

Folder: Day 30

Form: Biomarker-Plasma (Nic, Cot, tHCot) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:32:15

Generated On: 20 Jul 2016 16:51:47

Urine End Day

30

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 30

Form: Biomarker-Plasma (Nic, Cot, tHCot) (2)

Data signed: (hfarmer1) 27 Mar 2015 14:32:15

Generated On: 20 Jul 2016 16:51:47

Sample Barcode	05112430001917
Analyte	NIC
Sample type	PLASMA
Result	3.17
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-MAR-30
Timepoint-minutes	0
Urine Start Day	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Day 30

Form: Biomarker-Plasma (Nic, Cot, tHCot) (2)

Data signed: (hfarmer1) 27 Mar 2015 14:32:15

Generated On: 20 Jul 2016 16:51:47

Urine End Day

30

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Product Use

Form: Product administration-mCC

Data signed: (hcoleman1) 18 Jun 2015 21:06:55

Generated On: 20 Jul 2016 16:51:47

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Product Use

Form: Product administration-mCC (1)

Data signed: (hcoleman1) 18 Jun 2015 21:06:55

Generated On: 20 Jul 2016 16:51:47

Date of product use DD/MMM/YYYY	27 FEB 2014
------------------------------------	-------------

Visit	Day -1 <input checked="" type="radio"/>
-------	---

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	06:32
----------------------	-------

Time of butt return	06:39
---------------------	-------

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: 1181

Folder: Product Use

Form: Product administration-mCC (1)

Data signed: (hcoleman1) 18 Jun 2015 21:06:55

Generated On: 20 Jul 2016 16:51:47

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Product Use

Form: Product administration-mCC (2)

Data signed: (hcoleman1) 18 Jun 2015 21:06:55

Generated On: 20 Jul 2016 16:51:47

Date of product use DD/MMM/YYYY	27 FEB 2014
------------------------------------	-------------

Visit	Day -1 <input checked="" type="radio"/>
-------	---

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	08:18
----------------------	-------

Time of butt return	08:26
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Product Use

Form: Product administration-mCC (2)

Data signed: (hcoleman1) 18 Jun 2015 21:06:55

Generated On: 20 Jul 2016 16:51:47

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Product Use

Form: Product administration-mCC (3)

Data signed: (hcoleman1) 18 Jun 2015 21:06:55

Generated On: 20 Jul 2016 16:51:47

Date of product use DD/MMM/YYYY	27 FEB 2014
------------------------------------	-------------

Visit	Day -1 <input checked="" type="radio"/>
-------	---

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	10:14
----------------------	-------

Time of butt return	10:20
---------------------	-------

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: 1181

Folder: Product Use

Form: Product administration-mCC (3)

Data signed: (hcoleman1) 18 Jun 2015 21:06:55

Generated On: 20 Jul 2016 16:51:47

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Product Use

Form: Product administration-mCC (4)

Data signed: (hcoleman1) 18 Jun 2015 21:06:55

Generated On: 20 Jul 2016 16:51:47

Date of product use DD/MMM/YYYY	27 FEB 2014
------------------------------------	-------------

Visit	Day -1 <input checked="" type="radio"/>
-------	---

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	11:56
----------------------	-------

Time of butt return	12:04
---------------------	-------

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: 1181

Folder: Product Use

Form: Product administration-mCC (4)

Data signed: (hcoleman1) 18 Jun 2015 21:06:55

Generated On: 20 Jul 2016 16:51:47

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Product Use

Form: Product administration-mCC (5)

Data signed: (hcoleman1) 18 Jun 2015 21:06:55

Generated On: 20 Jul 2016 16:51:47

Date of product use DD/MMM/YYYY	27 FEB 2014
------------------------------------	-------------

Visit	Day -1 <input checked="" type="radio"/>
-------	---

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	12:12
----------------------	-------

Time of butt return	12:21
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Product Use

Form: Product administration-mCC (5)

Data signed: (hcoleman1) 18 Jun 2015 21:06:55

Generated On: 20 Jul 2016 16:51:47

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Product Use

Form: Product administration-mCC (6)

Data signed: (hcoleman1) 18 Jun 2015 21:06:55

Generated On: 20 Jul 2016 16:51:47

Date of product use DD/MMM/YYYY	27 FEB 2014
------------------------------------	-------------

Visit	Day -1 <input checked="" type="radio"/>
-------	---

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	14:28
----------------------	-------

Time of butt return	14:36
---------------------	-------

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: 1181

Folder: Product Use

Form: Product administration-mCC (6)

Data signed: (hcoleman1) 18 Jun 2015 21:06:55

Generated On: 20 Jul 2016 16:51:47

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Product Use

Form: Product administration-mCC (7)

Data signed: (hcoleman1) 18 Jun 2015 21:06:55

Generated On: 20 Jul 2016 16:51:47

Date of product use DD/MMM/YYYY	27 FEB 2014
------------------------------------	-------------

Visit	Day -1 <input checked="" type="radio"/>
-------	---

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	15:34
----------------------	-------

Time of butt return	15:43
---------------------	-------

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: 1181

Folder: Product Use

Form: Product administration-mCC (7)

Data signed: (hcoleman1) 18 Jun 2015 21:06:55

Generated On: 20 Jul 2016 16:51:47

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Product Use

Form: Product administration-mCC (8)

Data signed: (hcoleman1) 18 Jun 2015 21:06:55

Generated On: 20 Jul 2016 16:51:47

Date of product use DD/MMM/YYYY	27 FEB 2014
------------------------------------	-------------

Visit	Day -1 <input checked="" type="radio"/>
-------	---

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	15:45
----------------------	-------

Time of butt return	15:52
---------------------	-------

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: 1181

Folder: Product Use

Form: Product administration-mCC (8)

Data signed: (hcoleman1) 18 Jun 2015 21:06:55

Generated On: 20 Jul 2016 16:51:47

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Product Use

Form: Product administration-mCC (9)

Data signed: (hcoleman1) 18 Jun 2015 21:06:55

Generated On: 20 Jul 2016 16:51:47

Date of product use DD/MMM/YYYY	27 FEB 2014
------------------------------------	-------------

Visit	Day -1 <input checked="" type="radio"/>
-------	---

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	17:49
----------------------	-------

Time of butt return	17:58
---------------------	-------

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: 1181

Folder: Product Use

Form: Product administration-mCC (9)

Data signed: (hcoleman1) 18 Jun 2015 21:06:55

Generated On: 20 Jul 2016 16:51:47

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Product Use

Form: Product administration-mCC (10)

Data signed: (hcoleman1) 18 Jun 2015 21:06:55

Generated On: 20 Jul 2016 16:51:47

Date of product use DD/MMM/YYYY	27 FEB 2014
------------------------------------	-------------

Visit	Day -1 <input checked="" type="radio"/>
-------	---

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	19:28
----------------------	-------

Time of butt return	19:36
---------------------	-------

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: 1181

Folder: Product Use

Form: Product administration-mCC (10)

Data signed: (hcoleman1) 18 Jun 2015 21:06:55

Generated On: 20 Jul 2016 16:51:47

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Product Use

Form: Product administration-mCC (11)

Data signed: (hcoleman1) 18 Jun 2015 21:06:55

Generated On: 20 Jul 2016 16:51:47

Date of product use DD/MMM/YYYY	27 FEB 2014
------------------------------------	-------------

Visit	Day -1 <input checked="" type="radio"/>
-------	---

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	21:10
----------------------	-------

Time of butt return	21:17
---------------------	-------

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: 1181

Folder: Product Use

Form: Product administration-mCC (11)

Data signed: (hcoleman1) 18 Jun 2015 21:06:55

Generated On: 20 Jul 2016 16:51:47

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Product Use

Form: Product administration-mCC (12)

Data signed: (hcoleman1) 18 Jun 2015 21:06:55

Generated On: 20 Jul 2016 16:51:47

Date of product use DD/MMM/YYYY	28 FEB 2014
------------------------------------	-------------

Visit	Day 0 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	08:12
----------------------	-------

Time of butt return	08:19
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	161
---------------------	-----

SODIM sample holder number	0219
----------------------------	------

SODIM file number	08DY0161COHH10219001
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Product Use

Form: Product administration-mCC (12)

Data signed: (hcoleman1) 18 Jun 2015 21:06:55

Generated On: 20 Jul 2016 16:51:47

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Product Use

Form: Product administration-mCC (13)

Data signed: (hcoleman1) 18 Jun 2015 21:06:55

Generated On: 20 Jul 2016 16:51:47

Date of product use DD/MMM/YYYY	28 FEB 2014
------------------------------------	-------------

Visit	Day 0 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	08:59
----------------------	-------

Time of butt return	09:07
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	161
---------------------	-----

SODIM sample holder number	0219
----------------------------	------

SODIM file number	08DY0161COHH10219002
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Product Use

Form: Product administration-mCC (13)

Data signed: (hcoleman1) 18 Jun 2015 21:06:55

Generated On: 20 Jul 2016 16:51:47

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Product Use

Form: Product administration-mCC (14)

Data signed: (hcoleman1) 18 Jun 2015 21:06:55

Generated On: 20 Jul 2016 16:51:47

Date of product use DD/MMM/YYYY	28 FEB 2014
------------------------------------	-------------

Visit	Day 0 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	11:03
----------------------	-------

Time of butt return	11:12
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	161
---------------------	-----

SODIM sample holder number	0219
----------------------------	------

SODIM file number	08DY0161COHH10219003
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Product Use

Form: Product administration-mCC (14)

Data signed: (hcoleman1) 18 Jun 2015 21:06:55

Generated On: 20 Jul 2016 16:51:47

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Product Use

Form: Product administration-mCC (15)

Data signed: (hcoleman1) 18 Jun 2015 21:06:55

Generated On: 20 Jul 2016 16:51:47

Date of product use DD/MMM/YYYY	28 FEB 2014
------------------------------------	-------------

Visit	Day 0 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	12:11
----------------------	-------

Time of butt return	12:19
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	161
---------------------	-----

SODIM sample holder number	0219
----------------------------	------

SODIM file number	08DY0161COHH10219004
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Product Use

Form: Product administration-mCC (15)

Data signed: (hcoleman1) 18 Jun 2015 21:06:55

Generated On: 20 Jul 2016 16:51:47

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Product Use

Form: Product administration-mCC (16)

Data signed: (hcoleman1) 18 Jun 2015 21:06:55

Generated On: 20 Jul 2016 16:51:47

Date of product use DD/MMM/YYYY	28 FEB 2014
------------------------------------	-------------

Visit	Day 0 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	13:01
----------------------	-------

Time of butt return	13:10
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	161
---------------------	-----

SODIM sample holder number	0219
----------------------------	------

SODIM file number	08DY0161COHH10219005
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Product Use

Form: Product administration-mCC (16)

Data signed: (hcoleman1) 18 Jun 2015 21:06:55

Generated On: 20 Jul 2016 16:51:47

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Product Use

Form: Product administration-mCC (17)

Data signed: (hcoleman1) 18 Jun 2015 21:06:55

Generated On: 20 Jul 2016 16:51:47

Date of product use DD/MMM/YYYY	28 FEB 2014
------------------------------------	-------------

Visit	Day 0 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	14:42
----------------------	-------

Time of butt return	14:53
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	161
---------------------	-----

SODIM sample holder number	0219
----------------------------	------

SODIM file number	08DY0161COHH10219001
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Product Use

Form: Product administration-mCC (17)

Data signed: (hcoleman1) 18 Jun 2015 21:06:55

Generated On: 20 Jul 2016 16:51:47

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Product Use

Form: Product administration-mCC (18)

Data signed: (hcoleman1) 18 Jun 2015 21:06:55

Generated On: 20 Jul 2016 16:51:47

Date of product use DD/MMM/YYYY	28 FEB 2014
------------------------------------	-------------

Visit	Day 0 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	14:55
----------------------	-------

Time of butt return	15:01
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	161
---------------------	-----

SODIM sample holder number	0219
----------------------------	------

SODIM file number	08DY0161COHH10219001
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Product Use

Form: Product administration-mCC (18)

Data signed: (hcoleman1) 18 Jun 2015 21:06:55

Generated On: 20 Jul 2016 16:51:47

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Product Use

Form: Product administration-mCC (19)

Data signed: (hcoleman1) 18 Jun 2015 21:06:55

Generated On: 20 Jul 2016 16:51:47

Date of product use DD/MMM/YYYY	28 FEB 2014
------------------------------------	-------------

Visit	Day 0 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	15:13
----------------------	-------

Time of butt return	15:21
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	161
---------------------	-----

SODIM sample holder number	0219
----------------------------	------

SODIM file number	08DY0161COHH10219002
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Product Use

Form: Product administration-mCC (19)

Data signed: (hcoleman1) 18 Jun 2015 21:06:55

Generated On: 20 Jul 2016 16:51:47

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Product Use

Form: Product administration-mCC (20)

Data signed: (hcoleman1) 18 Jun 2015 21:06:55

Generated On: 20 Jul 2016 16:51:47

Date of product use DD/MMM/YYYY	28 FEB 2014
------------------------------------	-------------

Visit	Day 0 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	19:23
----------------------	-------

Time of butt return	19:31
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	161
---------------------	-----

SODIM sample holder number	0219
----------------------------	------

SODIM file number	08DY0161COHH10219002
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Product Use

Form: Product administration-mCC (20)

Data signed: (hcoleman1) 18 Jun 2015 21:06:55

Generated On: 20 Jul 2016 16:51:47

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Product Use

Form: Product administration-mCC (21)

Data signed: (hcoleman1) 18 Jun 2015 21:06:55

Generated On: 20 Jul 2016 16:51:47

Date of product use DD/MMM/YYYY	28 FEB 2014
------------------------------------	-------------

Visit	Day 0 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	20:07
----------------------	-------

Time of butt return	20:13
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	161
---------------------	-----

SODIM sample holder number	0219
----------------------------	------

SODIM file number	_____
-------------------	-------

Comment	SODIUM FILE NUMBER IS UNKNOWN
---------	----------------------------------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Product Use

Form: Product administration-mCC (21)

Data signed: (hcoleman1) 18 Jun 2015 21:06:55

Generated On: 20 Jul 2016 16:51:47

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Product Use

Form: Product administration-mCC (22)

Data signed: (hcoleman1) 18 Jun 2015 21:06:55

Generated On: 20 Jul 2016 16:51:47

Date of product use DD/MMM/YYYY	28 FEB 2014
------------------------------------	-------------

Visit	Day 0 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	20:48
----------------------	-------

Time of butt return	20:52
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	161
---------------------	-----

SODIM sample holder number	0219
----------------------------	------

SODIM file number	08DY0161COHH10219001
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Product Use

Form: Product administration-mCC (22)

Data signed: (hcoleman1) 18 Jun 2015 21:06:55

Generated On: 20 Jul 2016 16:51:47

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Product Use

Form: Product administration-mCC (23)

Data signed: (hcoleman1) 18 Jun 2015 21:06:55

Generated On: 20 Jul 2016 16:51:47

Date of product use DD/MMM/YYYY	28 FEB 2014
------------------------------------	-------------

Visit	Day 0 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	21:12
----------------------	-------

Time of butt return	21:18
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	161
---------------------	-----

SODIM sample holder number	0219
----------------------------	------

SODIM file number	08DY0161COHH10219002
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Product Use

Form: Product administration-mCC (23)

Data signed: (hcoleman1) 18 Jun 2015 21:06:55

Generated On: 20 Jul 2016 16:51:47

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Product Use

Form: Product administration-mCC (24)

Data signed: (hcoleman1) 18 Jun 2015 21:06:55

Generated On: 20 Jul 2016 16:51:47

Date of product use DD/MMM/YYYY	01 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	06:52
----------------------	-------

Time of butt return	07:01
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	161
---------------------	-----

SODIM sample holder number	0219
----------------------------	------

SODIM file number	08DY0161COHH10219003
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Product Use

Form: Product administration-mCC (24)

Data signed: (hcoleman1) 18 Jun 2015 21:06:55

Generated On: 20 Jul 2016 16:51:47

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Product Use

Form: Product administration-mCC (25)

Data signed: (hcoleman1) 18 Jun 2015 21:06:55

Generated On: 20 Jul 2016 16:51:47

Date of product use DD/MMM/YYYY	01 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	10:15
----------------------	-------

Time of butt return	10:23
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	161
---------------------	-----

SODIM sample holder number	0219
----------------------------	------

SODIM file number	08DY0161COHH10219004
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Product Use

Form: Product administration-mCC (25)

Data signed: (hcoleman1) 18 Jun 2015 21:06:55

Generated On: 20 Jul 2016 16:51:47

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Product Use

Form: Product administration-mCC (26)

Data signed: (hcoleman1) 18 Jun 2015 21:06:55

Generated On: 20 Jul 2016 16:51:47

Date of product use DD/MMM/YYYY	01 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	11:05
----------------------	-------

Time of butt return	11:12
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	161
---------------------	-----

SODIM sample holder number	0219
----------------------------	------

SODIM file number	08DY0161COHH10219001
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Product Use

Form: Product administration-mCC (26)

Data signed: (hcoleman1) 18 Jun 2015 21:06:55

Generated On: 20 Jul 2016 16:51:47

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Product Use

Form: Product administration-mCC (27)

Data signed: (hcoleman1) 18 Jun 2015 21:06:55

Generated On: 20 Jul 2016 16:51:47

Date of product use DD/MMM/YYYY	01 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	12:54
----------------------	-------

Time of butt return	13:01
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	161
---------------------	-----

SODIM sample holder number	0219
----------------------------	------

SODIM file number	08DY0161COHH10219002
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Product Use

Form: Product administration-mCC (27)

Data signed: (hcoleman1) 18 Jun 2015 21:06:55

Generated On: 20 Jul 2016 16:51:47

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Product Use

Form: Product administration-mCC (28)

Data signed: (hcoleman1) 18 Jun 2015 21:06:55

Generated On: 20 Jul 2016 16:51:47

Date of product use DD/MMM/YYYY	01 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	14:02
----------------------	-------

Time of butt return	14:08
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	161
---------------------	-----

SODIM sample holder number	0219
----------------------------	------

SODIM file number	08DY0161COHH10219003
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Product Use

Form: Product administration-mCC (28)

Data signed: (hcoleman1) 18 Jun 2015 21:06:55

Generated On: 20 Jul 2016 16:51:47

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Product Use

Form: Product administration-mCC (29)

Data signed: (hcoleman1) 18 Jun 2015 21:06:55

Generated On: 20 Jul 2016 16:51:47

Date of product use DD/MMM/YYYY	01 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	14:15
----------------------	-------

Time of butt return	14:24
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	161
---------------------	-----

SODIM sample holder number	0219
----------------------------	------

SODIM file number	08DY0161COHH10219004
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Product Use

Form: Product administration-mCC (29)

Data signed: (hcoleman1) 18 Jun 2015 21:06:55

Generated On: 20 Jul 2016 16:51:47

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Product Use

Form: Product administration-mCC (30)

Data signed: (hcoleman1) 18 Jun 2015 21:06:55

Generated On: 20 Jul 2016 16:51:47

Date of product use DD/MMM/YYYY	01 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	14:26
----------------------	-------

Time of butt return	14:34
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	161
---------------------	-----

SODIM sample holder number	0219
----------------------------	------

SODIM file number	08DY0161COHH10219005
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Product Use

Form: Product administration-mCC (30)

Data signed: (hcoleman1) 18 Jun 2015 21:06:55

Generated On: 20 Jul 2016 16:51:47

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Product Use

Form: Product administration-mCC (31)

Data signed: (hcoleman1) 18 Jun 2015 21:06:55

Generated On: 20 Jul 2016 16:51:47

Date of product use DD/MMM/YYYY	01 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	17:14
----------------------	-------

Time of butt return	17:22
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	161
---------------------	-----

SODIM sample holder number	0219
----------------------------	------

SODIM file number	08DY0161COHH10219001
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Product Use

Form: Product administration-mCC (31)

Data signed: (hcoleman1) 18 Jun 2015 21:06:55

Generated On: 20 Jul 2016 16:51:47

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Product Use

Form: Product administration-mCC (32)

Data signed: (hcoleman1) 18 Jun 2015 21:06:55

Generated On: 20 Jul 2016 16:51:47

Date of product use DD/MMM/YYYY	01 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	19:52
----------------------	-------

Time of butt return	20:00
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	161
---------------------	-----

SODIM sample holder number	0219
----------------------------	------

SODIM file number	08DY0161COHH10219002
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Product Use

Form: Product administration-mCC (32)

Data signed: (hcoleman1) 18 Jun 2015 21:06:55

Generated On: 20 Jul 2016 16:51:47

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Product Use

Form: Product administration-mCC (33)

Data signed: (hcoleman1) 18 Jun 2015 21:06:55

Generated On: 20 Jul 2016 16:51:47

Date of product use DD/MMM/YYYY	01 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	<hr/>
----------------------	-------

Time of butt return	<hr/>
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	161
---------------------	-----

SODIM sample holder number	0219
----------------------------	------

SODIM file number	<hr/>
-------------------	-------

Comment	SODIUM FILE NUMBER IS UNKNOWN
---------	----------------------------------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Product Use

Form: Product administration-mCC (33)

Data signed: (hcoleman1) 18 Jun 2015 21:06:55

Generated On: 20 Jul 2016 16:51:47

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Product Use

Form: Product administration-mCC (34)

Data signed: (hcoleman1) 18 Jun 2015 21:06:55

Generated On: 20 Jul 2016 16:51:47

Date of product use DD/MMM/YYYY	02 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	06:55
----------------------	-------

Time of butt return	07:03
---------------------	-------

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: 1181

Folder: Product Use

Form: Product administration-mCC (34)

Data signed: (hcoleman1) 18 Jun 2015 21:06:55

Generated On: 20 Jul 2016 16:51:47

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Product Use

Form: Product administration-mCC (35)

Data signed: (hcoleman1) 18 Jun 2015 21:06:55

Generated On: 20 Jul 2016 16:51:47

Date of product use DD/MMM/YYYY	02 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	07:04
----------------------	-------

Time of butt return	07:12
---------------------	-------

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: 1181

Folder: Product Use

Form: Product administration-mCC (35)

Data signed: (hcoleman1) 18 Jun 2015 21:06:55

Generated On: 20 Jul 2016 16:51:47

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Product Use

Form: Product administration-mCC (36)

Data signed: (hcoleman1) 18 Jun 2015 21:06:55

Generated On: 20 Jul 2016 16:51:47

Date of product use DD/MMM/YYYY	02 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	08:47
----------------------	-------

Time of butt return	08:57
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Product Use

Form: Product administration-mCC (36)

Data signed: (hcoleman1) 18 Jun 2015 21:06:55

Generated On: 20 Jul 2016 16:51:47

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Product Use

Form: Product administration-mCC (37)

Data signed: (hcoleman1) 18 Jun 2015 21:06:55

Generated On: 20 Jul 2016 16:51:47

Date of product use DD/MMM/YYYY	02 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	13:05
----------------------	-------

Time of butt return	13:14
---------------------	-------

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: 1181

Folder: Product Use

Form: Product administration-mCC (37)

Data signed: (hcoleman1) 18 Jun 2015 21:06:55

Generated On: 20 Jul 2016 16:51:47

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Product Use

Form: Product administration-mCC (38)

Data signed: (hcoleman1) 18 Jun 2015 21:06:55

Generated On: 20 Jul 2016 16:51:47

Date of product use DD/MMM/YYYY	02 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	15:33
----------------------	-------

Time of butt return	15:40
---------------------	-------

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: 1181

Folder: Product Use

Form: Product administration-mCC (38)

Data signed: (hcoleman1) 18 Jun 2015 21:06:55

Generated On: 20 Jul 2016 16:51:47

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Product Use

Form: Product administration-mCC (39)

Data signed: (hcoleman1) 18 Jun 2015 21:06:55

Generated On: 20 Jul 2016 16:51:47

Date of product use DD/MMM/YYYY	02 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	17:34
----------------------	-------

Time of butt return	17:42
---------------------	-------

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: 1181

Folder: Product Use

Form: Product administration-mCC (39)

Data signed: (hcoleman1) 18 Jun 2015 21:06:55

Generated On: 20 Jul 2016 16:51:47

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Product Use

Form: Product administration-mCC (40)

Data signed: (hcoleman1) 18 Jun 2015 21:06:55

Generated On: 20 Jul 2016 16:51:47

Date of product use DD/MMM/YYYY	02 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	17:42
----------------------	-------

Time of butt return	17:50
---------------------	-------

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: 1181

Folder: Product Use

Form: Product administration-mCC (40)

Data signed: (hcoleman1) 18 Jun 2015 21:06:55

Generated On: 20 Jul 2016 16:51:47

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Product Use

Form: Product administration-mCC (41)

Data signed: (hcoleman1) 18 Jun 2015 21:06:55

Generated On: 20 Jul 2016 16:51:47

Date of product use DD/MMM/YYYY	02 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	19:06
----------------------	-------

Time of butt return	19:12
---------------------	-------

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: 1181

Folder: Product Use

Form: Product administration-mCC (41)

Data signed: (hcoleman1) 18 Jun 2015 21:06:55

Generated On: 20 Jul 2016 16:51:47

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Product Use

Form: Product administration-mCC (42)

Data signed: (hcoleman1) 18 Jun 2015 21:06:55

Generated On: 20 Jul 2016 16:51:47

Date of product use DD/MMM/YYYY	02 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	20:49
----------------------	-------

Time of butt return	20:54
---------------------	-------

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: 1181

Folder: Product Use

Form: Product administration-mCC (42)

Data signed: (hcoleman1) 18 Jun 2015 21:06:55

Generated On: 20 Jul 2016 16:51:47

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Product Use

Form: Product administration-mCC (43)

Data signed: (hcoleman1) 18 Jun 2015 21:06:55

Generated On: 20 Jul 2016 16:51:47

Date of product use DD/MMM/YYYY	02 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	20:54
----------------------	-------

Time of butt return	21:01
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Product Use

Form: Product administration-mCC (43)

Data signed: (hcoleman1) 18 Jun 2015 21:06:55

Generated On: 20 Jul 2016 16:51:47

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Product Use

Form: Product administration-mCC (44)

Data signed: (hcoleman1) 18 Jun 2015 21:06:55

Generated On: 20 Jul 2016 16:51:47

Date of product use DD/MMM/YYYY	02 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	22:47
----------------------	-------

Time of butt return	22:53
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Product Use

Form: Product administration-mCC (44)

Data signed: (hcoleman1) 18 Jun 2015 21:06:55

Generated On: 20 Jul 2016 16:51:47

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Product Use

Form: Product administration-mCC (45)

Data signed: (hcoleman1) 18 Jun 2015 21:06:55

Generated On: 20 Jul 2016 16:51:47

Date of product use DD/MMM/YYYY	03 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	06:56
----------------------	-------

Time of butt return	07:02
---------------------	-------

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: 1181

Folder: Product Use

Form: Product administration-mCC (45)

Data signed: (hcoleman1) 18 Jun 2015 21:06:55

Generated On: 20 Jul 2016 16:51:47

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Product Use

Form: Product administration-mCC (46)

Data signed: (hcoleman1) 18 Jun 2015 21:06:55

Generated On: 20 Jul 2016 16:51:47

Date of product use DD/MMM/YYYY	03 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	08:16
----------------------	-------

Time of butt return	08:24
---------------------	-------

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: 1181

Folder: Product Use

Form: Product administration-mCC (46)

Data signed: (hcoleman1) 18 Jun 2015 21:06:55

Generated On: 20 Jul 2016 16:51:47

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Product Use

Form: Product administration-mCC (47)

Data signed: (hcoleman1) 18 Jun 2015 21:06:55

Generated On: 20 Jul 2016 16:51:47

Date of product use DD/MMM/YYYY	03 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	10:53
----------------------	-------

Time of butt return	10:58
---------------------	-------

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: 1181

Folder: Product Use

Form: Product administration-mCC (47)

Data signed: (hcoleman1) 18 Jun 2015 21:06:55

Generated On: 20 Jul 2016 16:51:47

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Product Use

Form: Product administration-mCC (48)

Data signed: (hcoleman1) 18 Jun 2015 21:06:55

Generated On: 20 Jul 2016 16:51:47

Date of product use DD/MMM/YYYY	03 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	12:53
----------------------	-------

Time of butt return	12:58
---------------------	-------

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: 1181

Folder: Product Use

Form: Product administration-mCC (48)

Data signed: (hcoleman1) 18 Jun 2015 21:06:55

Generated On: 20 Jul 2016 16:51:47

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Product Use

Form: Product administration-mCC (49)

Data signed: (hcoleman1) 18 Jun 2015 21:06:55

Generated On: 20 Jul 2016 16:51:47

Date of product use DD/MMM/YYYY	03 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	12:59
----------------------	-------

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: 1181

Folder: Product Use

Form: Product administration-mCC (49)

Data signed: (hcoleman1) 18 Jun 2015 21:06:55

Generated On: 20 Jul 2016 16:51:47

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Product Use

Form: Product administration-mCC (50)

Data signed: (hcoleman1) 18 Jun 2015 21:06:55

Generated On: 20 Jul 2016 16:51:47

Date of product use DD/MMM/YYYY	03 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	15:50
----------------------	-------

Time of butt return	15:55
---------------------	-------

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: 1181

Folder: Product Use

Form: Product administration-mCC (50)

Data signed: (hcoleman1) 18 Jun 2015 21:06:55

Generated On: 20 Jul 2016 16:51:47

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Product Use

Form: Product administration-mCC (51)

Data signed: (hcoleman1) 18 Jun 2015 21:06:55

Generated On: 20 Jul 2016 16:51:47

Date of product use DD/MMM/YYYY	03 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	15:56
----------------------	-------

Time of butt return	16:02
---------------------	-------

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: 1181

Folder: Product Use

Form: Product administration-mCC (51)

Data signed: (hcoleman1) 18 Jun 2015 21:06:55

Generated On: 20 Jul 2016 16:51:47

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Product Use

Form: Product administration-mCC (52)

Data signed: (hcoleman1) 18 Jun 2015 21:06:55

Generated On: 20 Jul 2016 16:51:47

Date of product use DD/MMM/YYYY	03 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	16:59
----------------------	-------

Time of butt return	17:08
---------------------	-------

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: 1181

Folder: Product Use

Form: Product administration-mCC (52)

Data signed: (hcoleman1) 18 Jun 2015 21:06:55

Generated On: 20 Jul 2016 16:51:47

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Product Use

Form: Product administration-mCC (53)

Data signed: (hcoleman1) 18 Jun 2015 21:06:55

Generated On: 20 Jul 2016 16:51:47

Date of product use DD/MMM/YYYY	03 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	19:09
----------------------	-------

Time of butt return	19:20
---------------------	-------

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: 1181

Folder: Product Use

Form: Product administration-mCC (53)

Data signed: (hcoleman1) 18 Jun 2015 21:06:55

Generated On: 20 Jul 2016 16:51:47

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Product Use

Form: Product administration-mCC (54)

Data signed: (hcoleman1) 18 Jun 2015 21:06:55

Generated On: 20 Jul 2016 16:51:47

Date of product use DD/MMM/YYYY	03 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	19:24
----------------------	-------

Time of butt return	19:29
---------------------	-------

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: 1181

Folder: Product Use

Form: Product administration-mCC (54)

Data signed: (hcoleman1) 18 Jun 2015 21:06:55

Generated On: 20 Jul 2016 16:51:47

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Product Use

Form: Product administration-mCC (55)

Data signed: (hcoleman1) 18 Jun 2015 21:06:55

Generated On: 20 Jul 2016 16:51:47

Date of product use DD/MMM/YYYY	04 MAR 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	07:17
----------------------	-------

Time of butt return	07:23
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	161
---------------------	-----

SODIM sample holder number	0219
----------------------------	------

SODIM file number	08DY0161COHH10219001
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Product Use

Form: Product administration-mCC (55)

Data signed: (hcoleman1) 18 Jun 2015 21:06:55

Generated On: 20 Jul 2016 16:51:47

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Product Use

Form: Product administration-mCC (56)

Data signed: (hcoleman1) 18 Jun 2015 21:06:55

Generated On: 20 Jul 2016 16:51:47

Date of product use DD/MMM/YYYY	04 MAR 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	08:45
----------------------	-------

Time of butt return	08:53
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	161
---------------------	-----

SODIM sample holder number	0219
----------------------------	------

SODIM file number	08DY0161COHH10219002
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Product Use

Form: Product administration-mCC (56)

Data signed: (hcoleman1) 18 Jun 2015 21:06:55

Generated On: 20 Jul 2016 16:51:47

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Product Use

Form: Product administration-mCC (57)

Data signed: (hcoleman1) 18 Jun 2015 21:06:55

Generated On: 20 Jul 2016 16:51:47

Date of product use DD/MMM/YYYY	04 MAR 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	10:15
----------------------	-------

Time of butt return	10:23
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	161
---------------------	-----

SODIM sample holder number	0219
----------------------------	------

SODIM file number	08DY0161COHH10219003
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Product Use

Form: Product administration-mCC (57)

Data signed: (hcoleman1) 18 Jun 2015 21:06:55

Generated On: 20 Jul 2016 16:51:47

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Product Use

Form: Product administration-mCC (58)

Data signed: (hcoleman1) 18 Jun 2015 21:06:55

Generated On: 20 Jul 2016 16:51:47

Date of product use DD/MMM/YYYY	04 MAR 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	10:24
----------------------	-------

Time of butt return	10:34
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	161
---------------------	-----

SODIM sample holder number	0219
----------------------------	------

SODIM file number	08DY0161COHH10219001
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Product Use

Form: Product administration-mCC (58)

Data signed: (hcoleman1) 18 Jun 2015 21:06:55

Generated On: 20 Jul 2016 16:51:47

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Product Use

Form: Product administration-mCC (59)

Data signed: (hcoleman1) 18 Jun 2015 21:06:55

Generated On: 20 Jul 2016 16:51:47

Date of product use DD/MMM/YYYY	04 MAR 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	11:58
----------------------	-------

Time of butt return	12:04
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	161
---------------------	-----

SODIM sample holder number	0219
----------------------------	------

SODIM file number	08DY0161COHH10219002
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Product Use

Form: Product administration-mCC (59)

Data signed: (hcoleman1) 18 Jun 2015 21:06:55

Generated On: 20 Jul 2016 16:51:47

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Product Use

Form: Product administration-mCC (60)

Data signed: (hcoleman1) 18 Jun 2015 21:06:55

Generated On: 20 Jul 2016 16:51:47

Date of product use DD/MMM/YYYY	04 MAR 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	12:06
----------------------	-------

Time of butt return	12:12
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	161
---------------------	-----

SODIM sample holder number	0219
----------------------------	------

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Product Use

Form: Product administration-mCC (60)

Data signed: (hcoleman1) 18 Jun 2015 21:06:55

Generated On: 20 Jul 2016 16:51:47

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Product Use

Form: Product administration-mCC (61)

Data signed: (hcoleman1) 18 Jun 2015 21:06:55

Generated On: 20 Jul 2016 16:51:47

Date of product use DD/MMM/YYYY	04 MAR 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	13:25
----------------------	-------

Time of butt return	13:31
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	161
---------------------	-----

SODIM sample holder number	0219
----------------------------	------

SODIM file number	08DY0161COHH10219001
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Product Use

Form: Product administration-mCC (61)

Data signed: (hcoleman1) 18 Jun 2015 21:06:55

Generated On: 20 Jul 2016 16:51:47

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Product Use

Form: Product administration-mCC (62)

Data signed: (hcoleman1) 18 Jun 2015 21:06:55

Generated On: 20 Jul 2016 16:51:47

Date of product use DD/MMM/YYYY	04 MAR 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	14:34
----------------------	-------

Time of butt return	14:40
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	161
---------------------	-----

SODIM sample holder number	0219
----------------------------	------

SODIM file number	08DY0161COHH10219002
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Product Use

Form: Product administration-mCC (62)

Data signed: (hcoleman1) 18 Jun 2015 21:06:55

Generated On: 20 Jul 2016 16:51:47

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Product Use

Form: Product administration-mCC (63)

Data signed: (hcoleman1) 18 Jun 2015 21:06:55

Generated On: 20 Jul 2016 16:51:47

Date of product use DD/MMM/YYYY	04 MAR 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	16:21
----------------------	-------

Time of butt return	16:27
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	161
---------------------	-----

SODIM sample holder number	0219
----------------------------	------

SODIM file number	08DY0161COHH10219003
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Product Use

Form: Product administration-mCC (63)

Data signed: (hcoleman1) 18 Jun 2015 21:06:55

Generated On: 20 Jul 2016 16:51:47

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Product Use

Form: Product administration-mCC (64)

Data signed: (hcoleman1) 18 Jun 2015 21:06:55

Generated On: 20 Jul 2016 16:51:47

Date of product use DD/MMM/YYYY	04 MAR 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	19:41
----------------------	-------

Time of butt return	19:48
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	161
---------------------	-----

SODIM sample holder number	0219
----------------------------	------

SODIM file number	08DY0161COHH10219004
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Product Use

Form: Product administration-mCC (64)

Data signed: (hcoleman1) 18 Jun 2015 21:06:55

Generated On: 20 Jul 2016 16:51:47

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Product Use

Form: Product administration-mCC (65)

Data signed: (hcoleman1) 18 Jun 2015 21:06:55

Generated On: 20 Jul 2016 16:51:47

Date of product use DD/MMM/YYYY	04 MAR 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	20:45
----------------------	-------

Time of butt return	20:53
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	161
---------------------	-----

SODIM sample holder number	0219
----------------------------	------

SODIM file number	08DY0161COHH10219001
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Product Use

Form: Product administration-mCC (65)

Data signed: (hcoleman1) 18 Jun 2015 21:06:55

Generated On: 20 Jul 2016 16:51:47

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Product Use

Form: Product administration-mCC (66)

Data signed: (hcoleman1) 18 Jun 2015 21:06:55

Generated On: 20 Jul 2016 16:51:47

Date of product use DD/MMM/YYYY	05 MAR 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	06:39
----------------------	-------

Time of butt return	06:47
---------------------	-------

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: 1181

Folder: Product Use

Form: Product administration-mCC (66)

Data signed: (hcoleman1) 18 Jun 2015 21:06:55

Generated On: 20 Jul 2016 16:51:47

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Product Use

Form: Product administration-mCC (67)

Data signed: (hcoleman1) 18 Jun 2015 21:06:55

Generated On: 20 Jul 2016 16:51:47

Date of product use DD/MMM/YYYY	05 MAR 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	06:48
----------------------	-------

Time of butt return	06:56
---------------------	-------

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: 1181

Folder: Product Use

Form: Product administration-mCC (67)

Data signed: (hcoleman1) 18 Jun 2015 21:06:55

Generated On: 20 Jul 2016 16:51:47

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Product Use

Form: Product administration-mCC (68)

Data signed: (hcoleman1) 18 Jun 2015 21:06:55

Generated On: 20 Jul 2016 16:51:47

Date of product use DD/MMM/YYYY	05 MAR 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	08:09
----------------------	-------

Time of butt return	08:14
---------------------	-------

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: 1181

Folder: Product Use

Form: Product administration-mCC (68)

Data signed: (hcoleman1) 18 Jun 2015 21:06:55

Generated On: 20 Jul 2016 16:51:47

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Product Use

Form: Product administration-mCC (69)

Data signed: (hcoleman1) 18 Jun 2015 21:06:55

Generated On: 20 Jul 2016 16:51:47

Date of product use DD/MMM/YYYY	05 MAR 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	10:42
----------------------	-------

Time of butt return	10:47
---------------------	-------

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: 1181

Folder: Product Use

Form: Product administration-mCC (69)

Data signed: (hcoleman1) 18 Jun 2015 21:06:55

Generated On: 20 Jul 2016 16:51:47

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Product Use

Form: Product administration-mCC (70)

Data signed: (hcoleman1) 18 Jun 2015 21:06:55

Generated On: 20 Jul 2016 16:51:47

Date of product use DD/MMM/YYYY	05 MAR 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	12:44
----------------------	-------

Time of butt return	12:49
---------------------	-------

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: 1181

Folder: Product Use

Form: Product administration-mCC (70)

Data signed: (hcoleman1) 18 Jun 2015 21:06:55

Generated On: 20 Jul 2016 16:51:47

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Product Use

Form: Product administration-mCC (71)

Data signed: (hcoleman1) 18 Jun 2015 21:06:55

Generated On: 20 Jul 2016 16:51:47

Date of product use DD/MMM/YYYY	05 MAR 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	13:49
----------------------	-------

Time of butt return	13:54
---------------------	-------

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: 1181

Folder: Product Use

Form: Product administration-mCC (71)

Data signed: (hcoleman1) 18 Jun 2015 21:06:55

Generated On: 20 Jul 2016 16:51:47

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Product Use

Form: Product administration-mCC (72)

Data signed: (hcoleman1) 18 Jun 2015 21:06:55

Generated On: 20 Jul 2016 16:51:47

Date of product use DD/MMM/YYYY	05 MAR 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	15:49
----------------------	-------

Time of butt return	15:54
---------------------	-------

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: 1181

Folder: Product Use

Form: Product administration-mCC (72)

Data signed: (hcoleman1) 18 Jun 2015 21:06:55

Generated On: 20 Jul 2016 16:51:47

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Product Use

Form: Product administration-mCC (73)

Data signed: (hcoleman1) 18 Jun 2015 21:06:55

Generated On: 20 Jul 2016 16:51:47

Date of product use DD/MMM/YYYY	05 MAR 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	16:50
----------------------	-------

Time of butt return	16:55
---------------------	-------

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: 1181

Folder: Product Use

Form: Product administration-mCC (73)

Data signed: (hcoleman1) 18 Jun 2015 21:06:55

Generated On: 20 Jul 2016 16:51:47

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Product Use

Form: Product administration-mCC (74)

Data signed: (hcoleman1) 18 Jun 2015 21:06:55

Generated On: 20 Jul 2016 16:51:47

Date of product use DD/MMM/YYYY	05 MAR 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	17:40
----------------------	-------

Time of butt return	17:45
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Product Use

Form: Product administration-mCC (74)

Data signed: (hcoleman1) 18 Jun 2015 21:06:55

Generated On: 20 Jul 2016 16:51:47

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Product Use

Form: Product administration-mCC (75)

Data signed: (hcoleman1) 18 Jun 2015 21:06:55

Generated On: 20 Jul 2016 16:51:47

Date of product use DD/MMM/YYYY	05 MAR 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	19:25
----------------------	-------

Time of butt return	19:29
---------------------	-------

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: 1181

Folder: Product Use

Form: Product administration-mCC (75)

Data signed: (hcoleman1) 18 Jun 2015 21:06:55

Generated On: 20 Jul 2016 16:51:47

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Product Use

Form: Product administration-mCC (76)

Data signed: (hcoleman1) 18 Jun 2015 21:06:55

Generated On: 20 Jul 2016 16:51:47

Date of product use DD/MMM/YYYY	05 MAR 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	21:27
----------------------	-------

Time of butt return	21:31
---------------------	-------

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: 1181

Folder: Product Use

Form: Product administration-mCC (76)

Data signed: (hcoleman1) 18 Jun 2015 21:06:55

Generated On: 20 Jul 2016 16:51:47

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Product Use

Form: Product administration-mCC (77)

Data signed: (hcoleman1) 18 Jun 2015 21:06:55

Generated On: 20 Jul 2016 16:51:47

Date of product use DD/MMM/YYYY	06 MAR 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	07:39
----------------------	-------

Time of butt return	07:44
---------------------	-------

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: 1181

Folder: Product Use

Form: Product administration-mCC (77)

Data signed: (hcoleman1) 18 Jun 2015 21:06:55

Generated On: 20 Jul 2016 16:51:47

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Product Use

Form: Product administration-mCC (78)

Data signed: (hcoleman1) 18 Jun 2015 21:06:55

Generated On: 20 Jul 2016 16:51:47

Date of product use DD/MMM/YYYY	06 MAR 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	09:16
----------------------	-------

Time of butt return	09:22
---------------------	-------

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: 1181

Folder: Product Use

Form: Product administration-mCC (78)

Data signed: (hcoleman1) 18 Jun 2015 21:06:55

Generated On: 20 Jul 2016 16:51:47

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Product Use

Form: Product administration-mCC (79)

Data signed: (hcoleman1) 18 Jun 2015 21:06:55

Generated On: 20 Jul 2016 16:51:47

Date of product use DD/MMM/YYYY	30 MAR 2014
------------------------------------	-------------

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	165
---------------------	-----

SODIM sample holder number	0205
----------------------------	------

SODIM file number	08DY0165COHH30205001
-------------------	----------------------

Comment	<hr/>
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Product Use

Form: Product administration-mCC (79)

Data signed: (hcoleman1) 18 Jun 2015 21:06:55

Generated On: 20 Jul 2016 16:51:47

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Product Use

Form: Product administration-mCC (80)

Data signed: (hcoleman1) 18 Jun 2015 21:06:55

Generated On: 20 Jul 2016 16:51:47

Date of product use DD/MMM/YYYY	30 MAR 2014
------------------------------------	-------------

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	165
---------------------	-----

SODIM sample holder number	0205
----------------------------	------

SODIM file number	08DY0165COHH30205002
-------------------	----------------------

Comment	<hr/>
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Product Use

Form: Product administration-mCC (80)

Data signed: (hcoleman1) 18 Jun 2015 21:06:55

Generated On: 20 Jul 2016 16:51:47

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Product Use

Form: Product administration-mCC (81)

Data signed: (hcoleman1) 18 Jun 2015 21:06:55

Generated On: 20 Jul 2016 16:51:47

Date of product use DD/MMM/YYYY	30 MAR 2014
------------------------------------	-------------

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	165
---------------------	-----

SODIM sample holder number	0205
----------------------------	------

SODIM file number	08DY0165COHH30205003
-------------------	----------------------

Comment	<hr/>
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Product Use

Form: Product administration-mCC (81)

Data signed: (hcoleman1) 18 Jun 2015 21:06:55

Generated On: 20 Jul 2016 16:51:47

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Product Use

Form: Product administration-THS menthol

Data signed: (hfarmer1) 27 Mar 2015 14:32:26

Generated On: 20 Jul 2016 16:51:47

At Day 0, Day 1 and Day 4 complete all SODIM related questions

At Day 30, Day 60, Day 90 complete the Time in 'HST' Form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Product Use

Form: Product administration-THS menthol (1)

Data signed: (hfarmer1) 27 Mar 2015 14:32:26

Generated On: 20 Jul 2016 16:51:47

Date of product use DD/MMM/YYYY	26 FEB 2014
------------------------------------	-------------

Visit	Day -2 <input checked="" type="radio"/>
-------	---

Type of Product Use	THS 2.2 Menthol <input checked="" type="radio"/>
---------------------	--

If type of Product Use different from the randomization please explain	PRODUCT TEST
---	--------------

Time of distribution	15:00
----------------------	-------

Time of product return	<hr/>
------------------------	-------

SODIM device number	<hr/>
---------------------	-------

SODIM sample holder number	<hr/>
----------------------------	-------

Tobacco plug kit number	<hr/>
-------------------------	-------

Tobacco plug vial number	<hr/>
--------------------------	-------

SODIM file number	<hr/>
-------------------	-------

Comment	<hr/>
---------	-------

Batch Number	B08545
--------------	--------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Folder: Product Use

Form: Product administration-THS menthol (1)

Data signed: (hfarmer1) 27 Mar 2015 14:32:26

Generated On: 20 Jul 2016 16:51:47

At Day 0, Day 1 and Day 4 complete all SODIM related questions

At Day 30, Day 60, Day 90 complete the Time in 'HST' Form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Product Use

Form: HST 4 hours (1)

Data signed: (hfarmer1) 27 Mar 2015 14:32:26

Generated On: 20 Jul 2016 16:51:47

Visit	Day 30 <input type="radio"/>
-------	------------------------------

Not Done	False
----------	-------

If Not Done, please specify _____

Date	30 MAR 2014
DD/MMM/YYYY	

SODIM device distribution time	08:46
hour:min 24-hour clock	

SODIM device collection time	12:46
hour:min 24-hour clock	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Product Use

Form: HST 4 hours (2)

Data signed: (hfarmer1) 27 Mar 2015 14:32:26

Generated On: 20 Jul 2016 16:51:47

Visit	Day 60 <input checked="" type="radio"/>
-------	---

Not Done	True
----------	------

If Not Done, please specify	SUBJECT LOST TO FOLLOW UP
-----------------------------	------------------------------

Date DD/MMM/YYYY	<hr/>
---------------------	-------

SODIM device distribution time hour:min 24-hour clock	<hr/>
--	-------

SODIM device collection time hour:min 24-hour clock	<hr/>
--	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Product Use

Form: HST 4 hours (3)

Data signed: (hfarmer1) 27 Mar 2015 14:32:26

Generated On: 20 Jul 2016 16:51:47

Visit	Day 90 <input checked="" type="radio"/>
-------	---

Not Done	True
----------	------

If Not Done, please specify	SUBJECT LOST TO FOLLOW UP
-----------------------------	------------------------------

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: 1181**

Folder: Product Use

Form: Topography files status for mCC (1)

Generated On: 20 Jul 2016 16:51:47

SODIM file number

File Status

Rejection / Error reason

Date of analysis
DD/MMM/YYYY

Operator

Comment

Modified File Number

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Product Use

Form: Topography files status for mCC (2)

Generated On: 20 Jul 2016 16:51:47

SODIM file number

File Status

Rejection / Error reason

Date of analysis
DD/MMM/YYYY

Operator

Comment

Modified File Number

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Product Use

Form: Topography files status for mCC (3)

Generated On: 20 Jul 2016 16:51:47

SODIM file number

File Status

Rejection / Error reason

Date of analysis
DD/MMM/YYYY

Operator

Comment

Modified File Number

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Product Use

Form: Topography files status for mCC (4)

Generated On: 20 Jul 2016 16:51:47

SODIM file number

File Status

Rejection / Error reason

Date of analysis
DD/MMM/YYYY

Operator

Comment

Modified File Number

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Product Use

Form: Topography files status for mCC (5)

Generated On: 20 Jul 2016 16:51:47

SODIM file number

File Status

Rejection / Error reason

Date of analysis
DD/MMM/YYYY

Operator

Comment

Modified File Number

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Product Use

Form: Topography files status for mCC (6)

Generated On: 20 Jul 2016 16:51:47

SODIM file number

File Status

Rejection / Error reason

Date of analysis
DD/MMM/YYYY

Operator

Comment

Modified File Number

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Product Use

Form: Topography files status for mCC (7)

Generated On: 20 Jul 2016 16:51:47

SODIM file number

File Status

Rejection / Error reason

Date of analysis
DD/MMM/YYYY

Operator

Comment

Modified File Number

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Product Use

Form: Topography files status for mCC (8)

Generated On: 20 Jul 2016 16:51:47

SODIM file number

File Status

Rejection / Error reason

Date of analysis
DD/MMM/YYYY

Operator

Comment

Modified File Number

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Product Use

Form: Topography files status for mCC (9)

Generated On: 20 Jul 2016 16:51:47

SODIM file number

File Status

Rejection / Error reason

Date of analysis
DD/MMM/YYYY

Operator

Comment

Modified File Number

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Product Use

Form: Topography files status for mCC (10)

Generated On: 20 Jul 2016 16:51:47

SODIM file number

File Status

Rejection / Error reason

Date of analysis
DD/MMM/YYYY

Operator

Comment

Modified File Number

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Product Use

Form: Topography files status for mCC (11)

Generated On: 20 Jul 2016 16:51:47

SODIM file number

File Status

Rejection / Error reason

Date of analysis
DD/MMM/YYYY

Operator

Comment

Modified File Number

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Product Use

Form: Topography files status for mCC (21)

Generated On: 20 Jul 2016 16:51:47

SODIM file number

File Status

Rejection / Error reason

Date of analysis
DD/MMM/YYYY

Operator

Comment

Modified File Number

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Product Use

Form: Topography files status for mCC (33)

Generated On: 20 Jul 2016 16:51:47

SODIM file number

File Status

Rejection / Error reason

Date of analysis
DD/MMM/YYYY

Operator

Comment

Modified File Number

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Product Use

Form: Topography files status for mCC (34)

Generated On: 20 Jul 2016 16:51:47

SODIM file number

File Status

Rejection / Error reason

Date of analysis
DD/MMM/YYYY

Operator

Comment

Modified File Number

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Product Use

Form: Topography files status for mCC (35)

Generated On: 20 Jul 2016 16:51:47

SODIM file number

File Status

Rejection / Error reason

Date of analysis
DD/MMM/YYYY

Operator

Comment

Modified File Number

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Product Use

Form: Topography files status for mCC (36)

Generated On: 20 Jul 2016 16:51:47

SODIM file number

File Status

Rejection / Error reason

Date of analysis
DD/MMM/YYYY

Operator

Comment

Modified File Number

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Product Use

Form: Topography files status for mCC (37)

Generated On: 20 Jul 2016 16:51:47

SODIM file number

File Status

Rejection / Error reason

Date of analysis
DD/MMM/YYYY

Operator

Comment

Modified File Number

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Product Use

Form: Topography files status for mCC (38)

Generated On: 20 Jul 2016 16:51:47

SODIM file number

File Status

Rejection / Error reason

Date of analysis
DD/MMM/YYYY

Operator

Comment

Modified File Number

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Product Use

Form: Topography files status for mCC (39)

Generated On: 20 Jul 2016 16:51:47

SODIM file number

File Status

Rejection / Error reason

Date of analysis
DD/MMM/YYYY

Operator

Comment

Modified File Number

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Product Use

Form: Topography files status for mCC (40)

Generated On: 20 Jul 2016 16:51:47

SODIM file number

File Status

Rejection / Error reason

Date of analysis
DD/MMM/YYYY

Operator

Comment

Modified File Number

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Product Use

Form: Topography files status for mCC (41)

Generated On: 20 Jul 2016 16:51:47

SODIM file number

File Status

Rejection / Error reason

Date of analysis
DD/MMM/YYYY

Operator

Comment

Modified File Number

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Product Use

Form: Topography files status for mCC (42)

Generated On: 20 Jul 2016 16:51:47

SODIM file number

File Status

Rejection / Error reason

Date of analysis
DD/MMM/YYYY

Operator

Comment

Modified File Number

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Product Use

Form: Topography files status for mCC (43)

Generated On: 20 Jul 2016 16:51:47

SODIM file number

File Status

Rejection / Error reason

Date of analysis
DD/MMM/YYYY

Operator

Comment

Modified File Number

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Product Use

Form: Topography files status for mCC (44)

Generated On: 20 Jul 2016 16:51:47

SODIM file number

File Status

Rejection / Error reason

Date of analysis
DD/MMM/YYYY

Operator

Comment

Modified File Number

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Product Use

Form: Topography files status for mCC (45)

Generated On: 20 Jul 2016 16:51:47

SODIM file number

File Status

Rejection / Error reason

Date of analysis
DD/MMM/YYYY

Operator

Comment

Modified File Number

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Product Use

Form: Topography files status for mCC (46)

Generated On: 20 Jul 2016 16:51:47

SODIM file number

File Status

Rejection / Error reason

Date of analysis
DD/MMM/YYYY

Operator

Comment

Modified File Number

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Product Use

Form: Topography files status for mCC (47)

Generated On: 20 Jul 2016 16:51:47

SODIM file number

File Status

Rejection / Error reason

Date of analysis
DD/MMM/YYYY

Operator

Comment

Modified File Number

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Product Use

Form: Topography files status for mCC (48)

Generated On: 20 Jul 2016 16:51:47

SODIM file number

File Status

Rejection / Error reason

Date of analysis
DD/MMM/YYYY

Operator

Comment

Modified File Number

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Product Use

Form: Topography files status for mCC (49)

Generated On: 20 Jul 2016 16:51:47

SODIM file number

File Status

Rejection / Error reason

Date of analysis
DD/MMM/YYYY

Operator

Comment

Modified File Number

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Product Use

Form: Topography files status for mCC (50)

Generated On: 20 Jul 2016 16:51:47

SODIM file number

File Status

Rejection / Error reason

Date of analysis
DD/MMM/YYYY

Operator

Comment

Modified File Number

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Product Use

Form: Topography files status for mCC (51)

Generated On: 20 Jul 2016 16:51:47

SODIM file number

File Status

Rejection / Error reason

Date of analysis
DD/MMM/YYYY

Operator

Comment

Modified File Number

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Product Use

Form: Topography files status for mCC (52)

Generated On: 20 Jul 2016 16:51:47

SODIM file number

File Status

Rejection / Error reason

Date of analysis
DD/MMM/YYYY

Operator

Comment

Modified File Number

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Product Use

Form: Topography files status for mCC (53)

Generated On: 20 Jul 2016 16:51:47

SODIM file number

File Status

Rejection / Error reason

Date of analysis
DD/MMM/YYYY

Operator

Comment

Modified File Number

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Product Use

Form: Topography files status for mCC (54)

Generated On: 20 Jul 2016 16:51:47

SODIM file number

File Status

Rejection / Error reason

Date of analysis
DD/MMM/YYYY

Operator

Comment

Modified File Number

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Product Use

Form: Topography files status for mCC (60)

Generated On: 20 Jul 2016 16:51:47

SODIM file number

File Status

Rejection / Error reason

Date of analysis
DD/MMM/YYYY

Operator

Comment

Modified File Number

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Product Use

Form: Topography files status for mCC (66)

Generated On: 20 Jul 2016 16:51:47

SODIM file number

File Status

Rejection / Error reason

Date of analysis
DD/MMM/YYYY

Operator

Comment

Modified File Number

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Product Use

Form: Topography files status for mCC (67)

Generated On: 20 Jul 2016 16:51:47

SODIM file number

File Status

Rejection / Error reason

Date of analysis
DD/MMM/YYYY

Operator

Comment

Modified File Number

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Product Use

Form: Topography files status for mCC (68)

Generated On: 20 Jul 2016 16:51:47

SODIM file number

File Status

Rejection / Error reason

Date of analysis
DD/MMM/YYYY

Operator

Comment

Modified File Number

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Product Use

Form: Topography files status for mCC (69)

Generated On: 20 Jul 2016 16:51:47

SODIM file number

File Status

Rejection / Error reason

Date of analysis
DD/MMM/YYYY

Operator

Comment

Modified File Number

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Product Use

Form: Topography files status for mCC (70)

Generated On: 20 Jul 2016 16:51:47

SODIM file number

File Status

Rejection / Error reason

Date of analysis
DD/MMM/YYYY

Operator

Comment

Modified File Number

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Product Use

Form: Topography files status for mCC (71)

Generated On: 20 Jul 2016 16:51:47

SODIM file number

File Status

Rejection / Error reason

Date of analysis
DD/MMM/YYYY

Operator

Comment

Modified File Number

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Product Use

Form: Topography files status for mCC (72)

Generated On: 20 Jul 2016 16:51:47

SODIM file number

File Status

Rejection / Error reason

Date of analysis
DD/MMM/YYYY

Operator

Comment

Modified File Number

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Product Use

Form: Topography files status for mCC (73)

Generated On: 20 Jul 2016 16:51:47

SODIM file number

File Status

Rejection / Error reason

Date of analysis
DD/MMM/YYYY

Operator

Comment

Modified File Number

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Product Use

Form: Topography files status for mCC (74)

Generated On: 20 Jul 2016 16:51:47

SODIM file number

File Status

Rejection / Error reason

Date of analysis
DD/MMM/YYYY

Operator

Comment

Modified File Number

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Product Use

Form: Topography files status for mCC (75)

Generated On: 20 Jul 2016 16:51:47

SODIM file number

File Status

Rejection / Error reason

Date of analysis
DD/MMM/YYYY

Operator

Comment

Modified File Number

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Product Use

Form: Topography files status for mCC (76)

Generated On: 20 Jul 2016 16:51:47

SODIM file number

File Status

Rejection / Error reason

Date of analysis
DD/MMM/YYYY

Operator

Comment

Modified File Number

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Product Use

Form: Topography files status for mCC (77)

Generated On: 20 Jul 2016 16:51:47

SODIM file number

File Status

Rejection / Error reason

Date of analysis
DD/MMM/YYYY

Operator

Comment

Modified File Number

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Product Use

Form: Topography files status for mCC (78)

Generated On: 20 Jul 2016 16:51:47

SODIM file number

File Status

Rejection / Error reason

Date of analysis
DD/MMM/YYYY

Operator

Comment

Modified File Number

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Product Use

Form: Topography files status for mCC (79)

Generated On: 20 Jul 2016 16:51:47

SODIM file number	08DY0165COHH30205001
-------------------	----------------------

File Status	Accepted <input checked="" type="radio"/>
-------------	---

Rejection / Error reason	
--------------------------	--

Date of analysis DD/MMM/YYYY	28 AUG 2014
---------------------------------	-------------

Operator	Thierry Bachmann <input checked="" type="radio"/>
----------	---

Comment	
---------	--

Modified File Number	
----------------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Product Use

Form: Topography files status for mCC (80)

Generated On: 20 Jul 2016 16:51:47

SODIM file number	08DY0165COHH30205002
-------------------	----------------------

File Status	Accepted <input checked="" type="radio"/>
-------------	---

Rejection / Error reason	
--------------------------	--

Date of analysis DD/MMM/YYYY	28 AUG 2014
---------------------------------	-------------

Operator	Thierry Bachmann <input checked="" type="radio"/>
----------	---

Comment	
---------	--

Modified File Number	
----------------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Product Use

Form: Topography files status for mCC (81)

Generated On: 20 Jul 2016 16:51:47

SODIM file number	08DY0165COHH30205003
-------------------	----------------------

File Status	Accepted <input checked="" type="radio"/>
-------------	---

Rejection / Error reason	<hr/>
--------------------------	-------

Date of analysis DD/MMM/YYYY	28 AUG 2014
---------------------------------	-------------

Operator	Thierry Bachmann <input checked="" type="radio"/>
----------	---

Comment	<hr/>
---------	-------

Modified File Number	<hr/>
----------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Product Use

Form: Product use diary(Paper)

Data signed: (hcoleman1) 18 Jun 2015 21:06:55

Generated On: 20 Jul 2016 16:51:47

Was paper questionnaire used?

No ☒

Reason not done

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Product Use

Form: Product use diary(Paper) (1)

Data signed: (hcoleman1) 18 Jun 2015 21:06:55

Generated On: 20 Jul 2016 16:51:47

Was paper questionnaire used?

No ☐

Reason not done

Date of completion
DD/MMM/YYYY

Time of completion
hh:mm

Date the questionnaire was completed for
DD/MMM/YYYY

What tobacco/nicotine product did you use today?

How many THS 2.2 tobacco sticks did you use today?

How many CC/ roll-your-own did you smoke today?

What NRT product did you used today?

How many times did you use an inhaler today?

How many times did you use a nasal spray today?

How many gums did you use today?

How many lozenges did you use today?

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Product Use

Form: Product use diary(Paper) (1)

Data signed: (hcoleman1) 18 Jun 2015 21:06:55

Generated On: 20 Jul 2016 16:51:47

How many patches did you use today? _____

How many times did you use other NRT products today
not listed previously? _____

What other tobacco product did you used today? _____

How many times did you use chewable/smokeless
tobacco today? _____

How many cigars/cigarillos did you smoke today? _____

How many times did you smoke a pipe today? _____

How many times did you use a tobacco product today
not listed previously? _____

How many times did you use an electronic cigarette
today? _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Adverse Events

Form: Adverse Events Y/N

Data signed: (hfarmer1) 27 Mar 2015 14:32:27

Generated On: 20 Jul 2016 16:51:47

Was there any Adverse Event for this subject?

No ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1181**

Folder: Previous and Concomitant Medication

Form: Previous and Concomitant Medication Y/N

Data signed: (hfarmer1) 27 Mar 2015 14:32:27

Generated On: 20 Jul 2016 16:51:47

Has the subject taken previous or concomitant
medication?

No ☒

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Form: Product use diary (1)

Data signed: (hfarmer1) 27 Mar 2015 14:29:38

Generated On: 20 Jul 2016 16:51:47

Date of Birth

(b) (6)

Date of completion
DD/MMM/YYYY

2014 MAR 06

Time of completion
hh:mm

20:05

Date the questionnaire was completed for
DD/MMM/YYYY

2014 MAR 06

Assessment Status

Completed ☒

What tobacco/nicotine product did you use today?

CC ☒

How many THS 2.2 tobacco sticks did you use today?

-9

How many CC/ roll-your-own did you smoke today?

10

What NRT product did you used today?

Not Applicable ☒

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: 1181

Form: Product use diary (1)

Data signed: (hfarmer1) 27 Mar 2015 14:29:38

Generated On: 20 Jul 2016 16:51:47

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: 1181

Form: Product use diary (2)

Data signed: (hfarmer1) 27 Mar 2015 14:29:38

Generated On: 20 Jul 2016 16:51:47

Date of Birth

(b) (6)

Date of completion
DD/MMM/YYYY

2014 MAR 08

Time of completion
hh:mm

19:20

Date the questionnaire was completed for
DD/MMM/YYYY

2014 MAR 08

Assessment Status

Completed ☒

What tobacco/nicotine product did you use today?

CC ☒

How many THS 2.2 tobacco sticks did you use today?

-9

How many CC/ roll-your-own did you smoke today?

10

What NRT product did you used today?

Not Applicable ☒

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: 1181

Form: Product use diary (2)

Data signed: (hfarmer1) 27 Mar 2015 14:29:38

Generated On: 20 Jul 2016 16:51:47

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: 1181

Form: Product use diary (3)

Data signed: (hfarmer1) 27 Mar 2015 14:29:38

Generated On: 20 Jul 2016 16:51:47

Date of Birth	(b) (6)
Date of completion DD/MMM/YYYY	2014 MAR 09
Time of completion hh:mm	19:54
Date the questionnaire was completed for DD/MMM/YYYY	2014 MAR 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?	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: 1181

Form: Product use diary (3)

Data signed: (hfarmer1) 27 Mar 2015 14:29:38

Generated On: 20 Jul 2016 16:51:47

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: 1181

Form: Product use diary (4)

Data signed: (hfarmer1) 27 Mar 2015 14:29:38

Generated On: 20 Jul 2016 16:51:47

Date of Birth

(b) (6)

Date of completion
DD/MMM/YYYY

2014 MAR 10

Time of completion
hh:mm

19:33

Date the questionnaire was completed for
DD/MMM/YYYY

2014 MAR 10

Assessment Status

Completed ☒

What tobacco/nicotine product did you use today?

CC ☒

How many THS 2.2 tobacco sticks did you use today?

-9

How many CC/ roll-your-own did you smoke today?

10

What NRT product did you used today?

Not Applicable ☒

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: 1181

Form: Product use diary (4)

Data signed: (hfarmer1) 27 Mar 2015 14:29:38

Generated On: 20 Jul 2016 16:51:47

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: 1181

Form: Product use diary (5)

Data signed: (hfarmer1) 27 Mar 2015 14:29:38

Generated On: 20 Jul 2016 16:51:47

Date of Birth	(b) (6)
Date of completion DD/MMM/YYYY	2014 MAR 11
Time of completion hh:mm	20:01
Date the questionnaire was completed for DD/MMM/YYYY	2014 MAR 11
Assessment Status	Completed <input checked="" type="radio"/>
What tobacco/nicotine product did you use today?	CC <input checked="" type="radio"/>
How many THS 2.2 tobacco sticks did you use today?	-9
How many CC/ roll-your-own did you smoke today?	10
What NRT product did you used today?	Not Applicable <input checked="" type="radio"/>
How many times did you use an inhaler today?	-9
How many times did you use a nasal spray today?	-9
How many gums did you use today?	-9
How many lozenges did you use today?	-9

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Form: Product use diary (5)

Data signed: (hfarmer1) 27 Mar 2015 14:29:38

Generated On: 20 Jul 2016 16:51:47

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: 1181

Form: Product use diary (6)

Data signed: (hfarmer1) 27 Mar 2015 14:29:38

Generated On: 20 Jul 2016 16:51:47

Date of Birth

(b) (6)

Date of completion
DD/MMM/YYYY

2014 MAR 12

Time of completion
hh:mm

20:01

Date the questionnaire was completed for
DD/MMM/YYYY

2014 MAR 12

Assessment Status

Completed ☒

What tobacco/nicotine product did you use today?

CC ☒

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 ☒

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 (6)

Data signed: (hfarmer1) 27 Mar 2015 14:29:38

Generated On: 20 Jul 2016 16:51:47

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: 1181

Form: Product use diary (7)

Data signed: (hfarmer1) 27 Mar 2015 14:29:38

Generated On: 20 Jul 2016 16:51:47

Date of Birth	(b) (6)
Date of completion DD/MMM/YYYY	2014 MAR 13
Time of completion hh:mm	20:00
Date the questionnaire was completed for DD/MMM/YYYY	2014 MAR 13
Assessment Status	Completed <input checked="" type="radio"/>
What tobacco/nicotine product did you use today?	CC <input checked="" type="radio"/>
How many THS 2.2 tobacco sticks did you use today?	-9
How many CC/ roll-your-own did you smoke today?	10
What NRT product did you used today?	Not Applicable <input checked="" type="radio"/>
How many times did you use an inhaler today?	-9
How many times did you use a nasal spray today?	-9
How many gums did you use today?	-9
How many lozenges did you use today?	-9

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Form: Product use diary (7)

Data signed: (hfarmer1) 27 Mar 2015 14:29:38

Generated On: 20 Jul 2016 16:51:47

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: 1181

Form: Product use diary (8)

Data signed: (hfarmer1) 27 Mar 2015 14:29:38

Generated On: 20 Jul 2016 16:51:47

Date of Birth

(b) (6)

Date of completion
DD/MMM/YYYY

2014 MAR 14

Time of completion
hh:mm

19:08

Date the questionnaire was completed for
DD/MMM/YYYY

2014 MAR 14

Assessment Status

Completed ☒

What tobacco/nicotine product did you use today?

CC ☒

How many THS 2.2 tobacco sticks did you use today?

-9

How many CC/ roll-your-own did you smoke today?

10

What NRT product did you used today?

Not Applicable ☒

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: 1181

Form: Product use diary (8)

Data signed: (hfarmer1) 27 Mar 2015 14:29:38

Generated On: 20 Jul 2016 16:51:47

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: 1181

Form: Product use diary (9)

Data signed: (hfarmer1) 27 Mar 2015 14:29:38

Generated On: 20 Jul 2016 16:51:47

Date of Birth

(b) (6)

Date of completion
DD/MMM/YYYY

2014 MAR 15

Time of completion
hh:mm

19:02

Date the questionnaire was completed for
DD/MMM/YYYY

2014 MAR 15

Assessment Status

Completed ☒

What tobacco/nicotine product did you use today?

CC ☒

How many THS 2.2 tobacco sticks did you use today?

-9

How many CC/ roll-your-own did you smoke today?

10

What NRT product did you used today?

Not Applicable ☒

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: 1181

Form: Product use diary (9)

Data signed: (hfarmer1) 27 Mar 2015 14:29:38

Generated On: 20 Jul 2016 16:51:47

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: 1181

Form: Product use diary (10)

Data signed: (hfarmer1) 27 Mar 2015 14:29:38

Generated On: 20 Jul 2016 16:51:47

Date of Birth

(b) (6)

Date of completion
DD/MMM/YYYY

2014 MAR 16

Time of completion
hh:mm

20:01

Date the questionnaire was completed for
DD/MMM/YYYY

2014 MAR 16

Assessment Status

Completed ☒

What tobacco/nicotine product did you use today?

CC ☒

How many THS 2.2 tobacco sticks did you use today?

-9

How many CC/ roll-your-own did you smoke today?

10

What NRT product did you used today?

Not Applicable ☒

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: 1181

Form: Product use diary (10)

Data signed: (hfarmer1) 27 Mar 2015 14:29:38

Generated On: 20 Jul 2016 16:51:47

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: 1181

Form: Product use diary (11)

Data signed: (hfarmer1) 27 Mar 2015 14:29:38

Generated On: 20 Jul 2016 16:51:47

Date of Birth

(b) (6)

Date of completion
DD/MMM/YYYY

2014 MAR 17

Time of completion
hh:mm

20:01

Date the questionnaire was completed for
DD/MMM/YYYY

2014 MAR 17

Assessment Status

Completed ☒

What tobacco/nicotine product did you use today?

CC ☒

How many THS 2.2 tobacco sticks did you use today?

-9

How many CC/ roll-your-own did you smoke today?

10

What NRT product did you used today?

Not Applicable ☒

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: 1181

Form: Product use diary (11)

Data signed: (hfarmer1) 27 Mar 2015 14:29:38

Generated On: 20 Jul 2016 16:51:47

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: 1181

Form: Product use diary (12)

Data signed: (hfarmer1) 27 Mar 2015 14:29:38

Generated On: 20 Jul 2016 16:51:47

Date of Birth	(b) (6)
Date of completion DD/MMM/YYYY	2014 MAR 18
Time of completion hh:mm	20:01
Date the questionnaire was completed for DD/MMM/YYYY	2014 MAR 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?	10
What NRT product did you used today?	Not Applicable <input checked="" type="radio"/>
How many times did you use an inhaler today?	-9
How many times did you use a nasal spray today?	-9
How many gums did you use today?	-9
How many lozenges did you use today?	-9

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Form: Product use diary (12)

Data signed: (hfarmer1) 27 Mar 2015 14:29:38

Generated On: 20 Jul 2016 16:51:47

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: 1181

Form: Product use diary (13)

Data signed: (hfarmer1) 27 Mar 2015 14:29:38

Generated On: 20 Jul 2016 16:51:47

Date of Birth

(b) (6)

Date of completion
DD/MMM/YYYY

2014 MAR 19

Time of completion
hh:mm

20:01

Date the questionnaire was completed for
DD/MMM/YYYY

2014 MAR 19

Assessment Status

Completed ☒

What tobacco/nicotine product did you use today?

CC ☒

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 ☒

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: 1181

Form: Product use diary (13)

Data signed: (hfarmer1) 27 Mar 2015 14:29:38

Generated On: 20 Jul 2016 16:51:47

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: 1181

Form: Product use diary (14)

Data signed: (hfarmer1) 27 Mar 2015 14:29:38

Generated On: 20 Jul 2016 16:51:47

Date of Birth

(b) (6)

Date of completion
DD/MMM/YYYY

2014 MAR 20

Time of completion
hh:mm

21:01

Date the questionnaire was completed for
DD/MMM/YYYY

2014 MAR 20

Assessment Status

Completed ☒

What tobacco/nicotine product did you use today?

CC ☒

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 ☒

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: 1181

Form: Product use diary (14)

Data signed: (hfarmer1) 27 Mar 2015 14:29:38

Generated On: 20 Jul 2016 16:51:47

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: 1181

Form: Product use diary (15)

Data signed: (hfarmer1) 27 Mar 2015 14:29:38

Generated On: 20 Jul 2016 16:51:47

Date of Birth	(b) (6)
Date of completion DD/MMM/YYYY	2014 MAR 21
Time of completion hh:mm	20:01
Date the questionnaire was completed for DD/MMM/YYYY	2014 MAR 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?	10
What NRT product did you used today?	Not Applicable <input checked="" type="radio"/>
How many times did you use an inhaler today?	-9
How many times did you use a nasal spray today?	-9
How many gums did you use today?	-9
How many lozenges did you use today?	-9

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Form: Product use diary (15)

Data signed: (hfarmer1) 27 Mar 2015 14:29:38

Generated On: 20 Jul 2016 16:51:47

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: 1181

Form: Product use diary (16)

Data signed: (hfarmer1) 27 Mar 2015 14:29:38

Generated On: 20 Jul 2016 16:51:47

Date of Birth

(b) (6)

Date of completion
DD/MMM/YYYY

2014 MAR 22

Time of completion
hh:mm

20:01

Date the questionnaire was completed for
DD/MMM/YYYY

2014 MAR 22

Assessment Status

Completed ☒

What tobacco/nicotine product did you use today?

CC ☒

How many THS 2.2 tobacco sticks did you use today?

-9

How many CC/ roll-your-own did you smoke today?

10

What NRT product did you used today?

Not Applicable ☒

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: 1181

Form: Product use diary (16)

Data signed: (hfarmer1) 27 Mar 2015 14:29:38

Generated On: 20 Jul 2016 16:51:47

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: 1181

Form: Product use diary (17)

Data signed: (hfarmer1) 27 Mar 2015 14:29:38

Generated On: 20 Jul 2016 16:51:47

Date of Birth

(b) (6)

Date of completion
DD/MMM/YYYY

2014 MAR 23

Time of completion
hh:mm

21:02

Date the questionnaire was completed for
DD/MMM/YYYY

2014 MAR 23

Assessment Status

Completed ☒

What tobacco/nicotine product did you use today?

CC ☒

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 ☒

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: 1181

Form: Product use diary (17)

Data signed: (hfarmer1) 27 Mar 2015 14:29:38

Generated On: 20 Jul 2016 16:51:47

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: 1181

Form: Product use diary (18)

Data signed: (hfarmer1) 27 Mar 2015 14:29:38

Generated On: 20 Jul 2016 16:51:47

Date of Birth

(b) (6)

Date of completion
DD/MMM/YYYY

2014 MAR 24

Time of completion
hh:mm

19:31

Date the questionnaire was completed for
DD/MMM/YYYY

2014 MAR 24

Assessment Status

Completed ☒

What tobacco/nicotine product did you use today?

CC ☒

How many THS 2.2 tobacco sticks did you use today?

-9

How many CC/ roll-your-own did you smoke today?

10

What NRT product did you used today?

Not Applicable ☒

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: 1181

Form: Product use diary (18)

Data signed: (hfarmer1) 27 Mar 2015 14:29:38

Generated On: 20 Jul 2016 16:51:47

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: 1181

Form: Product use diary (19)

Data signed: (hfarmer1) 27 Mar 2015 14:29:38

Generated On: 20 Jul 2016 16:51:47

Date of Birth

(b) (6)

Date of completion
DD/MMM/YYYY

2014 MAR 25

Time of completion
hh:mm

20:01

Date the questionnaire was completed for
DD/MMM/YYYY

2014 MAR 25

Assessment Status

Completed ☒

What tobacco/nicotine product did you use today?

CC ☒

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 ☒

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: 1181

Form: Product use diary (19)

Data signed: (hfarmer1) 27 Mar 2015 14:29:38

Generated On: 20 Jul 2016 16:51:47

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: 1181

Form: Product use diary (20)

Data signed: (hfarmer1) 27 Mar 2015 14:29:38

Generated On: 20 Jul 2016 16:51:47

Date of Birth

(b) (6)

Date of completion
DD/MMM/YYYY

2014 MAR 26

Time of completion
hh:mm

19:27

Date the questionnaire was completed for
DD/MMM/YYYY

2014 MAR 26

Assessment Status

Completed ☒

What tobacco/nicotine product did you use today?

CC ☒

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 ☒

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: 1181

Form: Product use diary (20)

Data signed: (hfarmer1) 27 Mar 2015 14:29:38

Generated On: 20 Jul 2016 16:51:47

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: 1181

Form: Product use diary (21)

Data signed: (hfarmer1) 27 Mar 2015 14:29:38

Generated On: 20 Jul 2016 16:51:47

Date of Birth

(b) (6)

Date of completion
DD/MMM/YYYY

2014 MAR 28

Time of completion
hh:mm

09:02

Date the questionnaire was completed for
DD/MMM/YYYY

2014 MAR 27

Assessment Status

Completed ☒

What tobacco/nicotine product did you use today?

CC ☒

How many THS 2.2 tobacco sticks did you use today?

-9

How many CC/ roll-your-own did you smoke today?

10

What NRT product did you used today?

Not Applicable ☒

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: 1181

Form: Product use diary (21)

Data signed: (hfarmer1) 27 Mar 2015 14:29:38

Generated On: 20 Jul 2016 16:51:47

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: 1181

Form: Product use diary (22)

Data signed: (hfarmer1) 27 Mar 2015 14:29:38

Generated On: 20 Jul 2016 16:51:47

Date of Birth	(b) (6)
Date of completion DD/MMM/YYYY	2014 MAR 28
Time of completion hh:mm	19:42
Date the questionnaire was completed for DD/MMM/YYYY	2014 MAR 28
Assessment Status	Completed
What tobacco/nicotine product did you use today?	CC
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
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: 1181

Form: Product use diary (22)

Data signed: (hfarmer1) 27 Mar 2015 14:29:38

Generated On: 20 Jul 2016 16:51:47

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: 1181

Form: Product use diary (23)

Data signed: (hfarmer1) 27 Mar 2015 14:29:38

Generated On: 20 Jul 2016 16:51:47

Date of Birth

(b) (6)

Date of completion
DD/MMM/YYYY

2014 MAR 29

Time of completion
hh:mm

19:55

Date the questionnaire was completed for
DD/MMM/YYYY

2014 MAR 29

Assessment Status

Completed ☒

What tobacco/nicotine product did you use today?

CC ☒

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 ☒

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: 1181

Form: Product use diary (23)

Data signed: (hfarmer1) 27 Mar 2015 14:29:38

Generated On: 20 Jul 2016 16:51:47

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: 1181

Form: Product use diary (24)

Data signed: (hfarmer1) 27 Mar 2015 14:29:38

Generated On: 20 Jul 2016 16:51:47

Date of Birth

(b) (6)

Date of completion
DD/MMM/YYYY

2014 MAR 30

Time of completion
hh:mm

20:01

Date the questionnaire was completed for
DD/MMM/YYYY

2014 MAR 30

Assessment Status

Completed ☒

What tobacco/nicotine product did you use today?

CC ☒

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 ☒

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: 1181

Form: Product use diary (24)

Data signed: (hfarmer1) 27 Mar 2015 14:29:38

Generated On: 20 Jul 2016 16:51:47

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: 1181

Form: Product use diary (25)

Data signed: (hfarmer1) 27 Mar 2015 14:29:38

Generated On: 20 Jul 2016 16:51:47

Date of Birth

(b) (6)

Date of completion
DD/MMM/YYYY

2014 MAR 31

Time of completion
hh:mm

20:01

Date the questionnaire was completed for
DD/MMM/YYYY

2014 MAR 31

Assessment Status

Completed ☒

What tobacco/nicotine product did you use today?

CC ☒

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 ☒

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: 1181

Form: Product use diary (25)

Data signed: (hfarmer1) 27 Mar 2015 14:29:38

Generated On: 20 Jul 2016 16:51:47

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: 1181

Form: Product use diary (26)

Data signed: (hfarmer1) 27 Mar 2015 14:29:38

Generated On: 20 Jul 2016 16:51:47

Date of Birth	(b) (6)
Date of completion DD/MMM/YYYY	2014 APR 01
Time of completion hh:mm	20:00
Date the questionnaire was completed for DD/MMM/YYYY	2014 APR 01
Assessment Status	Completed <input checked="" type="radio"/>
What tobacco/nicotine product did you use today?	CC <input checked="" type="radio"/>
How many THS 2.2 tobacco sticks did you use today?	-9
How many CC/ roll-your-own did you smoke today?	10
What NRT product did you used today?	Not Applicable <input checked="" type="radio"/>
How many times did you use an inhaler today?	-9
How many times did you use a nasal spray today?	-9
How many gums did you use today?	-9
How many lozenges did you use today?	-9

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Form: Product use diary (26)

Data signed: (hfarmer1) 27 Mar 2015 14:29:38

Generated On: 20 Jul 2016 16:51:47

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: 1181

Form: Product use diary (27)

Data signed: (hfarmer1) 27 Mar 2015 14:29:38

Generated On: 20 Jul 2016 16:51:47

Date of Birth	(b) (6)
Date of completion DD/MMM/YYYY	2014 APR 02
Time of completion hh:mm	20:00
Date the questionnaire was completed for DD/MMM/YYYY	2014 APR 02
Assessment Status	Completed <input checked="" type="radio"/>
What tobacco/nicotine product did you use today?	CC <input checked="" type="radio"/>
How many THS 2.2 tobacco sticks did you use today?	-9
How many CC/ roll-your-own did you smoke today?	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: 1181

Form: Product use diary (27)

Data signed: (hfarmer1) 27 Mar 2015 14:29:38

Generated On: 20 Jul 2016 16:51:47

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: 1181

Form: Product use diary (28)

Data signed: (hfarmer1) 27 Mar 2015 14:29:38

Generated On: 20 Jul 2016 16:51:47

Date of Birth

(b) (6)

Date of completion
DD/MMM/YYYY

2014 APR 03

Time of completion
hh:mm

20:01

Date the questionnaire was completed for
DD/MMM/YYYY

2014 APR 03

Assessment Status

Completed ☒

What tobacco/nicotine product did you use today?

CC ☒

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 ☒

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: 1181

Form: Product use diary (28)

Data signed: (hfarmer1) 27 Mar 2015 14:29:38

Generated On: 20 Jul 2016 16:51:47

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: 1181

Form: Product use diary (29)

Data signed: (hfarmer1) 27 Mar 2015 14:29:38

Generated On: 20 Jul 2016 16:51:47

Date of Birth

(b) (6)

Date of completion
DD/MMM/YYYY

2014 APR 05

Time of completion
hh:mm

06:48

Date the questionnaire was completed for
DD/MMM/YYYY

2014 APR 04

Assessment Status

Completed ☒

What tobacco/nicotine product did you use today?

CC ☒

How many THS 2.2 tobacco sticks did you use today?

-9

How many CC/ roll-your-own did you smoke today?

1

What NRT product did you used today?

Not Applicable ☒

How many times did you use an inhaler today?

-9

How many times did you use a nasal spray today?

-9

How many gums did you use today?

-9

How many lozenges did you use today?

-9

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1181

Form: Product use diary (29)

Data signed: (hfarmer1) 27 Mar 2015 14:29:38

Generated On: 20 Jul 2016 16:51:47

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: 1181

Form: Product use diary (30)

Data signed: (hfarmer1) 27 Mar 2015 14:29:38

Generated On: 20 Jul 2016 16:51:47

Date of Birth

(b) (6)

Date of completion
DD/MMM/YYYY

2014 APR 05

Time of completion
hh:mm

20:00

Date the questionnaire was completed for
DD/MMM/YYYY

2014 APR 05

Assessment Status

Completed ☒

What tobacco/nicotine product did you use today?

CC ☒

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 ☒

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: 1181

Form: Product use diary (30)

Data signed: (hfarmer1) 27 Mar 2015 14:29:38

Generated On: 20 Jul 2016 16:51:47

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: 1181**

Form: End of study

Data signed: (hcoleman1) 18 Jun 2015 21:06:54

Generated On: 20 Jul 2016 16:51:47

End of study date

13 MAY 2014
DD/MMM/YYYY

Has the subject completed the study ?

No ☒

If No, please specify the reason:

Lost To Follow-up ☒

Details:
