

Subject Case Report Forms

1261 (Prod: Covance Clinical Development Services, Daytona Beach, Florida)

Generated On: 20 Jul 2016 22:42:34

All time stamps listed in this document are displayed in GMT

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Form: Subject

Data signed: (hfarmer1) 30 Mar 2015 12:26:56

Generated On: 20 Jul 2016 22:42:34

Screening number	1261
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Site number	DAY
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Subject Status

Form: Subject Status

Data signed: (hfarmer1) 30 Mar 2015 12:27:10

Generated On: 20 Jul 2016 22:42:34

Date of 'Screen Failed' Event

Date of 'Discontinued From
Enrollment' Event

Randomization Date

13 APR 2014
DD/MMM/YYYY

Randomization Time

10:09
hour:min 24-hour clock

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Screening

Form: Date of Visit

Data signed: (hfarmer1) 30 Mar 2015 12:27:14

Generated On: 20 Jul 2016 22:42:34

Date of Visit

02 APR 2014
DD/MMM/YYYY

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Screening

Form: Additional Informed Consent

Data signed: (hfarmer1) 30 Mar 2015 12:27:11

Generated On: 20 Jul 2016 22:42:34

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

Yes ☒

Consent Date

02 APR 2014
DD/MMM/YYYY

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

Yes ☒

Consent Date

02 APR 2014
DD/MMM/YYYY

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Screening

Form: Inclusion Criteria

Data signed: (hfarmer1) 30 Mar 2015 12:27:12

Generated On: 20 Jul 2016 22:42:34

*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: 1261**

Folder: Screening

Form: Inclusion Criteria (1)

Data signed: (hfarmer1) 30 Mar 2015 12:27:12

Generated On: 20 Jul 2016 22:42:34

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Screening

Form: Inclusion Criteria (2)

Data signed: (hfarmer1) 30 Mar 2015 12:27:12

Generated On: 20 Jul 2016 22:42:34

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

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1261

Folder: Screening

Form: Inclusion Criteria (3)

Data signed: (hfarmer1) 30 Mar 2015 12:27:12

Generated On: 20 Jul 2016 22:42:34

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: 1261

Folder: Screening

Form: Inclusion Criteria (4)

Data signed: (hfarmer1) 30 Mar 2015 12:27:12

Generated On: 20 Jul 2016 22:42:34

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Screening

Form: Inclusion Criteria (5)

Data signed: (hfarmer1) 30 Mar 2015 12:27:12

Generated On: 20 Jul 2016 22:42:34

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Screening

Form: Inclusion Criteria (6)

Data signed: (hfarmer1) 30 Mar 2015 12:27:12

Generated On: 20 Jul 2016 22:42:34

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Screening

Form: Exclusion Criteria

Data signed: (hfarmer1) 30 Mar 2015 12:27:11

Generated On: 20 Jul 2016 22:42:34

*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: 1261**

Folder: Screening

Form: Exclusion Criteria (1)

Data signed: (hfarmer1) 30 Mar 2015 12:27:11

Generated On: 20 Jul 2016 22:42:34

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: 1261

Folder: Screening

Form: Exclusion Criteria (2)

Data signed: (hfarmer1) 30 Mar 2015 12:27:11

Generated On: 20 Jul 2016 22:42:34

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
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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: 1261

Folder: Screening

Form: Exclusion Criteria (3)

Data signed: (hfarmer1) 30 Mar 2015 12:27:11

Generated On: 20 Jul 2016 22:42:34

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: 1261**

Folder: Screening

Form: Exclusion Criteria (4)

Data signed: (hfarmer1) 30 Mar 2015 12:27:11

Generated On: 20 Jul 2016 22:42:34

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

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1261

Folder: Screening

Form: Exclusion Criteria (5)

Data signed: (hfarmer1) 30 Mar 2015 12:27:11

Generated On: 20 Jul 2016 22:42:34

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Screening

Form: Exclusion Criteria (6)

Data signed: (hfarmer1) 30 Mar 2015 12:27:11

Generated On: 20 Jul 2016 22:42:34

Exclusion Criterion Number	6
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Exclusion Criterion	Subjects with renal insufficiency as defined by serum creatinine levels of >1.3 mg/dL for females and >1.5 mg/dL for males.
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Result	No
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*If any has been answered Yes, subject must not be included in the study.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Screening

Form: Exclusion Criteria (7)

Data signed: (hfarmer1) 30 Mar 2015 12:27:11

Generated On: 20 Jul 2016 22:42:34

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

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1261

Folder: Screening

Form: Exclusion Criteria (8)

Data signed: (hfarmer1) 30 Mar 2015 12:27:11

Generated On: 20 Jul 2016 22:42:34

Exclusion Criterion Number	8
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Exclusion Criterion	As per Investigator judgment, the subject has medical conditions which require or will require in the course of the study, a medical intervention (e.g., start of treatment, surgery, hospitalization) which may interfere with the study participation and/or study results.
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Result	No
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*If any has been answered Yes, subject must not be included in the study.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Screening

Form: Exclusion Criteria (9)

Data signed: (hfarmer1) 30 Mar 2015 12:27:11

Generated On: 20 Jul 2016 22:42:34

Exclusion Criterion Number	9
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Exclusion Criterion	Any subject with an history of adverse events linked to caffeine or caffeine containing drugs (e.g., Vivarin), such as but not limited to hypersensitivity or allergy.
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Result	No
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*If any has been answered Yes, subject must not be included in the study.

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1261

Folder: Screening

Form: Exclusion Criteria (10)

Data signed: (hfarmer1) 30 Mar 2015 12:27:11

Generated On: 20 Jul 2016 22:42:34

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: 1261

Folder: Screening

Form: Exclusion Criteria (11)

Data signed: (hfarmer1) 30 Mar 2015 12:27:11

Generated On: 20 Jul 2016 22:42:34

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: 1261**

Folder: Screening

Form: Exclusion Criteria (12)

Data signed: (hfarmer1) 30 Mar 2015 12:27:11

Generated On: 20 Jul 2016 22:42:34

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: 1261**

Folder: Screening

Form: Exclusion Criteria (13)

Data signed: (hfarmer1) 30 Mar 2015 12:27:11

Generated On: 20 Jul 2016 22:42:34

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: 1261**

Folder: Screening

Form: Exclusion Criteria (14)

Data signed: (hfarmer1) 30 Mar 2015 12:27:11

Generated On: 20 Jul 2016 22:42:34

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: 1261**

Folder: Screening

Form: Exclusion Criteria (15)

Data signed: (hfarmer1) 30 Mar 2015 12:27:11

Generated On: 20 Jul 2016 22:42:34

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Screening

Form: Exclusion Criteria (16)

Data signed: (hfarmer1) 30 Mar 2015 12:27:11

Generated On: 20 Jul 2016 22:42:34

Exclusion Criterion Number	17
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Exclusion Criterion	Donation or receipt of whole blood or blood products within 3 months prior to Admission.	<input checked="" type="radio"/>
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Result	No	<input 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: 1261**

Folder: Screening

Form: Exclusion Criteria (17)

Data signed: (hfarmer1) 30 Mar 2015 12:27:11

Generated On: 20 Jul 2016 22:42:34

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
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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: 1261**

Folder: Screening

Form: Exclusion Criteria (18)

Data signed: (hfarmer1) 30 Mar 2015 12:27:11

Generated On: 20 Jul 2016 22:42:34

Exclusion Criterion Number	19
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Exclusion Criterion	The subject is an employee of the investigational site or any other parties involved in the study or of their first degree relatives (parent, sibling, and child).
---------------------	--

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: 1261**

Folder: Screening

Form: Exclusion Criteria (19)

Data signed: (hfarmer1) 30 Mar 2015 12:27:11

Generated On: 20 Jul 2016 22:42:34

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

Exclusion Criterion	The subject has participated in a clinical study within 3 months prior to the Screening Visit.
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Result	No
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*If any has been answered Yes, subject must not be included in the study.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Screening

Form: Exclusion Criteria (20)

Data signed: (hfarmer1) 30 Mar 2015 12:27:11

Generated On: 20 Jul 2016 22:42:34

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Screening

Form: Exclusion Criteria (21)

Data signed: (hfarmer1) 30 Mar 2015 12:27:11

Generated On: 20 Jul 2016 22:42:34

Exclusion Criterion Number	22
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Exclusion Criterion	For women only : Subject does not agree to use an acceptable method of effective contraception
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Result	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: 1261**

Folder: Screening

Form: Demographics

Data signed: (hfarmer1) 30 Mar 2015 12:27:10

Generated On: 20 Jul 2016 22:42:34

Date of Birth

(b) (6)

Sex

Female ☒

Race

White ☒

Other, specify _____

Ethnicity

Not Hispanic ☒

Date the Subject signed the Informed Consent

02 APR 2014
DD/MMM/YYYY

Time the Subject signed the Informed Consent

09:26
hour:min 24-hour clock

Age(Derived)

32

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Screening

Form: Medical History/Concomitant Disease

Data signed: (hfarmer1) 30 Mar 2015 12:27:12

Generated On: 20 Jul 2016 22:42:34

Date of collection

02 APR 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: 1261**

Folder: Screening

Form: Medical History/Concomitant Disease (1)

Data signed: (hfarmer1) 30 Mar 2015 12:27:12

Generated On: 20 Jul 2016 22:42:34

Date of collection	02 APR 2014 DD/MMM/YYYY
--------------------	----------------------------

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

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

Diagnosis Description	MYPOIA
-----------------------	--------

Onset Date DD/MMM/YYYY	UN UNK 1989
---------------------------	-------------

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

Ongoing?	True
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Screening

Form: Medical History/Concomitant Disease (2)

Data signed: (hfarmer1) 30 Mar 2015 12:27:12

Generated On: 20 Jul 2016 22:42:34

Date of collection	02 APR 2014 DD/MMM/YYYY
--------------------	----------------------------

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

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

Diagnosis Description	TONSILLECTOMY
-----------------------	---------------

Onset Date DD/MMM/YYYY	UN UNK 1991
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Stop Date DD/MMM/YYYY	UN UNK 1991
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Ongoing?	False
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Screening

Form: Medical History/Concomitant Disease (3)

Data signed: (hfarmer1) 30 Mar 2015 12:27:12

Generated On: 20 Jul 2016 22:42:34

Date of collection	02 APR 2014 DD/MMM/YYYY
--------------------	----------------------------

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

Number	3
--------	---

Diagnosis Description	MYRINGOTOMY
-----------------------	-------------

Onset Date DD/MMM/YYYY	UN UNK 1983
---------------------------	-------------

Stop Date DD/MMM/YYYY	UN UNK 1983
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Ongoing?	False
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Screening

Form: Medical History/Concomitant Disease (4)

Data signed: (hfarmer1) 30 Mar 2015 12:27:12

Generated On: 20 Jul 2016 22:42:34

Date of collection	02 APR 2014 DD/MMM/YYYY
--------------------	----------------------------

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

Number	4
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Diagnosis Description	NO TEETH, 2 FRONT, MILD
-----------------------	-------------------------

Onset Date DD/MMM/YYYY	UN UNK 2013
---------------------------	-------------

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

Ongoing?	True
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Screening

Form: Medical History/Concomitant Disease (5)

Data signed: (hfarmer1) 30 Mar 2015 12:27:12

Generated On: 20 Jul 2016 22:42:34

Date of collection	02 APR 2014 DD/MMM/YYYY
--------------------	----------------------------

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

Number	5
--------	---

Diagnosis Description	TUBAL LIGATION
-----------------------	----------------

Onset Date DD/MMM/YYYY	05 MAY 2006
---------------------------	-------------

Stop Date DD/MMM/YYYY	05 MAY 2006
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Ongoing?	False
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Screening

Form: Medical History/Concomitant Disease (6)

Data signed: (hfarmer1) 30 Mar 2015 12:27:12

Generated On: 20 Jul 2016 22:42:34

Date of collection

02 APR 2014
DD/MMM/YYYY

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

Yes ☒

Number

6

Diagnosis Description

NORMAL VAGINAL BIRTH

Onset Date
DD/MMM/YYYY

(b) (6)

Stop Date
DD/MMM/YYYY

(b) (6)

Ongoing?

False

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Screening

Form: Medical History/Concomitant Disease (7)

Data signed: (hfarmer1) 30 Mar 2015 12:27:12

Generated On: 20 Jul 2016 22:42:34

Date of collection

02 APR 2014
DD/MMM/YYYY

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

Yes ☒

Number

7

Diagnosis Description

NORMAL VAGINAL BIRTH

Onset Date
DD/MMM/YYYY

(b) (6)

Stop Date
DD/MMM/YYYY

(b) (6)

Ongoing?

False

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Screening

Form: Medical History/Concomitant Disease (8)

Data signed: (hfarmer1) 30 Mar 2015 12:27:12

Generated On: 20 Jul 2016 22:42:34

Date of collection

02 APR 2014
DD/MMM/YYYY

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

Yes ☒

Number

8

Diagnosis Description

NORMAL VAGINAL BIRTH

Onset Date
DD/MMM/YYYY

(b) (6)

Stop Date
DD/MMM/YYYY

(b) (6)

Ongoing?

False

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Screening

Form: Vital Signs<Screening/<

Data signed: (hfarmer1) 30 Mar 2015 12:27:14

Generated On: 20 Jul 2016 22:42:34

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

02 APR 2014
DD/MMM/YYYY

Time of assessment

10:20
hour:min 24-hour clock

Pulse rate

66
beats per minute

Respiratory rate

16
breaths per minute

Blood Pressure (systolic)

113
mmHg

Blood Pressure (diastolic)

82
mmHg

Vital Signs Position of Subject

Supine ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Screening

Form: Physical Examination

Data signed: (hfarmer1) 30 Mar 2015 12:27:13

Generated On: 20 Jul 2016 22:42:34

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

02 APR 2014
DD/MMM/YYYY

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Screening

Form: Physical Examination (1)

Data signed: (hfarmer1) 30 Mar 2015 12:27:13

Generated On: 20 Jul 2016 22:42:34

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of assessment 02 APR 2014
DD/MMM/YYYY

System General Appearance ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Screening

Form: Physical Examination (2)

Data signed: (hfarmer1) 30 Mar 2015 12:27:13

Generated On: 20 Jul 2016 22:42:34

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

02 APR 2014
DD/MMM/YYYY

System

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

Outcome

Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done

False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Screening

Form: Physical Examination (3)

Data signed: (hfarmer1) 30 Mar 2015 12:27:13

Generated On: 20 Jul 2016 22:42:34

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of assessment 02 APR 2014
DD/MMM/YYYY

System Thyroid Gland ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Screening

Form: Physical Examination (4)

Data signed: (hfarmer1) 30 Mar 2015 12:27:13

Generated On: 20 Jul 2016 22:42:34

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of assessment 02 APR 2014
DD/MMM/YYYY

System Heart ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Screening

Form: Physical Examination (5)

Data signed: (hfarmer1) 30 Mar 2015 12:27:13

Generated On: 20 Jul 2016 22:42:34

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

02 APR 2014
DD/MMM/YYYY

System

Chest ☒

Outcome

Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done

False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Screening

Form: Physical Examination (6)

Data signed: (hfarmer1) 30 Mar 2015 12:27:13

Generated On: 20 Jul 2016 22:42:34

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of assessment 02 APR 2014
DD/MMM/YYYY

System Lungs ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Screening

Form: Physical Examination (7)

Data signed: (hfarmer1) 30 Mar 2015 12:27:13

Generated On: 20 Jul 2016 22:42:34

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of assessment 02 APR 2014
DD/MMM/YYYY

System Gastrointestinal ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Screening

Form: Physical Examination (8)

Data signed: (hfarmer1) 30 Mar 2015 12:27:13

Generated On: 20 Jul 2016 22:42:34

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of assessment 02 APR 2014
DD/MMM/YYYY

System Cardiovascular System ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Screening

Form: Physical Examination (9)

Data signed: (hfarmer1) 30 Mar 2015 12:27:13

Generated On: 20 Jul 2016 22:42:34

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of assessment 02 APR 2014
DD/MMM/YYYY

System Neurologic ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Screening

Form: Physical Examination (10)

Data signed: (hfarmer1) 30 Mar 2015 12:27:13

Generated On: 20 Jul 2016 22:42:34

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of assessment 02 APR 2014
DD/MMM/YYYY

System Skin ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Screening

Form: Physical Examination (11)

Data signed: (hfarmer1) 30 Mar 2015 12:27:13

Generated On: 20 Jul 2016 22:42:34

Was the physical examination performed? Yes ☐

If No, please specify the reason: _____

Date of assessment 02 APR 2014
DD/MMM/YYYY

System Back ☐

Outcome Normal ☐

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Screening

Form: Physical Examination (12)

Data signed: (hfarmer1) 30 Mar 2015 12:27:13

Generated On: 20 Jul 2016 22:42:34

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of assessment 02 APR 2014
DD/MMM/YYYY

System Musculoskeletal ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Screening

Form: Physical Examination (13)

Data signed: (hfarmer1) 30 Mar 2015 12:27:13

Generated On: 20 Jul 2016 22:42:34

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of assessment 02 APR 2014
DD/MMM/YYYY

System Abdomen ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Screening

Form: Physical Examination (14)

Data signed: (hfarmer1) 30 Mar 2015 12:27:13

Generated On: 20 Jul 2016 22:42:34

Was the physical examination performed? Yes ☐

If No, please specify the reason: _____

Date of assessment 02 APR 2014
DD/MMM/YYYY

System Dentition ☐

Outcome Abnormal ☐

Abnormal, please specify MANY DECAYED TEETH

Clinically significant No ☐

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Screening

Form: Physical Examination (15)

Data signed: (hfarmer1) 30 Mar 2015 12:27:13

Generated On: 20 Jul 2016 22:42:34

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

02 APR 2014
DD/MMM/YYYY

System

Other ☒

Other, Specify _____

Outcome _____

Abnormal, please specify _____

Clinically significant _____

Not Done

True

Not Done; please specify the reason: _____

NOT EXAMINED

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Screening

Form: Physical Examination (16)

Data signed: (hfarmer1) 30 Mar 2015 12:27:13

Generated On: 20 Jul 2016 22:42:34

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

02 APR 2014
DD/MMM/YYYY

System

Other ☒

Other, Specify _____

Outcome _____

Abnormal, please specify _____

Clinically significant _____

Not Done

True

Not Done; please specify the reason: _____

NOT EXAMINED

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Screening

Form: Physical Examination (17)

Data signed: (hfarmer1) 30 Mar 2015 12:27:13

Generated On: 20 Jul 2016 22:42:34

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

02 APR 2014
DD/MMM/YYYY

System

Other ☒

Other, Specify _____

Outcome _____

Abnormal, please specify _____

Clinically significant _____

Not Done

True

Not Done; please specify the reason: _____

NOT EXAMINED

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Screening

Form: Physical Examination (18)

Data signed: (hfarmer1) 30 Mar 2015 12:27:13

Generated On: 20 Jul 2016 22:42:34

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

02 APR 2014
DD/MMM/YYYY

System

Other ☒

Other, Specify _____

Outcome _____

Abnormal, please specify _____

Clinically significant _____

Not Done

True

Not Done; please specify the reason: _____

NOT EXAMINED

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Screening

Form: Physical Examination (19)

Data signed: (hfarmer1) 30 Mar 2015 12:27:13

Generated On: 20 Jul 2016 22:42:34

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

02 APR 2014
DD/MMM/YYYY

System

Other ☒

Other, Specify _____

Outcome _____

Abnormal, please specify _____

Clinically significant _____

Not Done

True

Not Done; please specify the reason: _____

NOT EXAMINED

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Screening

Form: Advice on the risk of smoking and debriefing

Data signed: (hfarmer1) 30 Mar 2015 12:27:14

Generated On: 20 Jul 2016 22:42:34

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: 1261**

Folder: Screening

Form: Identification of Current Cigarette Brand

Data signed: (hfarmer1) 30 Mar 2015 12:27:14

Generated On: 20 Jul 2016 22:42:34

Date

02 APR 2014
DD/MMM/YYYY

Brand name

L&M MENTHOL

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Screening

Form: THS 2.2 menthol product demonstration

Data signed: (hfarmer1) 30 Mar 2015 12:27:14

Generated On: 20 Jul 2016 22:42:34

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: 1261**

Folder: Screening

Form: Smoking History

Data signed: (hfarmer1) 30 Mar 2015 12:27:14

Generated On: 20 Jul 2016 22:42:34

Date of Assessment

02 APR 2014
DD/MMM/YYYY

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

No ☐

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

Yes ☐

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

>19 ☐

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

Yes ☐

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

No ☐

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Screening

Form: Weight and Height

Data signed: (hfarmer1) 30 Mar 2015 12:27:15

Generated On: 20 Jul 2016 22:42:34

Measurement(s) assessed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

02 APR 2014
DD/MMM/YYYY

Weight

71.3
kg

Height

159.8
cm

BMI (Derived)

27.9
kg/m2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Screening

Form: ECG (12-Lead Standard)

Data signed: (hfarmer1) 30 Mar 2015 12:27:11

Generated On: 20 Jul 2016 22:42:34

Was the ECG performed? Yes ☒

If No, please specify the reason: _____

Date of assessment: 02 APR 2014
DD/MMM/YYYY

Position Supine ☒

Heart Rate 63
beats per minute

QRS Interval 93
msec

QT Interval 393
msec

QTcB Interval 405
msec

QTcF Interval 401
msec

PR Interval 153
msec

Interpretation Normal ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Screening

Form: ECG (12-Lead Standard)

Data signed: (hfarmer1) 30 Mar 2015 12:27:11

Generated On: 20 Jul 2016 22:42:34

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: 1261**

Folder: Screening

Form: Spirometry (1)

Data signed: (hfarmer1) 30 Mar 2015 12:27:14

Generated On: 20 Jul 2016 22:42:34

Was the spirometry performed? Yes ☒

If No, please specify the reason: _____

Category Without short-acting ☒
bronchodilator

Position SITTING

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

Date of assessment DD/MMM/YYYY 02 APR 2014

Time of assessment 10:57

Predicted FVC value 3.64
L

Best measured FVC value 3.92
L

Percent of predicted FVC value 108
%

Best measured FEV1 value 2.83
L

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Screening

Form: Spirometry (1)

Data signed: (hfarmer1) 30 Mar 2015 12:27:14

Generated On: 20 Jul 2016 22:42:34

Predicted FEV1 value	3.06 L
----------------------	-----------

Percent of predicted FEV1 value	93 %
---------------------------------	---------

Calculated ratio between FEV1/FVC	0.72
-----------------------------------	------

MEF 25/75 value	1.85 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: 1261**

Folder: Screening

Form: Spirometry (2)

Data signed: (hfarmer1) 30 Mar 2015 12:27:14

Generated On: 20 Jul 2016 22:42:34

Was the spirometry performed? Yes ☒

If No, please specify the reason: _____

Category With short-acting bronchodilator ☒

Position SITTING

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

Date of assessment DD/MMM/YYYY 02 APR 2014

Time of assessment 11:24

Name of bronchodilator ALBUTEROL SULFATE

Dose 180 MCG

Predicted FVC value 3.64 L

Best measured FVC value 4.08 L

Percent of predicted FVC value 112 %

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Screening

Form: Spirometry (2)

Data signed: (hfarmer1) 30 Mar 2015 12:27:14

Generated On: 20 Jul 2016 22:42:34

Best measured FEV1 value	2.82 L
Predicted FEV1 value	3.06 L
Percent of predicted FEV1 value	92 %
Calculated ratio between FEV1/FVC	0.69
MEF 25/75 value	1.63 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: 1261**

Folder: Screening

Form: Chest X-Ray

Data signed: (hfarmer1) 30 Mar 2015 12:27:15

Generated On: 20 Jul 2016 22:42:34

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

Yes ☒

If No, please specify the reason: _____

Date of assessment

07 APR 2014
DD/MMM/YYYY

System

Chest ☒

Interpretation

Normal ☒

Clinically significant _____

Abnormal, please specify: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Screening

Form: Haematology

Data signed: (hfarmer1) 30 Mar 2015 12:27:12

Generated On: 20 Jul 2016 22:42:34

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: 1261**

Folder: Screening

Form: Clinical Chemistry

Data signed: (hfarmer1) 30 Mar 2015 12:27:12

Generated On: 20 Jul 2016 22:42:34

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: 1261**

Folder: Screening

Form: Urine analysis

Data signed: (hfarmer1) 30 Mar 2015 12:27:12

Generated On: 20 Jul 2016 22:42:34

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: 1261**

Folder: Screening

Form: Serology for HIV and Hepatitis B and C

Data signed: (hfarmer1) 30 Mar 2015 12:27:12

Generated On: 20 Jul 2016 22:42:34

Category

Serology ☒

Not Done

False

If Not Done, please specify the reason:

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1261

Folder: Screening

Form: Urine Drug Screen

Data signed: (hfarmer1) 30 Mar 2015 12:27:12

Generated On: 20 Jul 2016 22:42:34

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

If Not Done, please specify the reason: _____

Date of sample collection	02 APR 2014 DD/MMM/YYYY
---------------------------	----------------------------

Time of sample collection	10:09 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: 1261

Folder: Screening

Form: Urine Drug Screen (4)

Data signed: (hfarmer1) 30 Mar 2015 12:27:12

Generated On: 20 Jul 2016 22:42:34

Drug type	Result
Cannabinoids	Negative
Cocaine	Negative
Opiates	Negative

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Screening

Form: Alcohol Test

Data signed: (hfarmer1) 30 Mar 2015 12:27:12

Generated On: 20 Jul 2016 22:42:34

Was the alcohol test performed? Yes ☒

If No, please specify the reason: _____

Method used Breath test ☒

Date of assessment 02 APR 2014
DD/MMM/YYYY

Time of assessment 10:13
hour:min 24-hour clock

Result Negative ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Screening

Form: Urine Pregnancy Test

Generated On: 20 Jul 2016 22:42:34

Category	Pregnancy Testing <input checked="" type="radio"/>
----------	--

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

If Not Done, specify reason	<hr/>
-----------------------------	-------

Date of Test	02 APR 2014 DD/MMM/YYYY
--------------	----------------------------

Time of Test	10:20 hour:min 24-hour clock
--------------	---------------------------------

Specify result	Negative <input checked="" type="radio"/>
----------------	---

If unclear, please confirm with FSH test	<hr/>
--	-------

Specify result of FSH test	<hr/>
----------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Screening

Form: Urine Cotinine Test

Data signed: (hfarmer1) 30 Mar 2015 12:27:12

Generated On: 20 Jul 2016 22:42:34

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

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

If Not Done, please specify the reason: _____

Date of Sample Collection	02 APR 2014 DD/MMM/YYYY
---------------------------	----------------------------

Time of Sample Collection	10:09 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: 1261**

Folder: Screening

Form: Lab-BU-LabCorp CHEMISTRY(02 APR 2014)

Data signed: (hfarmer1) 30 Mar 2015 12:27:15

Generated On: 20 Jul 2016 22:42:34

Experiment Type

CHEMISTRY

Date of Sample Collection
YYYY/MM/DD

02 APR 2014

Please document clinically relevant abnormalities in the AE form

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Screening

Form: Lab-BU-LabCorp CHEMISTRY(02 APR 2014)

Data signed: (hfarmer1) 30 Mar 2015 12:27:15

Generated On: 20 Jul 2016 22:42:34

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

Date of Sample Collection YYYY/MM/DD	02 APR 2014
---	-------------

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

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

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

Time of Sample Collection	11:14
---------------------------	-------

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

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

Result	87
--------	----

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

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

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

Flag	
------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Screening

Form: Lab-BU-LabCorp CHEMISTRY(02 APR 2014)

Data signed: (hfarmer1) 30 Mar 2015 12:27:15

Generated On: 20 Jul 2016 22:42:34

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

09257100150

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Screening

Form: Lab-BU-LabCorp (2)

Data signed: (hfarmer1) 30 Mar 2015 12:27:15

Generated On: 20 Jul 2016 22:42:34

Experiment Type	CHEMISTRY
Date of Sample Collection YYYY/MM/DD	02 APR 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Female <input checked="" type="radio"/>
Time of Sample Collection	11:14
Analyte Name	BUN
Code	001040
Result	12
Unit	MG/DL
Lower limit	6
Upper limit	20
Flag	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Screening

Form: Lab-BU-LabCorp (2)

Data signed: (hfarmer1) 30 Mar 2015 12:27:15

Generated On: 20 Jul 2016 22:42:34

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

09257100150

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Screening

Form: Lab-BU-LabCorp (3)

Data signed: (hfarmer1) 30 Mar 2015 12:27:15

Generated On: 20 Jul 2016 22:42:34

Experiment Type	CHEMISTRY
Date of Sample Collection YYYY/MM/DD	02 APR 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Female <input checked="" type="radio"/>
Time of Sample Collection	11:14
Analyte Name	CHOLESTEROL, TOTAL
Code	001065
Result	211
Unit	MG/DL
Lower limit	100
Upper limit	199
Flag	High <input checked="" type="radio"/>

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Screening

Form: Lab-BU-LabCorp (3)

Data signed: (hfarmer1) 30 Mar 2015 12:27:15

Generated On: 20 Jul 2016 22:42:34

Clinically Significant?

No ☒

Comment

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

09257100150

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Screening

Form: Lab-BU-LabCorp (4)

Data signed: (hfarmer1) 30 Mar 2015 12:27:15

Generated On: 20 Jul 2016 22:42:34

Experiment Type

CHEMISTRY

Date of Sample Collection
YYYY/MM/DD

02 APR 2014

Subject Number

Date of Birth

(b) (6)

Gender

Female ☒

Time of Sample Collection

11:14

Analyte Name

PROTEIN, TOTAL, SERUM

Code

001073

Result

6.2

Unit

G/DL

Lower limit

6.0

Upper limit

8.5

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Screening

Form: Lab-BU-LabCorp (4)

Data signed: (hfarmer1) 30 Mar 2015 12:27:15

Generated On: 20 Jul 2016 22:42:34

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

09257100150

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Screening

Form: Lab-BU-LabCorp (5)

Data signed: (hfarmer1) 30 Mar 2015 12:27:15

Generated On: 20 Jul 2016 22:42:34

Experiment Type

CHEMISTRY

Date of Sample Collection
YYYY/MM/DD

02 APR 2014

Subject Number

Date of Birth

(b) (6)

Gender

Female ☒

Time of Sample Collection

11:14

Analyte Name

ALBUMIN, SERUM

Code

001081

Result

4.1

Unit

G/DL

Lower limit

3.5

Upper limit

5.5

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Screening

Form: Lab-BU-LabCorp (5)

Data signed: (hfarmer1) 30 Mar 2015 12:27:15

Generated On: 20 Jul 2016 22:42:34

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

09257100150

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Screening

Form: Lab-BU-LabCorp (6)

Data signed: (hfarmer1) 30 Mar 2015 12:27:15

Generated On: 20 Jul 2016 22:42:34

Experiment Type

CHEMISTRY

Date of Sample Collection
YYYY/MM/DD

02 APR 2014

Subject Number

Date of Birth

(b) (6)

Gender

Female ☒

Time of Sample Collection

11:14

Analyte Name

BILIRUBIN, TOTAL

Code

001099

Result

0.4

Unit

MG/DL

Lower limit

0.0

Upper limit

1.2

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Screening

Form: Lab-BU-LabCorp (6)

Data signed: (hfarmer1) 30 Mar 2015 12:27:15

Generated On: 20 Jul 2016 22:42:34

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

09257100150

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Screening

Form: Lab-BU-LabCorp (7)

Data signed: (hfarmer1) 30 Mar 2015 12:27:15

Generated On: 20 Jul 2016 22:42:34

Experiment Type

CHEMISTRY

Date of Sample Collection
YYYY/MM/DD

02 APR 2014

Subject Number

Date of Birth

(b) (6)

Gender

Female ☒

Time of Sample Collection

11:14

Analyte Name

ALKALINE PHOSPHATASE, S

Code

001107

Result

49

Unit

IU/L

Lower limit

39

Upper limit

117

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Screening

Form: Lab-BU-LabCorp (7)

Data signed: (hfarmer1) 30 Mar 2015 12:27:15

Generated On: 20 Jul 2016 22:42:34

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

09257100150

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Screening

Form: Lab-BU-LabCorp (8)

Data signed: (hfarmer1) 30 Mar 2015 12:27:15

Generated On: 20 Jul 2016 22:42:34

Experiment Type	CHEMISTRY
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Date of Sample Collection YYYY/MM/DD	02 APR 2014
---	-------------

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

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

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

Time of Sample Collection	11:14
---------------------------	-------

Analyte Name	LDH
--------------	-----

Code	001115
------	--------

Result	174
--------	-----

Unit	IU/L
------	------

Lower limit	0
-------------	---

Upper limit	214
-------------	-----

Flag	
------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Screening

Form: Lab-BU-LabCorp (8)

Data signed: (hfarmer1) 30 Mar 2015 12:27:15

Generated On: 20 Jul 2016 22:42:34

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

09257100150

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Screening

Form: Lab-BU-LabCorp (9)

Data signed: (hfarmer1) 30 Mar 2015 12:27:15

Generated On: 20 Jul 2016 22:42:34

Experiment Type

CHEMISTRY

Date of Sample Collection
YYYY/MM/DD

02 APR 2014

Subject Number

Date of Birth

(b) (6)

Gender

Female ☒

Time of Sample Collection

11:14

Analyte Name

AST (SGOT)

Code

001123

Result

15

Unit

IU/L

Lower limit

0

Upper limit

40

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Screening

Form: Lab-BU-LabCorp (9)

Data signed: (hfarmer1) 30 Mar 2015 12:27:15

Generated On: 20 Jul 2016 22:42:34

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

09257100150

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Screening

Form: Lab-BU-LabCorp (10)

Data signed: (hfarmer1) 30 Mar 2015 12:27:15

Generated On: 20 Jul 2016 22:42:34

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

Date of Sample Collection YYYY/MM/DD	02 APR 2014
---	-------------

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

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

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

Time of Sample Collection	11:14
---------------------------	-------

Analyte Name	TRIGLYCERIDES
--------------	---------------

Code	001172
------	--------

Result	123
--------	-----

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

Lower limit	0
-------------	---

Upper limit	149
-------------	-----

Flag	
------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Screening

Form: Lab-BU-LabCorp (10)

Data signed: (hfarmer1) 30 Mar 2015 12:27:15

Generated On: 20 Jul 2016 22:42:34

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

09257100150

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Screening

Form: Lab-BU-LabCorp (11)

Data signed: (hfarmer1) 30 Mar 2015 12:27:15

Generated On: 20 Jul 2016 22:42:34

Experiment Type	CHEMISTRY
Date of Sample Collection YYYY/MM/DD	02 APR 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Female <input checked="" type="radio"/>
Time of Sample Collection	11:14
Analyte Name	POTASSIUM, SERUM
Code	001180
Result	4.1
Unit	MMOL/L
Lower limit	3.5
Upper limit	5.2
Flag	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Screening

Form: Lab-BU-LabCorp (11)

Data signed: (hfarmer1) 30 Mar 2015 12:27:15

Generated On: 20 Jul 2016 22:42:34

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

09257100150

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Screening

Form: Lab-BU-LabCorp (12)

Data signed: (hfarmer1) 30 Mar 2015 12:27:15

Generated On: 20 Jul 2016 22:42:34

Experiment Type	CHEMISTRY
Date of Sample Collection YYYY/MM/DD	02 APR 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Female <input checked="" type="radio"/>
Time of Sample Collection	11:14
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: 1261**

Folder: Screening

Form: Lab-BU-LabCorp (12)

Data signed: (hfarmer1) 30 Mar 2015 12:27:15

Generated On: 20 Jul 2016 22:42:34

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

09257100150

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Screening

Form: Lab-BU-LabCorp (13)

Data signed: (hfarmer1) 30 Mar 2015 12:27:15

Generated On: 20 Jul 2016 22:42:34

Experiment Type

CHEMISTRY

Date of Sample Collection
YYYY/MM/DD

02 APR 2014

Subject Number

Date of Birth

(b) (6)

Gender

Female ☒

Time of Sample Collection

11:14

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: 1261**

Folder: Screening

Form: Lab-BU-LabCorp (13)

Data signed: (hfarmer1) 30 Mar 2015 12:27:15

Generated On: 20 Jul 2016 22:42:34

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

09257100150

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Screening

Form: Lab-BU-LabCorp (14)

Data signed: (hfarmer1) 30 Mar 2015 12:27:15

Generated On: 20 Jul 2016 22:42:34

Experiment Type	CHEMISTRY
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Date of Sample Collection YYYY/MM/DD	02 APR 2014
---	-------------

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

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

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

Time of Sample Collection	11:14
---------------------------	-------

Analyte Name	CREATININE, SERUM
--------------	-------------------

Code	001370
------	--------

Result	0.63
--------	------

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

Lower limit	0.57
-------------	------

Upper limit	1.00
-------------	------

Flag	
------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Screening

Form: Lab-BU-LabCorp (14)

Data signed: (hfarmer1) 30 Mar 2015 12:27:15

Generated On: 20 Jul 2016 22:42:34

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

09257100150

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Screening

Form: Lab-BU-LabCorp (15)

Data signed: (hfarmer1) 30 Mar 2015 12:27:15

Generated On: 20 Jul 2016 22:42:34

Experiment Type

CHEMISTRY

Date of Sample Collection
YYYY/MM/DD

02 APR 2014

Subject Number

Date of Birth

(b) (6)

Gender

Female ☒

Time of Sample Collection

11:14

Analyte Name

ALT (SGPT)

Code

001545

Result

21

Unit

IU/L

Lower limit

0

Upper limit

32

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Screening

Form: Lab-BU-LabCorp (15)

Data signed: (hfarmer1) 30 Mar 2015 12:27:15

Generated On: 20 Jul 2016 22:42:34

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

09257100150

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Screening

Form: Lab-BU-LabCorp (16)

Data signed: (hfarmer1) 30 Mar 2015 12:27:15

Generated On: 20 Jul 2016 22:42:34

Experiment Type	CHEMISTRY
Date of Sample Collection YYYY/MM/DD	02 APR 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Female <input checked="" type="radio"/>
Time of Sample Collection	11:14
Analyte Name	GGT
Code	001958
Result	18
Unit	IU/L
Lower limit	0
Upper limit	60
Flag	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Screening

Form: Lab-BU-LabCorp (16)

Data signed: (hfarmer1) 30 Mar 2015 12:27:15

Generated On: 20 Jul 2016 22:42:34

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

09257100150

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Screening

Form: Lab-BU-LabCorp (17)

Data signed: (hfarmer1) 30 Mar 2015 12:27:15

Generated On: 20 Jul 2016 22:42:34

Experiment Type	CHEMISTRY
Date of Sample Collection YYYY/MM/DD	02 APR 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Female <input checked="" type="radio"/>
Time of Sample Collection	11:14
Analyte Name	HEP C VIRUS AB
Code	140683
Result	<0.1
Unit	S/CO RATIO
Lower limit	0.0
Upper limit	0.9
Flag	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Screening

Form: Lab-BU-LabCorp (17)

Data signed: (hfarmer1) 30 Mar 2015 12:27:15

Generated On: 20 Jul 2016 22:42:34

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

09257100150

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Screening

Form: Lab-BU-LabCorp SEROLOGY(02 APR 2014)

Data signed: (hfarmer1) 30 Mar 2015 12:27:16

Generated On: 20 Jul 2016 22:42:34

Experiment Type

SEROLOGY

Date of Sample Collection
YYYY/MM/DD

02 APR 2014

Please document clinically relevant abnormalities in the AE form

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Screening

Form: Lab-BU-LabCorp SEROLOGY(02 APR 2014)

Data signed: (hfarmer1) 30 Mar 2015 12:27:16

Generated On: 20 Jul 2016 22:42:34

Experiment Type

SEROLOGY

Date of Sample Collection
YYYY/MM/DD

02 APR 2014

Subject Number

Date of Birth

(b) (6)

Gender

Female ☒

Time of Sample Collection

11:14

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: 1261**

Folder: Screening

Form: Lab-BU-LabCorp SEROLOGY(02 APR 2014)

Data signed: (hfarmer1) 30 Mar 2015 12:27:16

Generated On: 20 Jul 2016 22:42:34

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

09257100150

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Screening

Form: Lab-BU-LabCorp (2)

Data signed: (hfarmer1) 30 Mar 2015 12:27:16

Generated On: 20 Jul 2016 22:42:34

Experiment Type

SEROLOGY

Date of Sample Collection
YYYY/MM/DD

02 APR 2014

Subject Number

Date of Birth

(b) (6)

Gender

Female ☒

Time of Sample Collection

11:14

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: 1261**

Folder: Screening

Form: Lab-BU-LabCorp (2)

Data signed: (hfarmer1) 30 Mar 2015 12:27:16

Generated On: 20 Jul 2016 22:42:34

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

09257100150

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Screening

Form: Lab-BU-LabCorp (3)

Data signed: (hfarmer1) 30 Mar 2015 12:27:16

Generated On: 20 Jul 2016 22:42:34

Experiment Type

SEROLOGY

Date of Sample Collection
YYYY/MM/DD

02 APR 2014

Subject Number

Date of Birth

(b) (6)

Gender

Female ☒

Time of Sample Collection

11:14

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: 1261**

Folder: Screening

Form: Lab-BU-LabCorp (3)

Data signed: (hfarmer1) 30 Mar 2015 12:27:16

Generated On: 20 Jul 2016 22:42:34

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

09257100150

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Screening

Form: Lab-BU-LabCorp HEMATOLOGY(02 APR 2014)

Data signed: (hfarmer1) 30 Mar 2015 12:27:16

Generated On: 20 Jul 2016 22:42:34

Experiment Type

HEMATOLOGY

Date of Sample Collection
YYYY/MM/DD

02 APR 2014

Please document clinically relevant abnormalities in the AE form

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Screening

Form: Lab-BU-LabCorp HEMATOLOGY(02 APR 2014)

Data signed: (hfarmer1) 30 Mar 2015 12:27:16

Generated On: 20 Jul 2016 22:42:34

Experiment Type	HEMATOLOGY
Date of Sample Collection YYYY/MM/DD	02 APR 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Female <input checked="" type="radio"/>
Time of Sample Collection	11:14
Analyte Name	WBC
Code	005025
Result	10.6
Unit	X10E3/UL
Lower limit	3.4
Upper limit	10.8
Flag	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Screening

Form: Lab-BU-LabCorp HEMATOLOGY(02 APR 2014)

Data signed: (hfarmer1) 30 Mar 2015 12:27:16

Generated On: 20 Jul 2016 22:42:34

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

09257100150

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Screening

Form: Lab-BU-LabCorp (2)

Data signed: (hfarmer1) 30 Mar 2015 12:27:16

Generated On: 20 Jul 2016 22:42:34

Experiment Type

HEMATOLOGY

Date of Sample Collection
YYYY/MM/DD

02 APR 2014

Subject Number

Date of Birth

(b) (6)

Gender

Female ☒

Time of Sample Collection

11:14

Analyte Name

RBC

Code

005033

Result

4.79

Unit

X10E6/UL

Lower limit

3.77

Upper limit

5.28

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Screening

Form: Lab-BU-LabCorp (2)

Data signed: (hfarmer1) 30 Mar 2015 12:27:16

Generated On: 20 Jul 2016 22:42:34

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

09257100150

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Screening

Form: Lab-BU-LabCorp (3)

Data signed: (hfarmer1) 30 Mar 2015 12:27:16

Generated On: 20 Jul 2016 22:42:34

Experiment Type

HEMATOLOGY

Date of Sample Collection
YYYY/MM/DD

02 APR 2014

Subject Number

Date of Birth

(b) (6)

Gender

Female ☒

Time of Sample Collection

11:14

Analyte Name

HEMOGLOBIN

Code

005041

Result

14.5

Unit

G/DL

Lower limit

11.1

Upper limit

15.9

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Screening

Form: Lab-BU-LabCorp (3)

Data signed: (hfarmer1) 30 Mar 2015 12:27:16

Generated On: 20 Jul 2016 22:42:34

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

09257100150

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Screening

Form: Lab-BU-LabCorp (4)

Data signed: (hfarmer1) 30 Mar 2015 12:27:16

Generated On: 20 Jul 2016 22:42:34

Experiment Type

HEMATOLOGY

Date of Sample Collection
YYYY/MM/DD

02 APR 2014

Subject Number

Date of Birth

(b) (6)

Gender

Female ☒

Time of Sample Collection

11:14

Analyte Name

HEMATOCRIT

Code

005058

Result

43.2

Unit

%

Lower limit

34.0

Upper limit

46.6

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Screening

Form: Lab-BU-LabCorp (4)

Data signed: (hfarmer1) 30 Mar 2015 12:27:16

Generated On: 20 Jul 2016 22:42:34

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

09257100150

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Screening

Form: Lab-BU-LabCorp (5)

Data signed: (hfarmer1) 30 Mar 2015 12:27:16

Generated On: 20 Jul 2016 22:42:34

Experiment Type	HEMATOLOGY
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Date of Sample Collection YYYY/MM/DD	02 APR 2014
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Subject Number	
----------------	--

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

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

Time of Sample Collection	11:14
---------------------------	-------

Analyte Name	MCV
--------------	-----

Code	015065
------	--------

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

Unit	FL
------	----

Lower limit	79
-------------	----

Upper limit	97
-------------	----

Flag	
------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Screening

Form: Lab-BU-LabCorp (5)

Data signed: (hfarmer1) 30 Mar 2015 12:27:16

Generated On: 20 Jul 2016 22:42:34

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

09257100150

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Screening

Form: Lab-BU-LabCorp (6)

Data signed: (hfarmer1) 30 Mar 2015 12:27:16

Generated On: 20 Jul 2016 22:42:34

Experiment Type

HEMATOLOGY

Date of Sample Collection
YYYY/MM/DD

02 APR 2014

Subject Number

Date of Birth

(b) (6)

Gender

Female ☒

Time of Sample Collection

11:14

Analyte Name

MCH

Code

015073

Result

30.3

Unit

PG

Lower limit

26.6

Upper limit

33.0

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Screening

Form: Lab-BU-LabCorp (6)

Data signed: (hfarmer1) 30 Mar 2015 12:27:16

Generated On: 20 Jul 2016 22:42:34

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

09257100150

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Screening

Form: Lab-BU-LabCorp (7)

Data signed: (hfarmer1) 30 Mar 2015 12:27:16

Generated On: 20 Jul 2016 22:42:34

Experiment Type

HEMATOLOGY

Date of Sample Collection
YYYY/MM/DD

02 APR 2014

Subject Number

Date of Birth

(b) (6)

Gender

Female ☒

Time of Sample Collection

11:14

Analyte Name

MCHC

Code

015081

Result

33.6

Unit

G/DL

Lower limit

31.5

Upper limit

35.7

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Screening

Form: Lab-BU-LabCorp (7)

Data signed: (hfarmer1) 30 Mar 2015 12:27:16

Generated On: 20 Jul 2016 22:42:34

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

09257100150

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Screening

Form: Lab-BU-LabCorp (8)

Data signed: (hfarmer1) 30 Mar 2015 12:27:16

Generated On: 20 Jul 2016 22:42:34

Experiment Type

HEMATOLOGY

Date of Sample Collection
YYYY/MM/DD

02 APR 2014

Subject Number

Date of Birth

(b) (6)

Gender

Female ☒

Time of Sample Collection

11:14

Analyte Name

NEUTROPHILS

Code

015107

Result

57

Unit

%

Lower limit

40

Upper limit

74

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Screening

Form: Lab-BU-LabCorp (8)

Data signed: (hfarmer1) 30 Mar 2015 12:27:16

Generated On: 20 Jul 2016 22:42:34

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

09257100150

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Screening

Form: Lab-BU-LabCorp (9)

Data signed: (hfarmer1) 30 Mar 2015 12:27:16

Generated On: 20 Jul 2016 22:42:34

Experiment Type

HEMATOLOGY

Date of Sample Collection
YYYY/MM/DD

02 APR 2014

Subject Number

Date of Birth

(b) (6)

Gender

Female ☒

Time of Sample Collection

11:14

Analyte Name

LYMPHS

Code

015123

Result

30

Unit

%

Lower limit

14

Upper limit

46

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Screening

Form: Lab-BU-LabCorp (9)

Data signed: (hfarmer1) 30 Mar 2015 12:27:16

Generated On: 20 Jul 2016 22:42:34

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

09257100150

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Screening

Form: Lab-BU-LabCorp (10)

Data signed: (hfarmer1) 30 Mar 2015 12:27:16

Generated On: 20 Jul 2016 22:42:34

Experiment Type

HEMATOLOGY

Date of Sample Collection
YYYY/MM/DD

02 APR 2014

Subject Number

Date of Birth

(b) (6)

Gender

Female ☒

Time of Sample Collection

11:14

Analyte Name

MONOCYTES

Code

015131

Result

8

Unit

%

Lower limit

4

Upper limit

12

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Screening

Form: Lab-BU-LabCorp (10)

Data signed: (hfarmer1) 30 Mar 2015 12:27:16

Generated On: 20 Jul 2016 22:42:34

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

09257100150

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Screening

Form: Lab-BU-LabCorp (11)

Data signed: (hfarmer1) 30 Mar 2015 12:27:16

Generated On: 20 Jul 2016 22:42:34

Experiment Type	HEMATOLOGY
Date of Sample Collection YYYY/MM/DD	02 APR 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Female <input checked="" type="radio"/>
Time of Sample Collection	11:14
Analyte Name	EOS
Code	015149
Result	4
Unit	%
Lower limit	0
Upper limit	5
Flag	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Screening

Form: Lab-BU-LabCorp (11)

Data signed: (hfarmer1) 30 Mar 2015 12:27:16

Generated On: 20 Jul 2016 22:42:34

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

09257100150

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Screening

Form: Lab-BU-LabCorp (12)

Data signed: (hfarmer1) 30 Mar 2015 12:27:16

Generated On: 20 Jul 2016 22:42:34

Experiment Type

HEMATOLOGY

Date of Sample Collection
YYYY/MM/DD

02 APR 2014

Subject Number

Date of Birth

(b) (6)

Gender

Female ☒

Time of Sample Collection

11:14

Analyte Name

BASOS

Code

015156

Result

1

Unit

%

Lower limit

0

Upper limit

3

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Screening

Form: Lab-BU-LabCorp (12)

Data signed: (hfarmer1) 30 Mar 2015 12:27:16

Generated On: 20 Jul 2016 22:42:34

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

09257100150

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Screening

Form: Lab-BU-LabCorp (13)

Data signed: (hfarmer1) 30 Mar 2015 12:27:16

Generated On: 20 Jul 2016 22:42:34

Experiment Type	HEMATOLOGY
Date of Sample Collection YYYY/MM/DD	02 APR 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Female <input checked="" type="radio"/>
Time of Sample Collection	11:14
Analyte Name	PLATELETS
Code	015172
Result	231
Unit	X10E3/UL
Lower limit	155
Upper limit	379
Flag	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Screening

Form: Lab-BU-LabCorp (13)

Data signed: (hfarmer1) 30 Mar 2015 12:27:16

Generated On: 20 Jul 2016 22:42:34

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

09257100150

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Screening

Form: Lab-BU-LabCorp (14)

Data signed: (hfarmer1) 30 Mar 2015 12:27:16

Generated On: 20 Jul 2016 22:42:34

Experiment Type	HEMATOLOGY
Date of Sample Collection YYYY/MM/DD	02 APR 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Female <input checked="" type="radio"/>
Time of Sample Collection	11:14
Analyte Name	NEUTROPHILS (ABSOLUTE)
Code	015909
Result	6.1
Unit	X10E3/UL
Lower limit	1.4
Upper limit	7.0
Flag	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Screening

Form: Lab-BU-LabCorp (14)

Data signed: (hfarmer1) 30 Mar 2015 12:27:16

Generated On: 20 Jul 2016 22:42:34

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

09257100150

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Screening

Form: Lab-BU-LabCorp (15)

Data signed: (hfarmer1) 30 Mar 2015 12:27:16

Generated On: 20 Jul 2016 22:42:34

Experiment Type	HEMATOLOGY
Date of Sample Collection YYYY/MM/DD	02 APR 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Female <input checked="" type="radio"/>
Time of Sample Collection	11:14
Analyte Name	LYMPHS (ABSOLUTE)
Code	015917
Result	3.2
Unit	X10E3/UL
Lower limit	0.7
Upper limit	3.1
Flag	High <input checked="" type="radio"/>

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Screening

Form: Lab-BU-LabCorp (15)

Data signed: (hfarmer1) 30 Mar 2015 12:27:16

Generated On: 20 Jul 2016 22:42:34

Clinically Significant?

No ☒

Comment

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

09257100150

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Screening

Form: Lab-BU-LabCorp (16)

Data signed: (hfarmer1) 30 Mar 2015 12:27:16

Generated On: 20 Jul 2016 22:42:34

Experiment Type

HEMATOLOGY

Date of Sample Collection
YYYY/MM/DD

02 APR 2014

Subject Number

Date of Birth

(b) (6)

Gender

Female ☒

Time of Sample Collection

11:14

Analyte Name

MONOCYTES(ABSOLUTE)

Code

015925

Result

0.8

Unit

X10E3/UL

Lower limit

0.1

Upper limit

0.9

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Screening

Form: Lab-BU-LabCorp (16)

Data signed: (hfarmer1) 30 Mar 2015 12:27:16

Generated On: 20 Jul 2016 22:42:34

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

09257100150

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Screening

Form: Lab-BU-LabCorp (17)

Data signed: (hfarmer1) 30 Mar 2015 12:27:16

Generated On: 20 Jul 2016 22:42:34

Experiment Type	HEMATOLOGY
Date of Sample Collection YYYY/MM/DD	02 APR 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Female <input checked="" type="radio"/>
Time of Sample Collection	11:14
Analyte Name	EOS (ABSOLUTE)
Code	015933
Result	0.5
Unit	X10E3/UL
Lower limit	0.0
Upper limit	0.4
Flag	High <input checked="" type="radio"/>

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Screening

Form: Lab-BU-LabCorp (17)

Data signed: (hfarmer1) 30 Mar 2015 12:27:16

Generated On: 20 Jul 2016 22:42:34

Clinically Significant?

No ☒

Comment

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

09257100150

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Screening

Form: Lab-BU-LabCorp (18)

Data signed: (hfarmer1) 30 Mar 2015 12:27:16

Generated On: 20 Jul 2016 22:42:34

Experiment Type

HEMATOLOGY

Date of Sample Collection
YYYY/MM/DD

02 APR 2014

Subject Number

Date of Birth

(b) (6)

Gender

Female ☒

Time of Sample Collection

11:14

Analyte Name

BASO (ABSOLUTE)

Code

015941

Result

0.1

Unit

X10E3/UL

Lower limit

0.0

Upper limit

0.2

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Screening

Form: Lab-BU-LabCorp (18)

Data signed: (hfarmer1) 30 Mar 2015 12:27:16

Generated On: 20 Jul 2016 22:42:34

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

09257100150

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Screening

Form: Lab-BU-LabCorp URINALYSIS(2 APR 2014)

Data signed: (hfarmer1) 30 Mar 2015 12:27:17

Generated On: 20 Jul 2016 22:42:34

Experiment Type

URINALYSIS

Date of Sample Collection
YYYY/MM/DD

2 APR 2014

Please document clinically relevant abnormalities in the AE form

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Screening

Form: Lab-BU-LabCorp URINALYSIS(2 APR 2014)

Data signed: (hfarmer1) 30 Mar 2015 12:27:17

Generated On: 20 Jul 2016 22:42:34

Experiment Type	URINALYSIS
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Date of Sample Collection YYYY/MM/DD	2 APR 2014
---	------------

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

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

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

Time of Sample Collection	10:25
---------------------------	-------

Analyte Name	SPECIFIC GRAVITY
--------------	------------------

Code	13060
------	-------

Result	1.01
--------	------

Unit	
------	--

Lower limit	1.001
-------------	-------

Upper limit	1.035
-------------	-------

Flag	
------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Screening

Form: Lab-BU-LabCorp URINALYSIS(2 APR 2014)

Data signed: (hfarmer1) 30 Mar 2015 12:27:17

Generated On: 20 Jul 2016 22:42:34

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: 1261**

Folder: Screening

Form: Lab-BU-LabCorp (2)

Data signed: (hfarmer1) 30 Mar 2015 12:27:17

Generated On: 20 Jul 2016 22:42:34

Experiment Type	URINALYSIS
Date of Sample Collection YYYY/MM/DD	2 APR 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Female <input checked="" type="radio"/>
Time of Sample Collection	10:25
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: 1261**

Folder: Screening

Form: Lab-BU-LabCorp (2)

Data signed: (hfarmer1) 30 Mar 2015 12:27:17

Generated On: 20 Jul 2016 22:42:34

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: 1261**

Folder: Screening

Form: Lab-BU-LabCorp (3)

Data signed: (hfarmer1) 30 Mar 2015 12:27:17

Generated On: 20 Jul 2016 22:42:34

Experiment Type

URINALYSIS

Date of Sample Collection
YYYY/MM/DD

2 APR 2014

Subject Number

Date of Birth

(b) (6)

Gender

Female ☒

Time of Sample Collection

10:25

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: 1261**

Folder: Screening

Form: Lab-BU-LabCorp (3)

Data signed: (hfarmer1) 30 Mar 2015 12:27:17

Generated On: 20 Jul 2016 22:42:34

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: 1261**

Folder: Screening

Form: Lab-BU-LabCorp (4)

Data signed: (hfarmer1) 30 Mar 2015 12:27:17

Generated On: 20 Jul 2016 22:42:34

Experiment Type

URINALYSIS

Date of Sample Collection
YYYY/MM/DD

2 APR 2014

Subject Number

Date of Birth

(b) (6)

Gender

Female ☒

Time of Sample Collection

10:25

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: 1261**

Folder: Screening

Form: Lab-BU-LabCorp (4)

Data signed: (hfarmer1) 30 Mar 2015 12:27:17

Generated On: 20 Jul 2016 22:42:34

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: 1261**

Folder: Screening

Form: Lab-BU-LabCorp (5)

Data signed: (hfarmer1) 30 Mar 2015 12:27:17

Generated On: 20 Jul 2016 22:42:34

Experiment Type

URINALYSIS

Date of Sample Collection
YYYY/MM/DD

2 APR 2014

Subject Number

Date of Birth

(b) (6)

Gender

Female ☒

Time of Sample Collection

10:25

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: 1261**

Folder: Screening

Form: Lab-BU-LabCorp (5)

Data signed: (hfarmer1) 30 Mar 2015 12:27:17

Generated On: 20 Jul 2016 22:42:34

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: 1261**

Folder: Screening

Form: Lab-BU-LabCorp (6)

Data signed: (hfarmer1) 30 Mar 2015 12:27:17

Generated On: 20 Jul 2016 22:42:34

Experiment Type

URINALYSIS

Date of Sample Collection
YYYY/MM/DD

2 APR 2014

Subject Number

Date of Birth

(b) (6)

Gender

Female ☒

Time of Sample Collection

10:25

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: 1261**

Folder: Screening

Form: Lab-BU-LabCorp (6)

Data signed: (hfarmer1) 30 Mar 2015 12:27:17

Generated On: 20 Jul 2016 22:42:34

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: 1261**

Folder: Screening

Form: Lab-BU-LabCorp (7)

Data signed: (hfarmer1) 30 Mar 2015 12:27:17

Generated On: 20 Jul 2016 22:42:34

Experiment Type	URINALYSIS
-----------------	------------

Date of Sample Collection YYYY/MM/DD	2 APR 2014
---	------------

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

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

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

Time of Sample Collection	10:25
---------------------------	-------

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: 1261**

Folder: Screening

Form: Lab-BU-LabCorp (7)

Data signed: (hfarmer1) 30 Mar 2015 12:27:17

Generated On: 20 Jul 2016 22:42:34

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: 1261**

Folder: Screening

Form: FTND Questionnaire

Generated On: 20 Jul 2016 22:42:34

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

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

Date of assessment	2014 APR 02
DD/MMM/YYYY	DD/MMM/YYYY

Time of assessment	11:34
	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?	After 60 minutes <input checked="" type="radio"/>
--	---

2. Do you find it difficult to refrain from smoking in places where it is forbidden?	No <input checked="" type="radio"/>
--	-------------------------------------

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

4. How many cigarettes per day do you smoke?	21-30 <input checked="" type="radio"/>
--	--

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

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

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1261

Folder: Screening

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

Data signed: (hfarmer1) 30 Mar 2015 12:27:14

Generated On: 20 Jul 2016 22:42:34

Was paper questionnaire used? Yes ☒

Reason not done _____

Type PROCHASKA STAGE OF
CHANGE QUESTIONNAIRE:
INTENTION TO QUIT
SMOKING

Date of assessment 02 APR 2014
DD/MMM/YYYY

Time of assessment 09:38
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: 1261**

Folder: Admission (Day -2)

Form: Date of Visit

Data signed: (hfarmer1) 30 Mar 2015 12:27:20

Generated On: 20 Jul 2016 22:42:34

Date of Visit

11 APR 2014
DD/MMM/YYYY

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Admission (Day -2)

Form: Inclusion Criteria

Data signed: (hfarmer1) 30 Mar 2015 12:27:18

Generated On: 20 Jul 2016 22:42:34

*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: 1261

Folder: Admission (Day -2)

Form: Inclusion Criteria (1)

Data signed: (hfarmer1) 30 Mar 2015 12:27:18

Generated On: 20 Jul 2016 22:42:34

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: 1261

Folder: Admission (Day -2)

Form: Inclusion Criteria (2)

Data signed: (hfarmer1) 30 Mar 2015 12:27:18

Generated On: 20 Jul 2016 22:42:34

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: 1261

Folder: Admission (Day -2)

Form: Inclusion Criteria (3)

Data signed: (hfarmer1) 30 Mar 2015 12:27:18

Generated On: 20 Jul 2016 22:42:34

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: 1261

Folder: Admission (Day -2)

Form: Inclusion Criteria (4)

Data signed: (hfarmer1) 30 Mar 2015 12:27:18

Generated On: 20 Jul 2016 22:42:34

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: 1261**

Folder: Admission (Day -2)

Form: Exclusion Criteria

Data signed: (hfarmer1) 30 Mar 2015 12:27:18

Generated On: 20 Jul 2016 22:42:34

*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: 1261**

Folder: Admission (Day -2)

Form: Exclusion Criteria (1)

Data signed: (hfarmer1) 30 Mar 2015 12:27:18

Generated On: 20 Jul 2016 22:42:34

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: 1261

Folder: Admission (Day -2)

Form: Exclusion Criteria (2)

Data signed: (hfarmer1) 30 Mar 2015 12:27:18

Generated On: 20 Jul 2016 22:42:34

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: 1261

Folder: Admission (Day -2)

Form: Exclusion Criteria (3)

Data signed: (hfarmer1) 30 Mar 2015 12:27:18

Generated On: 20 Jul 2016 22:42:34

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

Exclusion Criterion	The subject has a body mass index (BMI) <18.5 or ≥ 35 kg/m ² . <input checked="" type="radio"/>
---------------------	---

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

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

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1261

Folder: Admission (Day -2)

Form: Exclusion Criteria (4)

Data signed: (hfarmer1) 30 Mar 2015 12:27:18

Generated On: 20 Jul 2016 22:42:34

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: 1261

Folder: Admission (Day -2)

Form: Exclusion Criteria (5)

Data signed: (hfarmer1) 30 Mar 2015 12:27:18

Generated On: 20 Jul 2016 22:42:34

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: 1261

Folder: Admission (Day -2)

Form: Exclusion Criteria (6)

Data signed: (hfarmer1) 30 Mar 2015 12:27:18

Generated On: 20 Jul 2016 22:42:34

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

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

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

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

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1261

Folder: Admission (Day -2)

Form: Exclusion Criteria (7)

Data signed: (hfarmer1) 30 Mar 2015 12:27:18

Generated On: 20 Jul 2016 22:42:34

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: 1261

Folder: Admission (Day -2)

Form: Exclusion Criteria (8)

Data signed: (hfarmer1) 30 Mar 2015 12:27:18

Generated On: 20 Jul 2016 22:42:34

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

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

Result	No <input 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: 1261**

Folder: Admission (Day -2)

Form: Exclusion Criteria (9)

Data signed: (hfarmer1) 30 Mar 2015 12:27:18

Generated On: 20 Jul 2016 22:42:34

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

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

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

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

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1261

Folder: Admission (Day -2)

Form: Exclusion Criteria (10)

Data signed: (hfarmer1) 30 Mar 2015 12:27:18

Generated On: 20 Jul 2016 22:42:34

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

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

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

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Admission (Day -2)

Form: Exclusion Criteria (11)

Data signed: (hfarmer1) 30 Mar 2015 12:27:18

Generated On: 20 Jul 2016 22:42:34

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: 1261**

Folder: Admission (Day -2)

Form: Exclusion Criteria (12)

Data signed: (hfarmer1) 30 Mar 2015 12:27:18

Generated On: 20 Jul 2016 22:42:34

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: 1261**

Folder: Admission (Day -2)

Form: Exclusion Criteria (13)

Data signed: (hfarmer1) 30 Mar 2015 12:27:18

Generated On: 20 Jul 2016 22:42:34

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	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: 1261**

Folder: Admission (Day -2)

Form: Exclusion Criteria (14)

Data signed: (hfarmer1) 30 Mar 2015 12:27:18

Generated On: 20 Jul 2016 22:42:34

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

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

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

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Admission (Day -2)

Form: Vital Signs

Data signed: (hfarmer1) 30 Mar 2015 12:27:20

Generated On: 20 Jul 2016 22:42:34

Were Vitals Signs assessed? Yes ☒

If No, please specify the reason: _____

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

Time of assessment 12:17
hour:min 24-hour clock

Pulse rate 60
beats per minute

Respiratory rate 16
breaths per minute

Blood Pressure (systolic) 113
mmHg

Blood Pressure (diastolic) 77
mmHg

Vital Signs Position of Subject Supine ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Admission (Day -2)

Form: Product preference

Data signed: (hfarmer1) 30 Mar 2015 12:27:20

Generated On: 20 Jul 2016 22:42:34

Which Product Arm would you prefer to be randomized
to:

mCC 

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Admission (Day -2)

Form: Advice on the risk of smoking and debriefing

Data signed: (hfarmer1) 30 Mar 2015 12:27:20

Generated On: 20 Jul 2016 22:42:34

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: 1261**

Folder: Admission (Day -2)

Form: Physical Examination

Data signed: (hfarmer1) 30 Mar 2015 12:27:19

Generated On: 20 Jul 2016 22:42:34

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Admission (Day -2)

Form: Physical Examination (1)

Data signed: (hfarmer1) 30 Mar 2015 12:27:19

Generated On: 20 Jul 2016 22:42:34

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: 1261**

Folder: Admission (Day -2)

Form: Physical Examination (2)

Data signed: (hfarmer1) 30 Mar 2015 12:27:19

Generated On: 20 Jul 2016 22:42:34

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: 1261**

Folder: Admission (Day -2)

Form: Physical Examination (3)

Data signed: (hfarmer1) 30 Mar 2015 12:27:19

Generated On: 20 Jul 2016 22:42:34

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: 1261**

Folder: Admission (Day -2)

Form: Physical Examination (4)

Data signed: (hfarmer1) 30 Mar 2015 12:27:19

Generated On: 20 Jul 2016 22:42:34

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: 1261**

Folder: Admission (Day -2)

Form: Physical Examination (5)

Data signed: (hfarmer1) 30 Mar 2015 12:27:19

Generated On: 20 Jul 2016 22:42:34

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: 1261**

Folder: Admission (Day -2)

Form: Physical Examination (6)

Data signed: (hfarmer1) 30 Mar 2015 12:27:19

Generated On: 20 Jul 2016 22:42:34

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: 1261**

Folder: Admission (Day -2)

Form: Physical Examination (7)

Data signed: (hfarmer1) 30 Mar 2015 12:27:19

Generated On: 20 Jul 2016 22:42:34

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: 1261

Folder: Admission (Day -2)

Form: Physical Examination (8)

Data signed: (hfarmer1) 30 Mar 2015 12:27:19

Generated On: 20 Jul 2016 22:42:34

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: 1261**

Folder: Admission (Day -2)

Form: Physical Examination (9)

Data signed: (hfarmer1) 30 Mar 2015 12:27:19

Generated On: 20 Jul 2016 22:42:34

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: 1261**

Folder: Admission (Day -2)

Form: Physical Examination (10)

Data signed: (hfarmer1) 30 Mar 2015 12:27:19

Generated On: 20 Jul 2016 22:42:34

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: 1261**

Folder: Admission (Day -2)

Form: Physical Examination (11)

Data signed: (hfarmer1) 30 Mar 2015 12:27:19

Generated On: 20 Jul 2016 22:42:34

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: 1261**

Folder: Admission (Day -2)

Form: Physical Examination (12)

Data signed: (hfarmer1) 30 Mar 2015 12:27:19

Generated On: 20 Jul 2016 22:42:34

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: 1261**

Folder: Admission (Day -2)

Form: Physical Examination (13)

Data signed: (hfarmer1) 30 Mar 2015 12:27:19

Generated On: 20 Jul 2016 22:42:34

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: 1261**

Folder: Admission (Day -2)

Form: Physical Examination (14)

Data signed: (hfarmer1) 30 Mar 2015 12:27:19

Generated On: 20 Jul 2016 22:42:34

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

System Dentition ☒

Outcome Abnormal ☒

Abnormal, please specify MANY DECAYED TEETH

Clinically significant No ☒

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Admission (Day -2)

Form: Physical Examination (15)

Data signed: (hfarmer1) 30 Mar 2015 12:27:19

Generated On: 20 Jul 2016 22:42:34

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: 1261**

Folder: Admission (Day -2)

Form: Physical Examination (16)

Data signed: (hfarmer1) 30 Mar 2015 12:27:19

Generated On: 20 Jul 2016 22:42:34

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: 1261**

Folder: Admission (Day -2)

Form: Physical Examination (17)

Data signed: (hfarmer1) 30 Mar 2015 12:27:19

Generated On: 20 Jul 2016 22:42:34

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: 1261**

Folder: Admission (Day -2)

Form: Physical Examination (18)

Data signed: (hfarmer1) 30 Mar 2015 12:27:19

Generated On: 20 Jul 2016 22:42:34

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: 1261**

Folder: Admission (Day -2)

Form: Physical Examination (19)

Data signed: (hfarmer1) 30 Mar 2015 12:27:19

Generated On: 20 Jul 2016 22:42:34

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: 1261**

Folder: Admission (Day -2)

Form: Identification of Current Cigarette Brand

Data signed: (hfarmer1) 30 Mar 2015 12:27:20

Generated On: 20 Jul 2016 22:42:34

Brand name

L&M MENTHOL

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1261

Folder: Admission (Day -2)

Form: THS 2.2 menthol product test

Data signed: (hfarmer1) 30 Mar 2015 12:27:20

Generated On: 20 Jul 2016 22:42:34

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: 1261

Folder: Admission (Day -2)

Form: Smoking History

Data signed: (hfarmer1) 30 Mar 2015 12:27:20

Generated On: 20 Jul 2016 22:42:34

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

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

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

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Admission (Day -2)

Form: Weight

Data signed: (hfarmer1) 30 Mar 2015 12:27:21

Generated On: 20 Jul 2016 22:42:34

Measurement(s) assessed?

Yes ☒

If No, please specify the reason: _____

Time of assessment

11:27
hour:min 24-hour clock

Weight

71.5
kg

Waist circumference

92
cm

BMI

28.0

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1261

Folder: Admission (Day -2)

Form: Urine Drug Screen

Data signed: (hfarmer1) 30 Mar 2015 12:27:18

Generated On: 20 Jul 2016 22:42:34

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

If Not Done, please specify the reason: _____

Time of sample collection	11:48 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: 1261

Folder: Admission (Day -2)

Form: Urine Drug Screen (6)

Data signed: (hfarmer1) 30 Mar 2015 12:27:18

Generated On: 20 Jul 2016 22:42:34

Drug type	Result
Opiates	Negative

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Admission (Day -2)

Form: Alcohol Test

Data signed: (hfarmer1) 30 Mar 2015 12:27:18

Generated On: 20 Jul 2016 22:42:34

Was the alcohol test performed? Yes ☒

If No, please specify the reason: _____

Method used Breath test ☒

Time of assessment 12:09
hour:min 24-hour clock

Result Negative ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Admission (Day -2)

Form: Urine Pregnancy Test

Generated On: 20 Jul 2016 22:42:34

Not Done False

If Not Done, specify reason _____

Time of Test 12:19
hour:min 24-hour clock

Specify result Negative ☒

If unclear, please confirm with FSH test

Specify result of FSH test _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Admission (Day -2)

Form: CO Breath Test

Data signed: (hfarmer1) 30 Mar 2015 12:27:18

Generated On: 20 Jul 2016 22:42:34

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

If Not Done, please specify the reason: _____

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

Result	39
	ppm

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Admission (Day -2)

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

Data signed: (hfarmer1) 30 Mar 2015 12:27:20

Generated On: 20 Jul 2016 22:42:34

Was paper questionnaire used? Yes ☒

Reason not done _____

Type PROCHASKA STAGE OF
CHANGE QUESTIONNAIRE:
INTENTION TO QUIT
SMOKING

Date of assessment 11 APR 2014
DD/MMM/YYYY

Time of assessment 12:50
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: 1261**

Folder: Baseline (Day -1)

Form: Date of Visit

Data signed: (hfarmer1) 30 Mar 2015 12:27:23

Generated On: 20 Jul 2016 22:42:34

Date of Visit

12 APR 2014
DD/MMM/YYYY

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day -1)

Form: Vital Signs

Data signed: (hfarmer1) 30 Mar 2015 12:27:23

Generated On: 20 Jul 2016 22:42:34

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 10:54
hour:min 24-hour clock

Pulse rate 63
beats per minute

Respiratory rate 16
breaths per minute

Blood Pressure (systolic) 112
mmHg

Blood Pressure (diastolic) 68
mmHg

Vital Signs Position of Subject Supine ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day -1)

Form: CoHb Blood Sample

Data signed: (hfarmer1) 30 Mar 2015 12:27:21

Generated On: 20 Jul 2016 22:42:34

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	12 APR 2014
---------------------	-------------

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

Time hour:min 24-hour clock	20:09
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day -1)

Form: CO Breath Test (1)

Data signed: (hfarmer1) 30 Mar 2015 12:27:21

Generated On: 20 Jul 2016 22:42:34

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	06:36
---	-------

Result(ppm)	14
-------------	----

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day -1)

Form: CO Breath Test (2)

Data signed: (hfarmer1) 30 Mar 2015 12:27:21

Generated On: 20 Jul 2016 22:42:34

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	12:13
---	-------

Result(ppm)	27
-------------	----

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day -1)

Form: CO Breath Test (3)

Data signed: (hfarmer1) 30 Mar 2015 12:27:21

Generated On: 20 Jul 2016 22:42:34

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	16:23
---	-------

Result(ppm)	26
-------------	----

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day -1)

Form: CO Breath Test (4)

Data signed: (hfarmer1) 30 Mar 2015 12:27:21

Generated On: 20 Jul 2016 22:42:34

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

If Not Done, please specify the reason: _____

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

Actual Time of Assessment hour:min 24-hour clock	20:04
---	-------

Result(ppm)	22
-------------	----

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day -1)

Form: 4 hour urine collection

Data signed: (hfarmer1) 30 Mar 2015 12:27:23

Generated On: 20 Jul 2016 22:42:34

Start Time	10:03
	hour:min 24-hour clock

End Time	14:08
	hour:min 24-hour clock

Volume	733
	mL

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day -1)

Form: Sample Urine Collection (4 Hour collection)

Data signed: (hfarmer1) 30 Mar 2015 12:27:23

Generated On: 20 Jul 2016 22:42:34

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: 1261**

Folder: Baseline (Day -1)

Form: Lab_BU_COHB (1)

Data signed: (hfarmer1) 30 Mar 2015 12:27:23

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05115150004273
----------------	----------------

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

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

Result	7.20
--------	------

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

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

Sample comment	
----------------	--

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

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

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

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

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

Date of Collection	2014-APR-12
--------------------	-------------

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day -1)

Form: Lab_BU_COHB (1)

Data signed: (hfarmer1) 30 Mar 2015 12:27:23

Generated On: 20 Jul 2016 22:42:34

Start Day (24 hour urine only) _____

End Day (24 hour Urine Only) _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day -1)

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)

Data signed: (hfarmer1) 30 Mar 2015 12:27:23

Generated On: 20 Jul 2016 22:42:34

Date of Birth

(b) (6)

Date of assessment

2014 APR 12
DD/MMM/YYYY

DD/MMM/YYYY

Time of assessment

20:04
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?

Not at all ☒

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: 1261**

Folder: Baseline (Day -1)

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)

Data signed: (hfarmer1) 30 Mar 2015 12:27:23

Generated On: 20 Jul 2016 22:42:34

9. Did smoking make you dizzy? Not at all ☐

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

11. Did smoking immediately relieve your craving for a
cigarette? Not at all ☐

12. Did you enjoy smoking? Moderately ☐

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day -1)

Form: Behavioral Risk Factor Surveillance System Questionnaire

Data signed: (hfarmer1) 30 Mar 2015 12:27:21

Generated On: 20 Jul 2016 22:42:34

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

Was paper questionnaire used?	Yes <input type="radio"/>
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Reason not done	<hr/>
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Date of assessment	12 APR 2014 DD/MMM/YYYY
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Time of assessment	20:17 hour:min 24-hour clock
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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: 1261**

Folder: Baseline (Day -1)

Form: Behavioral Risk Factor Surveillance System Questionnaire

Data signed: (hfarmer1) 30 Mar 2015 12:27:21

Generated On: 20 Jul 2016 22:42:34

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: 1261

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ)

Data signed: (hfarmer1) 30 Mar 2015 12:27:21

Generated On: 20 Jul 2016 22:42:34

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

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

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

Date of assessment	12 APR 2014 DD/MMM/YYYY
--------------------	----------------------------

Time of assessment	20:21 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?	11 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: 1261**

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ)

Data signed: (hfarmer1) 30 Mar 2015 12:27:21

Generated On: 20 Jul 2016 22:42:34

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 L&M MENTHOL 100'S
predominantly smoke in the last 12 months of smoking?

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1261

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (1)

Data signed: (hfarmer1) 30 Mar 2015 12:27:21

Generated On: 20 Jul 2016 22:42:34

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

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

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

Date of assessment	12 APR 2014 DD/MMM/YYYY
--------------------	----------------------------

Time of assessment	20:21 hour:min 24-hour clock
--------------------	---------------------------------

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

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

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

4. If you ever smoked cigarettes regularly: At what age did you start to smoke regularly?	11 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: 1261

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (1)

Data signed: (hfarmer1) 30 Mar 2015 12:27:21

Generated On: 20 Jul 2016 22:42:34

Months

Days

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

Years 00 Years

Months 00 Months

Days 00 Days

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

Time Currently (last 3 months) ☒

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

Manufactured Cigarettes per day 20

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

Hand-rolled Cigarettes per day

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (1)

Data signed: (hfarmer1) 30 Mar 2015 12:27:21

Generated On: 20 Jul 2016 22:42:34

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: 1261

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (2)

Data signed: (hfarmer1) 30 Mar 2015 12:27:21

Generated On: 20 Jul 2016 22:42:34

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

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

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

Date of assessment	12 APR 2014 DD/MMM/YYYY
--------------------	----------------------------

Time of assessment	20:21 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?	11 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: 1261

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (2)

Data signed: (hfarmer1) 30 Mar 2015 12:27:21

Generated On: 20 Jul 2016 22:42:34

Months

Days

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

Years

00 Years

Months

00 Months

Days

00 Days

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

Time

1 year ago ☒

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

Manufactured Cigarettes
per day

20

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

None ☒

Hand-rolled Cigarettes
per day

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (2)

Data signed: (hfarmer1) 30 Mar 2015 12:27:21

Generated On: 20 Jul 2016 22:42:34

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: 1261

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (3)

Data signed: (hfarmer1) 30 Mar 2015 12:27:21

Generated On: 20 Jul 2016 22:42:34

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

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

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

Date of assessment	12 APR 2014 DD/MMM/YYYY
--------------------	----------------------------

Time of assessment	20:21 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?	11 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: 1261

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (3)

Data signed: (hfarmer1) 30 Mar 2015 12:27:21

Generated On: 20 Jul 2016 22:42:34

Months

Days

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

Years

00 Years

Months

00 Months

Days

00 Days

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

Time

5 years ago ☒

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

Manufactured Cigarettes
per day

20

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

None ☒

Hand-rolled Cigarettes
per day

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (3)

Data signed: (hfarmer1) 30 Mar 2015 12:27:21

Generated On: 20 Jul 2016 22:42:34

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: 1261

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (4)

Data signed: (hfarmer1) 30 Mar 2015 12:27:21

Generated On: 20 Jul 2016 22:42:34

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

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

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

Date of assessment	12 APR 2014 DD/MMM/YYYY
--------------------	----------------------------

Time of assessment	20:21 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?	11 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: 1261

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (4)

Data signed: (hfarmer1) 30 Mar 2015 12:27:21

Generated On: 20 Jul 2016 22:42:34

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

20

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

None ☒

Hand-rolled Cigarettes
per day

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (4)

Data signed: (hfarmer1) 30 Mar 2015 12:27:21

Generated On: 20 Jul 2016 22:42:34

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: 1261

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (5)

Data signed: (hfarmer1) 30 Mar 2015 12:27:21

Generated On: 20 Jul 2016 22:42:34

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

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

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

Date of assessment	12 APR 2014 DD/MMM/YYYY
--------------------	----------------------------

Time of assessment	20:21 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?	11 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: 1261

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (5)

Data signed: (hfarmer1) 30 Mar 2015 12:27:21

Generated On: 20 Jul 2016 22:42:34

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

20

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

None ☒

Hand-rolled Cigarettes
per day

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (5)

Data signed: (hfarmer1) 30 Mar 2015 12:27:21

Generated On: 20 Jul 2016 22:42:34

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: 1261

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (6)

Data signed: (hfarmer1) 30 Mar 2015 12:27:21

Generated On: 20 Jul 2016 22:42:34

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

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

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

Date of assessment	12 APR 2014 DD/MMM/YYYY
--------------------	----------------------------

Time of assessment	20:21 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?	11 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: 1261

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (6)

Data signed: (hfarmer1) 30 Mar 2015 12:27:21

Generated On: 20 Jul 2016 22:42:34

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

20

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

None ☒

Hand-rolled Cigarettes
per day

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (6)

Data signed: (hfarmer1) 30 Mar 2015 12:27:21

Generated On: 20 Jul 2016 22:42:34

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: 1261

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (7)

Data signed: (hfarmer1) 30 Mar 2015 12:27:21

Generated On: 20 Jul 2016 22:42:34

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

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

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

Date of assessment	12 APR 2014 DD/MMM/YYYY
--------------------	----------------------------

Time of assessment	20:21 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?	11 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: 1261

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (7)

Data signed: (hfarmer1) 30 Mar 2015 12:27:21

Generated On: 20 Jul 2016 22:42:34

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? L&M MENTHOL 100'S

Time More than 20 years ago ☒

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

Manufactured Cigarettes per day 20

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

Hand-rolled Cigarettes per day

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (7)

Data signed: (hfarmer1) 30 Mar 2015 12:27:21

Generated On: 20 Jul 2016 22:42:34

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: 1261**

Folder: Baseline (Day -1)

Form: Supplemental Questions

Data signed: (hfarmer1) 30 Mar 2015 12:27:22

Generated On: 20 Jul 2016 22:42:34

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

Date of Assessment	12 APR 2014 DD/MMM/YYYY
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Time of assessment	20:22
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1. How long it takes for the subject to complete the SQ	03 minutes
---	------------

Comments (open-end)	N/A
---------------------	-----

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day -1)

Form: Supplemental Questions (1)

Data signed: (hfarmer1) 30 Mar 2015 12:27:22

Generated On: 20 Jul 2016 22:42:34

Was paper questionnaire used? Yes ☐

Reason not done _____

Date of Assessment 12 APR 2014
DD/MMM/YYYY

Time of assessment 20:22

1. How long it takes for the subject to complete the SQ 03 minutes

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

Answer Yes ☐

Comments (open-end) N/A

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day -1)

Form: Supplemental Questions (2)

Data signed: (hfarmer1) 30 Mar 2015 12:27:22

Generated On: 20 Jul 2016 22:42:34

Was paper questionnaire used? Yes ☐

Reason not done _____

Date of Assessment 12 APR 2014
DD/MMM/YYYY

Time of assessment 20:22

1. How long it takes for the subject to complete the SQ 03 minutes

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

Answer Yes ☐

Comments (open-end) N/A

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1261

Folder: Baseline (Day -1)

Form: Supplemental Questions (3)

Data signed: (hfarmer1) 30 Mar 2015 12:27:22

Generated On: 20 Jul 2016 22:42:34

Was paper questionnaire used? Yes ☐

Reason not done _____

Date of Assessment 12 APR 2014
DD/MMM/YYYY

Time of assessment 20:22

1. How long it takes for the subject to complete the SQ 03 minutes

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

Answer Yes ☐

Comments (open-end) N/A

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1261

Folder: Baseline (Day -1)

Form: Supplemental Questions (4)

Data signed: (hfarmer1) 30 Mar 2015 12:27:22

Generated On: 20 Jul 2016 22:42:34

Was paper questionnaire used? Yes ☐

Reason not done _____

Date of Assessment 12 APR 2014
DD/MMM/YYYY

Time of assessment 20:22

1. How long it takes for the subject to complete the SQ 03 minutes

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

Answer Yes ☐

Comments (open-end) N/A

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1261

Folder: Baseline (Day -1)

Form: Supplemental Questions (5)

Data signed: (hfarmer1) 30 Mar 2015 12:27:22

Generated On: 20 Jul 2016 22:42:34

Was paper questionnaire used? Yes ☐

Reason not done _____

Date of Assessment 12 APR 2014
DD/MMM/YYYY

Time of assessment 20:22

1. How long it takes for the subject to complete the SQ 03 minutes

Question 6. Was the SQ self-explaining? ☐

Answer Yes ☐

Comments (open-end) N/A

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1261

Folder: Baseline (Day -1)

Form: Supplemental Questions (6)

Data signed: (hfarmer1) 30 Mar 2015 12:27:22

Generated On: 20 Jul 2016 22:42:34

Was paper questionnaire used? Yes ☒

Reason not done _____

Date of Assessment 12 APR 2014
DD/MMM/YYYY

Time of assessment 20:22

1. How long it takes for the subject to complete the SQ 03 minutes

Question 7. Was the SQ easy to use? ☒

Answer Yes ☒

Comments (open-end) N/A

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day -1)

Form: Questionnaire on smoking urges (QSU)

Data signed: (hfarmer1) 30 Mar 2015 12:27:23

Generated On: 20 Jul 2016 22:42:34

Type	QSU
------	-----

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

Date of assessment	2014 APR 12
--------------------	-------------

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	Strongly disagree <input checked="" type="radio"/>
--	--

2. Nothing would be better than smoking a cigarette right now	Strongly disagree <input checked="" type="radio"/>
---	--

3. If it were possible I would probably smoke now	Strongly disagree <input checked="" type="radio"/>
---	--

4. I could control things better right now if I could smoke	Strongly disagree <input checked="" type="radio"/>
---	--

5. All I want right now is a cigarette	Strongly disagree <input checked="" type="radio"/>
--	--

6. I have an urge for a cigarette	Strongly disagree <input checked="" type="radio"/>
-----------------------------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day -1)

Form: Questionnaire on smoking urges (QSU)

Data signed: (hfarmer1) 30 Mar 2015 12:27:23

Generated On: 20 Jul 2016 22:42:34

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: 1261**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (CEMA, HPMA, HBMA)

Data signed: (hfarmer1) 30 Mar 2015 12:27:24

Generated On: 20 Jul 2016 22:42:34

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (CEMA, HPMa, HBMA) (1)

Data signed: (hfarmer1) 30 Mar 2015 12:27:24

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05112450002914
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Analyte	HPMA
---------	------

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

Result	393
--------	-----

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

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

Sample comment	
----------------	--

Detection method	LC-MS/MS
------------------	----------

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

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

Celerion Study Number	AA99128-03
-----------------------	------------

Date of Collection	2014-APR-12
--------------------	-------------

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

Urine Start Day	
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (1)

Data signed: (hfarmer1) 30 Mar 2015 12:27:24

Generated On: 20 Jul 2016 22:42:34

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (2)

Data signed: (hfarmer1) 30 Mar 2015 12:27:24

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05112450002914
----------------	----------------

Analyte	CEMA
---------	------

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

Result	59.8
--------	------

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

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

Sample comment	
----------------	--

Detection method	LC-MS/MS
------------------	----------

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

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

Celerion Study Number	AA99128-03
-----------------------	------------

Date of Collection	2014-APR-12
--------------------	-------------

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

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (CEMA, HPMa, HBMA) (2)

Data signed: (hfarmer1) 30 Mar 2015 12:27:24

Generated On: 20 Jul 2016 22:42:34

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (3)

Data signed: (hfarmer1) 30 Mar 2015 12:27:24

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05112450002914
----------------	----------------

Analyte	HBMA
---------	------

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

Result	159
--------	-----

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

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

Sample comment	
----------------	--

Detection method	LC-MS/MS
------------------	----------

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

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

Celerion Study Number	AA99128-03
-----------------------	------------

Date of Collection	2014-APR-12
--------------------	-------------

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

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (3)

Data signed: (hfarmer1) 30 Mar 2015 12:27:24

Generated On: 20 Jul 2016 22:42:34

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (NNN, NNAL)

Data signed: (hfarmer1) 30 Mar 2015 12:27:24

Generated On: 20 Jul 2016 22:42:34

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (NNN, NNAL) (1)

Data signed: (hfarmer1) 30 Mar 2015 12:27:24

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05112460003483
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Analyte	NNAL
---------	------

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

Result	228
--------	-----

Result Unit	PG/ML
-------------	-------

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

Sample comment	
----------------	--

Detection method	LC-MS/MS
------------------	----------

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

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

Celerion Study Number	AA99128-04
-----------------------	------------

Date of Collection	2014-APR-12
--------------------	-------------

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

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (NNN, NNAL) (1)

Data signed: (hfarmer1) 30 Mar 2015 12:27:24

Generated On: 20 Jul 2016 22:42:34

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (NNN, NNAL) (2)

Data signed: (hfarmer1) 30 Mar 2015 12:27:24

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05112460003483
----------------	----------------

Analyte	NNN
---------	-----

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

Result	8.27
--------	------

Result Unit	PG/ML
-------------	-------

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

Sample comment	
----------------	--

Detection method	LC-MS/MS
------------------	----------

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

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

Celerion Study Number	AA99128-04
-----------------------	------------

Date of Collection	2014-APR-12
--------------------	-------------

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

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (NNN, NNAL) (2)

Data signed: (hfarmer1) 30 Mar 2015 12:27:24

Generated On: 20 Jul 2016 22:42:34

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (HEMA)

Data signed: (hfarmer1) 30 Mar 2015 12:27:24

Generated On: 20 Jul 2016 22:42:34

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (HEMA) (1)

Data signed: (hfarmer1) 30 Mar 2015 12:27:24

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05112470001741
----------------	----------------

Analyte	HEMA
---------	------

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

Result	7.75
--------	------

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

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

Sample comment	
----------------	--

Detection method	LC-MS/MS
------------------	----------

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

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

Celerion Study Number	AA99128-05
-----------------------	------------

Date of Collection	2014-APR-12
--------------------	-------------

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

Urine Start Day	
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (HEMA) (1)

Data signed: (hfarmer1) 30 Mar 2015 12:27:24

Generated On: 20 Jul 2016 22:42:34

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day -1)

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

Data signed: (hfarmer1) 30 Mar 2015 12:27:25

Generated On: 20 Jul 2016 22:42:34

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day -1)

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

Data signed: (hfarmer1) 30 Mar 2015 12:27:25

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05112480001156
Analyte	COT
Sample type	URINE
Result	1290
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	-1
Celerion Study Number	AA99128-06
Date of Collection	2014-APR-12
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day -1)

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

Data signed: (hfarmer1) 30 Mar 2015 12:27:25

Generated On: 20 Jul 2016 22:42:34

Urine Start Day

Urine End Day

-1

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1261

Folder: Baseline (Day -1)

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

Data signed: (hfarmer1) 30 Mar 2015 12:27:25

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05112480001156
Analyte	COT-GLUC
Sample type	URINE
Result	2590
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	-1
Celerion Study Number	AA99128-06
Date of Collection	2014-APR-12
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day -1)

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

Data signed: (hfarmer1) 30 Mar 2015 12:27:25

Generated On: 20 Jul 2016 22:42:34

Urine Start Day

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day -1)

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

Data signed: (hfarmer1) 30 Mar 2015 12:27:25

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05112480001156
Analyte	NIC
Sample type	URINE
Result	373
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	-1
Celerion Study Number	AA99128-06
Date of Collection	2014-APR-12
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day -1)

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

Data signed: (hfarmer1) 30 Mar 2015 12:27:25

Generated On: 20 Jul 2016 22:42:34

Urine Start Day

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day -1)

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

Data signed: (hfarmer1) 30 Mar 2015 12:27:25

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05112480001156
Analyte	NIC-GLUC
Sample type	URINE
Result	332
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	-1
Celerion Study Number	AA99128-06
Date of Collection	2014-APR-12
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day -1)

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

Data signed: (hfarmer1) 30 Mar 2015 12:27:25

Generated On: 20 Jul 2016 22:42:34

Urine Start Day

Urine End Day

-1

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1261

Folder: Baseline (Day -1)

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

Data signed: (hfarmer1) 30 Mar 2015 12:27:25

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05112480001156
Analyte	THCOT
Sample type	URINE
Result	1780
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	-1
Celerion Study Number	AA99128-06
Date of Collection	2014-APR-12
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day -1)

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

Data signed: (hfarmer1) 30 Mar 2015 12:27:25

Generated On: 20 Jul 2016 22:42:34

Urine Start Day

Urine End Day

-1

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1261

Folder: Baseline (Day -1)

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

Data signed: (hfarmer1) 30 Mar 2015 12:27:25

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05112480001156
Analyte	THCOT-GLUC
Sample type	URINE
Result	561
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	-1
Celerion Study Number	AA99128-06
Date of Collection	2014-APR-12
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day -1)

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

Data signed: (hfarmer1) 30 Mar 2015 12:27:25

Generated On: 20 Jul 2016 22:42:34

Urine Start Day

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (3-OH BaP)

Data signed: (hfarmer1) 30 Mar 2015 12:27:25

Generated On: 20 Jul 2016 22:42:34

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (3-OH BaP) (1)

Data signed: (hfarmer1) 30 Mar 2015 12:27:25

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05112490001741
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Analyte	3-OH BAP
---------	----------

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

Result	118
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Result Unit	FG/ML
-------------	-------

Lab Status	OK
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Sample comment	
----------------	--

Detection method	LC-MS/MS
------------------	----------

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

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

Celerion Study Number	AA99128-07
-----------------------	------------

Date of Collection	2014-APR-12
--------------------	-------------

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

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (3-OH BaP) (1)

Data signed: (hfarmer1) 30 Mar 2015 12:27:25

Generated On: 20 Jul 2016 22:42:34

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day -1)

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

Data signed: (hfarmer1) 30 Mar 2015 12:27:25

Generated On: 20 Jul 2016 22:42:34

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day -1)

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

Data signed: (hfarmer1) 30 Mar 2015 12:27:25

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05112510001763
----------------	----------------

Analyte	1-NA
---------	------

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

Result	43.7
--------	------

Result Unit	PG/ML
-------------	-------

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

Sample comment	
----------------	--

Detection method	LC-MS/MS
------------------	----------

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

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

Celerion Study Number	AA99128-09
-----------------------	------------

Date of Collection	2014-APR-12
--------------------	-------------

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

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day -1)

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

Data signed: (hfarmer1) 30 Mar 2015 12:27:25

Generated On: 20 Jul 2016 22:42:34

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day -1)

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

Data signed: (hfarmer1) 30 Mar 2015 12:27:25

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05112510001763
----------------	----------------

Analyte	2-NA
---------	------

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

Result	13.0
--------	------

Result Unit	PG/ML
-------------	-------

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

Sample comment	
----------------	--

Detection method	LC-MS/MS
------------------	----------

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

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

Celerion Study Number	AA99128-09
-----------------------	------------

Date of Collection	2014-APR-12
--------------------	-------------

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

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day -1)

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

Data signed: (hfarmer1) 30 Mar 2015 12:27:25

Generated On: 20 Jul 2016 22:42:34

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (3)

Data signed: (hfarmer1) 30 Mar 2015 12:27:25

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05112510001763
----------------	----------------

Analyte	4-ABP
---------	-------

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

Result	7.97
--------	------

Result Unit	PG/ML
-------------	-------

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

Sample comment	
----------------	--

Detection method	LC-MS/MS
------------------	----------

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

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

Celerion Study Number	AA99128-09
-----------------------	------------

Date of Collection	2014-APR-12
--------------------	-------------

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

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (3)

Data signed: (hfarmer1) 30 Mar 2015 12:27:25

Generated On: 20 Jul 2016 22:42:34

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day -1)

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

Data signed: (hfarmer1) 30 Mar 2015 12:27:25

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05112510001763
----------------	----------------

Analyte	O-TOL
---------	-------

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

Result	69.1
--------	------

Result Unit	PG/ML
-------------	-------

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

Sample comment	
----------------	--

Detection method	LC-MS/MS
------------------	----------

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

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

Celerion Study Number	AA99128-09
-----------------------	------------

Date of Collection	2014-APR-12
--------------------	-------------

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

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day -1)

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

Data signed: (hfarmer1) 30 Mar 2015 12:27:25

Generated On: 20 Jul 2016 22:42:34

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (11-dTXb2)

Data signed: (hfarmer1) 30 Mar 2015 12:27:24

Generated On: 20 Jul 2016 22:42:34

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (11-dTXb2) (1)

Data signed: (hfarmer1) 30 Mar 2015 12:27:24

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05112530000554
----------------	----------------

Analyte	11-DTXB2
---------	----------

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

Result	180
--------	-----

Result Unit	PG/ML
-------------	-------

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

Sample comment	
----------------	--

Detection method	LC-MS/MS
------------------	----------

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

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

Celerion Study Number	AA99128-11
-----------------------	------------

Date of Collection	2014-APR-12
--------------------	-------------

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

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (11-dTXb2) (1)

Data signed: (hfarmer1) 30 Mar 2015 12:27:24

Generated On: 20 Jul 2016 22:42:34

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (iPF2a-III)

Data signed: (hfarmer1) 30 Mar 2015 12:27:24

Generated On: 20 Jul 2016 22:42:34

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (iPF2a-III) (1)

Data signed: (hfarmer1) 30 Mar 2015 12:27:24

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05112540000547
----------------	----------------

Analyte	IPF2A-III
---------	-----------

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

Result	93.0
--------	------

Result Unit	PG/ML
-------------	-------

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

Sample comment	
----------------	--

Detection method	LC-MS/MS
------------------	----------

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

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

Celerion Study Number	AA99128-12
-----------------------	------------

Date of Collection	2014-APR-12
--------------------	-------------

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

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (iPF2a-III) (1)

Data signed: (hfarmer1) 30 Mar 2015 12:27:24

Generated On: 20 Jul 2016 22:42:34

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (1-OHP)

Data signed: (hfarmer1) 30 Mar 2015 12:27:26

Generated On: 20 Jul 2016 22:42:34

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day -1)

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

Data signed: (hfarmer1) 30 Mar 2015 12:27:26

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05115190003765
----------------	----------------

Analyte	1-OHP
---------	-------

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

Result	59.0
--------	------

Result Unit	PG/ML
-------------	-------

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

Sample comment	
----------------	--

Detection method	LC-MS/MS
------------------	----------

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

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

Celerion Study Number	AA99598-03
-----------------------	------------

Date of Collection	2014-APR-12
--------------------	-------------

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

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day -1)

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

Data signed: (hfarmer1) 30 Mar 2015 12:27:26

Generated On: 20 Jul 2016 22:42:34

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (SPMA, SBMA)

Data signed: (hfarmer1) 30 Mar 2015 12:27:24

Generated On: 20 Jul 2016 22:42:34

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day -1)

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

Data signed: (hfarmer1) 30 Mar 2015 12:27:24

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05115170003763
----------------	----------------

Analyte	SBMA
---------	------

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

Result	1.18
--------	------

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

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

Sample comment	
----------------	--

Detection method	LC-MS/MS
------------------	----------

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

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

Celerion Study Number	AA99598-01
-----------------------	------------

Date of Collection	2014-APR-12
--------------------	-------------

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

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day -1)

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

Data signed: (hfarmer1) 30 Mar 2015 12:27:24

Generated On: 20 Jul 2016 22:42:34

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (SPMA, SBMA) (2)

Data signed: (hfarmer1) 30 Mar 2015 12:27:24

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05115170003763
----------------	----------------

Analyte	SPMA
---------	------

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

Result	2.01
--------	------

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

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

Sample comment	
----------------	--

Detection method	LC-MS/MS
------------------	----------

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

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

Celerion Study Number	AA99598-01
-----------------------	------------

Date of Collection	2014-APR-12
--------------------	-------------

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

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (SPMA, SBMA) (2)

Data signed: (hfarmer1) 30 Mar 2015 12:27:24

Generated On: 20 Jul 2016 22:42:34

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (MHBMA)

Data signed: (hfarmer1) 30 Mar 2015 12:27:24

Generated On: 20 Jul 2016 22:42:34

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (MHBMA) (1)

Data signed: (hfarmer1) 30 Mar 2015 12:27:24

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05115180003765
----------------	----------------

Analyte	MHBMA
---------	-------

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

Result	0.482
--------	-------

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

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

Sample comment	
----------------	--

Detection method	LC-MS/MS
------------------	----------

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

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

Celerion Study Number	AA99598-02
-----------------------	------------

Date of Collection	2014-APR-12
--------------------	-------------

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

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (MHBMA) (1)

Data signed: (hfarmer1) 30 Mar 2015 12:27:24

Generated On: 20 Jul 2016 22:42:34

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (Creatinine)

Data signed: (hfarmer1) 30 Mar 2015 12:27:26

Generated On: 20 Jul 2016 22:42:34

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (Creatinine) (1)

Data signed: (hfarmer1) 30 Mar 2015 12:27:26

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05115160001741
----------------	----------------

Analyte	CREATININE
---------	------------

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

Result	34.1
--------	------

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

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

Sample comment	
----------------	--

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

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

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

Celerion Study Number	AA99128-14
-----------------------	------------

Date of Collection	2014-APR-12
--------------------	-------------

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

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (Creatinine) (1)

Data signed: (hfarmer1) 30 Mar 2015 12:27:26

Generated On: 20 Jul 2016 22:42:34

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day 0)

Form: Date of Visit

Data signed: (hfarmer1) 30 Mar 2015 12:27:28

Generated On: 20 Jul 2016 22:42:34

Date of Visit

13 APR 2014
DD/MMM/YYYY

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day 0)

Form: Randomization

Data signed: (hfarmer1) 30 Mar 2015 12:27:28

Generated On: 20 Jul 2016 22:42:34

Randomization number (4 digits)	4019
---------------------------------	------

Allocation Arm	mCC <input checked="" type="radio"/>
----------------	--------------------------------------

Cigarette Consumption	Greater than 19 conventional menthol cigarettes per day <input checked="" type="radio"/>
-----------------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day 0)

Form: Vital Signs

Data signed: (hfarmer1) 30 Mar 2015 12:27:28

Generated On: 20 Jul 2016 22:42:34

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 09:26
hour:min 24-hour clock

Pulse rate 67
beats per minute

Respiratory rate 20
breaths per minute

Blood Pressure (systolic) 116
mmHg

Blood Pressure (diastolic) 76
mmHg

Vital Signs Position of Subject Supine ☒

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1261

Folder: Baseline (Day 0)

Form: Gas Transfer

Data signed: (hfarmer1) 30 Mar 2015 12:27:27

Generated On: 20 Jul 2016 22:42:34

Was the Gas Transfer performed? Yes ☒

If No, please specify the reason: _____

Category _____

Position SITTING

Time of assessment 06:40

DLCO value 16.66
ml/min/mmHg

KCO value 1.12
mmol/min/kPa/L

DLCO/VA value 3.34
mL/min/mmHg/L

Interpretation Abnormal ☒

If Abnormal, Clinical Significance Not clinically significant ☒

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

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1261

Folder: Baseline (Day 0)

Form: Lung Volume Measurements

Data signed: (hfarmer1) 30 Mar 2015 12:27:27

Generated On: 20 Jul 2016 22:42:34

Were the Lung Volume Measurements performed? Yes ☒

If No, please specify the reason: _____

Category _____

Position SITTING

Time of assessment 06:59

VC value 3.83
L

TLC value 5.76
L

IC value 3.71
L

FRC value 2.05
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: 1261

Folder: Baseline (Day 0)

Form: Spirometry with a short-acting bronchodilator

Data signed: (hcoleman1) 18 Jun 2015 21:21:34

Generated On: 20 Jul 2016 22:42:34

Was the Spirometry with a short-acting bronchodilator performed?	Yes <input checked="" type="radio"/>
--	--------------------------------------

If No, please specify the reason: _____

Category	With short-acting bronchodilator <input checked="" type="radio"/>
----------	---

Position	SITTING
----------	---------

Time of assessment	07:33
--------------------	-------

Name of bronchodilator	ALBUTEROL SULFATE
------------------------	-------------------

Dose	180 MCG
------	---------

Predicted FVC value	3.64 L
---------------------	-----------

Best measured FVC value	3.67 L
-------------------------	-----------

Percent of predicted FVC value	100 %
--------------------------------	----------

Best measured FEV1 value	2.77 L
--------------------------	-----------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day 0)

Form: Spirometry with a short-acting bronchodilator

Data signed: (hcoleman1) 18 Jun 2015 21:21:34

Generated On: 20 Jul 2016 22:42:34

Predicted FEV1 value	3.06 L
----------------------	-----------

Percent of predicted FEV1 value	90 %
---------------------------------	---------

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

MEF 25/75 value	2.17 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: 1261**

Folder: Baseline (Day 0)

Form: Haematology

Data signed: (hfarmer1) 30 Mar 2015 12:27:26

Generated On: 20 Jul 2016 22:42:34

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: 1261**

Folder: Baseline (Day 0)

Form: Clinical Chemistry

Data signed: (hfarmer1) 30 Mar 2015 12:27:26

Generated On: 20 Jul 2016 22:42:34

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: 1261**

Folder: Baseline (Day 0)

Form: Urine analysis

Data signed: (hfarmer1) 30 Mar 2015 12:27:26

Generated On: 20 Jul 2016 22:42:34

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: 1261**

Folder: Baseline (Day 0)

Form: Plasma Nicotine Sample

Data signed: (hfarmer1) 30 Mar 2015 12:27:27

Generated On: 20 Jul 2016 22:42:34

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	13 APR 2014
---------------------	-------------

Time hour:min 24-hour clock	20:11
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day 0)

Form: Plasma Cotinine Sample

Data signed: (hfarmer1) 30 Mar 2015 12:27:26

Generated On: 20 Jul 2016 22:42:34

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	13 APR 2014
---------------------	-------------

Time hour:min 24-hour clock	20:11
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day 0)

Form: CoHb Blood Sample <D0> (1)

Data signed: (hfarmer1) 30 Mar 2015 12:27:26

Generated On: 20 Jul 2016 22:42:34

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	13 APR 2014
---------------------	-------------

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

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day 0)

Form: CoHb Blood Sample <D0> (2)

Data signed: (hfarmer1) 30 Mar 2015 12:27:26

Generated On: 20 Jul 2016 22:42:34

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	13 APR 2014
---------------------	-------------

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

Time hour:min 24-hour clock	20:11
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day 0)

Form: Oxysterols

Data signed: (hfarmer1) 30 Mar 2015 12:27:27

Generated On: 20 Jul 2016 22:42:34

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	13 APR 2014
---------------------	-------------

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day 0)

Form: CO Breath Test (1)

Data signed: (hfarmer1) 30 Mar 2015 12:27:26

Generated On: 20 Jul 2016 22:42:34

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	07:41
---	-------

Result(ppm)	18
-------------	----

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day 0)

Form: CO Breath Test (2)

Data signed: (hfarmer1) 30 Mar 2015 12:27:26

Generated On: 20 Jul 2016 22:42:34

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

If Not Done, please specify the reason: _____

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

Actual Time of Assessment hour:min 24-hour clock	12:03
---	-------

Result(ppm)	29
-------------	----

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day 0)

Form: CO Breath Test (3)

Data signed: (hfarmer1) 30 Mar 2015 12:27:26

Generated On: 20 Jul 2016 22:42:34

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

If Not Done, please specify the reason: _____

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

Actual Time of Assessment hour:min 24-hour clock	16:10
---	-------

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day 0)

Form: CO Breath Test (4)

Data signed: (hfarmer1) 30 Mar 2015 12:27:26

Generated On: 20 Jul 2016 22:42:34

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

If Not Done, please specify the reason: _____

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

Actual Time of Assessment hour:min 24-hour clock	20:02
---	-------

Result(ppm)	23
-------------	----

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1261

Folder: Baseline (Day 0)

Form: CYP2A6 activity Sample

Data signed: (hfarmer1) 30 Mar 2015 12:27:27

Generated On: 20 Jul 2016 22:42:34

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

13 APR 2014

05:37

trans-3'-hydroxyc
otinine

13 APR 2014

05:37

cotinine

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1261

Folder: Baseline (Day 0)

Form: CYP1A2 activity Sample

Data signed: (hfarmer1) 30 Mar 2015 12:27:27

Generated On: 20 Jul 2016 22:42:34

Time of caffeine tablet intake	10:58
	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
13 APR 2014	16:49	Caffeine
13 APR 2014	16:49	Paraxanthine

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day 0)

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

Data signed: (hfarmer1) 30 Mar 2015 12:27:27

Generated On: 20 Jul 2016 22:42:34

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	13 APR 2014
---------------------	-------------

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day 0)

Form: 24 hour urine collections

Data signed: (hfarmer1) 30 Mar 2015 12:27:28

Generated On: 20 Jul 2016 22:42:34

Start Date	13 APR 2014 DD/MMM/YYYY
------------	----------------------------

Start Time	07:18 hour:min 24-hour clock
------------	---------------------------------

End Date	14 APR 2014 DD/MMM/YYYY
----------	----------------------------

End Time	06:08 hour:min 24-hour clock
----------	---------------------------------

Volume	2195 mL
--------	------------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day 0)

Form: Sample Urine Collection

Data signed: (hfarmer1) 30 Mar 2015 12:27:28

Generated On: 20 Jul 2016 22:42:34

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: 1261

Folder: Baseline (Day 0)

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Data signed: (hfarmer1) 30 Mar 2015 12:27:29

Generated On: 20 Jul 2016 22:42:34

Date of Birth

(b) (6)

Date of assessment
DD/MMM/YYYY

2014 APR 13
DD/MMM/YYYY

Time of assessment

06:03
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: 1261

Folder: Baseline (Day 0)

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Data signed: (hfarmer1) 30 Mar 2015 12:27:29

Generated On: 20 Jul 2016 22:42:34

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

5. Difficulty concentrating

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

6. Increased appetite, hungry, weight gain

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

7. Insomnia, sleep problems, awakening at night

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

8. Restless

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

9. Impatient

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

10. Constipation

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

11. Dizziness

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

12. Coughing

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day 0)

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Data signed: (hfarmer1) 30 Mar 2015 12:27:29

Generated On: 20 Jul 2016 22:42:34

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: 1261

Folder: Baseline (Day 0)

Form: Cough Assessment

Data signed: (hfarmer1) 30 Mar 2015 12:27:28

Generated On: 20 Jul 2016 22:42:34

Date of Birth

(b) (6)

Date of assessment
DD/MMM/YYYY

2014 APR 13
DD/MMM/YYYY

Time of assessment

06:01
hour:min 24-hour clock

Assessment Status

Completed ☒

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

No ☒

If YES, please answer the following questions:

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

-9

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

Not Applicable ☒

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

Not Applicable ☒

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

Not Applicable ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day 0)

Form: Bio-banking (Transcriptomics)

Data signed: (hfarmer1) 30 Mar 2015 12:27:28

Generated On: 20 Jul 2016 22:42:34

Was a Bio-banking sample for transcriptomics taken?

Yes ☒

Time of Sample Collection

05:37
hour:min 24-hour clock

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

Yes ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day 0)

Form: Bio-banking (Biomarkers of exposure and risk markers)

Data signed: (hfarmer1) 30 Mar 2015 12:27:28

Generated On: 20 Jul 2016 22:42:34

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

Yes ☒

Time of Sample Collection

05:37
hour:min 24-hour clock

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

Yes ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day 0)

Form: Bio-banking (nasal epithelial collection/buccal collection)

Data signed: (hfarmer1) 30 Mar 2015 12:27:28

Generated On: 20 Jul 2016 22:42:34

Was a Bio-banking sample for nasal epithelial collection/buccal collection taken?	Yes <input checked="" type="radio"/>
---	--------------------------------------

Time of Buccal Collection	12:53
	hour:min 24-hour clock

Time of Nasal Epithelial Collection	12:50
	hour:min 24-hour clock

Was the subject fasting for at least 30 minutes at time of sample collection?	Yes <input checked="" type="radio"/>
---	--------------------------------------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (1)

Data signed: (hfarmer1) 30 Mar 2015 12:27:35

Generated On: 20 Jul 2016 22:42:34

Transmission Type Cumulative ☐

Subject ID or Number _____

Subject Sex F

Subject Date of Birth (b) (6)

Visit Name _____

Visit Type Scheduled ☐

Accession ID W715912

Actual Collection Date 2014 04 13

Actual Collection Time 05:37

Specimen Condition _____

Battery ID RC1029

Battery Name TRIGLYCERIDES

Lab Test ID RCT19

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1261

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (1)

Data signed: (hfarmer1) 30 Mar 2015 12:27:35

Generated On: 20 Jul 2016 22:42:34

Lab Test Name	TRIGLYCERIDES (GPO)
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	178
Reported Numeric Result	178
Reference Range low	39
Reference Range high	176
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: 1261**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (1)

Data signed: (hfarmer1) 30 Mar 2015 12:27:35

Generated On: 20 Jul 2016 22:42:34

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

High ☒

Clinically Significant?

No ☒

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (2)

Data signed: (hfarmer1) 30 Mar 2015 12:27:35

Generated On: 20 Jul 2016 22:42:34

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	F
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Subject Date of Birth	(b) (6) 
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	W715912
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Actual Collection Date	2014 04 13
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Actual Collection Time	05:37
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Specimen Condition	<hr/>
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Battery ID	RC1092
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Battery Name	FASTING GLUCOSE
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Lab Test ID	RCT142
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1261

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (2)

Data signed: (hfarmer1) 30 Mar 2015 12:27:35

Generated On: 20 Jul 2016 22:42:34

Lab Test Name	FASTING GLUCOSE
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	86
Reported Numeric Result	86
Reference Range low	70
Reference Range high	100
Range Units	MG/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (2)

Data signed: (hfarmer1) 30 Mar 2015 12:27:35

Generated On: 20 Jul 2016 22:42:34

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1261

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (3)

Data signed: (hfarmer1) 30 Mar 2015 12:27:35

Generated On: 20 Jul 2016 22:42:34

Transmission Type Cumulative ☐

Subject ID or Number _____

Subject Sex F

Subject Date of Birth (b) (6) 

Visit Name _____

Visit Type Scheduled ☐

Accession ID W715912

Actual Collection Date 2014 04 13

Actual Collection Time 05:37

Specimen Condition _____

Battery ID RC272

Battery Name TOTAL CHOLESTEROL

Lab Test ID RCT20

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (3)

Data signed: (hfarmer1) 30 Mar 2015 12:27:35

Generated On: 20 Jul 2016 22:42:34

Lab Test Name	CHOLESTEROL (HIGH PERFORMANCE)
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	205
Reported Numeric Result	205
Reference Range low	141
Reference Range high	240
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: 1261**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (3)

Data signed: (hfarmer1) 30 Mar 2015 12:27:35

Generated On: 20 Jul 2016 22:42:34

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: 1261**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (4)

Data signed: (hfarmer1) 30 Mar 2015 12:27:35

Generated On: 20 Jul 2016 22:42:34

Transmission Type Cumulative ☐

Subject ID or Number _____

Subject Sex F

Subject Date of Birth (b) (6) 

Visit Name _____

Visit Type Scheduled ☐

Accession ID W715912

Actual Collection Date 2014 04 13

Actual Collection Time 05:37

Specimen Condition _____

Battery ID RC9255

Battery Name CHEMISTRY PANEL

Lab Test ID RCT1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (4)

Data signed: (hfarmer1) 30 Mar 2015 12:27:35

Generated On: 20 Jul 2016 22:42:34

Lab Test Name	TOTAL BILIRUBIN
Test ID	
Test Status	Done <input type="checkbox"/>
Reported Text Result	0.3
Reported Numeric Result	0.3
Reference Range low	0.2
Reference Range high	1.2
Range Units	MG/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (4)

Data signed: (hfarmer1) 30 Mar 2015 12:27:35

Generated On: 20 Jul 2016 22:42:34

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (5)

Data signed: (hfarmer1) 30 Mar 2015 12:27:35

Generated On: 20 Jul 2016 22:42:34

Transmission Type Cumulative ☐

Subject ID or Number

Subject Sex F

Subject Date of Birth (b) (6) 

Visit Name

Visit Type Scheduled ☐

Accession ID W715912

Actual Collection Date 2014 04 13

Actual Collection Time 05:37

Specimen Condition

Battery ID RC9255

Battery Name CHEMISTRY PANEL

Lab Test ID RCT12

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1261

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (5)

Data signed: (hfarmer1) 30 Mar 2015 12:27:35

Generated On: 20 Jul 2016 22:42:34

Lab Test Name	TOTAL PROTEIN
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	6.6
Reported Numeric Result	6.6
Reference Range low	6.1
Reference Range high	8.4
Range Units	G/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (5)

Data signed: (hfarmer1) 30 Mar 2015 12:27:35

Generated On: 20 Jul 2016 22:42:34

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (6)

Data signed: (hfarmer1) 30 Mar 2015 12:27:35

Generated On: 20 Jul 2016 22:42:34

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex F

Subject Date of Birth (b) (6) ☒

Visit Name _____

Visit Type Scheduled ☒

Accession ID W715912

Actual Collection Date 2014 04 13

Actual Collection Time 05:37

Specimen Condition _____

Battery ID RC9255

Battery Name CHEMISTRY PANEL

Lab Test ID RCT13

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1261

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (6)

Data signed: (hfarmer1) 30 Mar 2015 12:27:35

Generated On: 20 Jul 2016 22:42:34

Lab Test Name	ALBUMIN
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	4.0
Reported Numeric Result	4.0
Reference Range low	3.3
Reference Range high	4.9
Range Units	G/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (6)

Data signed: (hfarmer1) 30 Mar 2015 12:27:35

Generated On: 20 Jul 2016 22:42:34

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (7)

Data signed: (hfarmer1) 30 Mar 2015 12:27:35

Generated On: 20 Jul 2016 22:42:34

Transmission Type Cumulative ☐

Subject ID or Number _____

Subject Sex F

Subject Date of Birth (b) (6)

Visit Name _____

Visit Type Scheduled ☐

Accession ID W715912

Actual Collection Date 2014 04 13

Actual Collection Time 05:37

Specimen Condition _____

Battery ID RC9255

Battery Name CHEMISTRY PANEL

Lab Test ID RCT1407

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1261

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (7)

Data signed: (hfarmer1) 30 Mar 2015 12:27:35

Generated On: 20 Jul 2016 22:42:34

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	106
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: 1261**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (7)

Data signed: (hfarmer1) 30 Mar 2015 12:27:35

Generated On: 20 Jul 2016 22:42:34

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (8)

Data signed: (hfarmer1) 30 Mar 2015 12:27:35

Generated On: 20 Jul 2016 22:42:34

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex F

Subject Date of Birth (b) (6) 

Visit Name _____

Visit Type Scheduled ☒

Accession ID W715912

Actual Collection Date 2014 04 13

Actual Collection Time 05:37

Specimen Condition _____

Battery ID RC9255

Battery Name CHEMISTRY PANEL

Lab Test ID RCT1408

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1261

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (8)

Data signed: (hfarmer1) 30 Mar 2015 12:27:35

Generated On: 20 Jul 2016 22:42:34

Lab Test Name	LDH
Test ID	
Test Status	Done <input type="checkbox"/>
Reported Text Result	147
Reported Numeric Result	147
Reference Range low	53
Reference Range high	234
Range Units	U/L
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (8)

Data signed: (hfarmer1) 30 Mar 2015 12:27:35

Generated On: 20 Jul 2016 22:42:34

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (9)

Data signed: (hfarmer1) 30 Mar 2015 12:27:35

Generated On: 20 Jul 2016 22:42:34

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex F

Subject Date of Birth (b) (6) 

Visit Name _____

Visit Type Scheduled ☒

Accession ID W715912

Actual Collection Date 2014 04 13

Actual Collection Time 05:37

Specimen Condition _____

Battery ID RC9255

Battery Name CHEMISTRY PANEL

Lab Test ID RCT15

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1261

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (9)

Data signed: (hfarmer1) 30 Mar 2015 12:27:35

Generated On: 20 Jul 2016 22:42:34

Lab Test Name	SERUM SODIUM
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	139
Reported Numeric Result	139
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: 1261**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (9)

Data signed: (hfarmer1) 30 Mar 2015 12:27:35

Generated On: 20 Jul 2016 22:42:34

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (10)

Data signed: (hfarmer1) 30 Mar 2015 12:27:35

Generated On: 20 Jul 2016 22:42:34

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	F
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Subject Date of Birth	(b) (6)
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	W715912
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Actual Collection Date	2014 04 13
------------------------	------------

Actual Collection Time	05:37
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Specimen Condition	<hr/>
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Battery ID	RC9255
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Battery Name	CHEMISTRY PANEL
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Lab Test ID	RCT16
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1261

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (10)

Data signed: (hfarmer1) 30 Mar 2015 12:27:35

Generated On: 20 Jul 2016 22:42:34

Lab Test Name	SERUM POTASSIUM
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	3.9
Reported Numeric Result	3.9
Reference Range low	3.4
Reference Range high	5.4
Range Units	MEQ/L
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (10)

Data signed: (hfarmer1) 30 Mar 2015 12:27:35

Generated On: 20 Jul 2016 22:42:34

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (11)

Data signed: (hfarmer1) 30 Mar 2015 12:27:35

Generated On: 20 Jul 2016 22:42:34

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex F

Subject Date of Birth (b) (6) 

Visit Name _____

Visit Type Scheduled ☒

Accession ID W715912

Actual Collection Date 2014 04 13

Actual Collection Time 05:37

Specimen Condition _____

Battery ID RC9255

Battery Name CHEMISTRY PANEL

Lab Test ID RCT29

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (11)

Data signed: (hfarmer1) 30 Mar 2015 12:27:35

Generated On: 20 Jul 2016 22:42:34

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: 1261**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (11)

Data signed: (hfarmer1) 30 Mar 2015 12:27:35

Generated On: 20 Jul 2016 22:42:34

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (12)

Data signed: (hfarmer1) 30 Mar 2015 12:27:35

Generated On: 20 Jul 2016 22:42:34

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

Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	W715912
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Actual Collection Date	2014 04 13
------------------------	------------

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

Specimen Condition	<hr/>
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Battery ID	RC9255
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Battery Name	CHEMISTRY PANEL
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Lab Test ID	RCT3
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1261

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (12)

Data signed: (hfarmer1) 30 Mar 2015 12:27:35

Generated On: 20 Jul 2016 22:42:34

Lab Test Name	GGT
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	18
Reported Numeric Result	18
Reference Range low	4
Reference Range high	49
Range Units	U/L
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (12)

Data signed: (hfarmer1) 30 Mar 2015 12:27:35

Generated On: 20 Jul 2016 22:42:34

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (13)

Data signed: (hfarmer1) 30 Mar 2015 12:27:35

Generated On: 20 Jul 2016 22:42:34

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	F
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Subject Date of Birth	(b) (6) 
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	W715912
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Actual Collection Date	2014 04 13
------------------------	------------

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

Specimen Condition	<hr/>
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Battery ID	RC9255
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Battery Name	CHEMISTRY PANEL
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Lab Test ID	RCT392
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (13)

Data signed: (hfarmer1) 30 Mar 2015 12:27:35

Generated On: 20 Jul 2016 22:42:34

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	0.7
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Reported Numeric Result	0.7
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Reference Range low	0.4
---------------------	-----

Reference Range high	1.1
----------------------	-----

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: 1261**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (13)

Data signed: (hfarmer1) 30 Mar 2015 12:27:35

Generated On: 20 Jul 2016 22:42:34

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (14)

Data signed: (hfarmer1) 30 Mar 2015 12:27:35

Generated On: 20 Jul 2016 22:42:34

Transmission Type Cumulative ☒

Subject ID or Number

Subject Sex F

Subject Date of Birth (b) (6)

Visit Name

Visit Type Scheduled ☒

Accession ID W715912

Actual Collection Date 2014 04 13

Actual Collection Time 05:37

Specimen Condition

Battery ID RC9255

Battery Name CHEMISTRY PANEL

Lab Test ID RCT4

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1261

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (14)

Data signed: (hfarmer1) 30 Mar 2015 12:27:35

Generated On: 20 Jul 2016 22:42:34

Lab Test Name	ALT (SGPT)
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	18
Reported Numeric Result	18
Reference Range low	6
Reference Range high	34
Range Units	U/L
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (14)

Data signed: (hfarmer1) 30 Mar 2015 12:27:35

Generated On: 20 Jul 2016 22:42:34

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (15)

Data signed: (hfarmer1) 30 Mar 2015 12:27:35

Generated On: 20 Jul 2016 22:42:34

Transmission Type Cumulative ☐

Subject ID or Number _____

Subject Sex F

Subject Date of Birth (b) (6)

Visit Name _____

Visit Type Scheduled ☐

Accession ID W715912

Actual Collection Date 2014 04 13

Actual Collection Time 05:37

Specimen Condition _____

Battery ID RC9255

Battery Name CHEMISTRY PANEL

Lab Test ID RCT5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (15)

Data signed: (hfarmer1) 30 Mar 2015 12:27:35

Generated On: 20 Jul 2016 22:42:34

Lab Test Name	AST (SGOT)
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	14
Reported Numeric Result	14
Reference Range low	9
Reference Range high	34
Range Units	U/L
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (15)

Data signed: (hfarmer1) 30 Mar 2015 12:27:35

Generated On: 20 Jul 2016 22:42:34

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (16)

Data signed: (hfarmer1) 30 Mar 2015 12:27:35

Generated On: 20 Jul 2016 22:42:34

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	F
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Subject Date of Birth	(b) (6)
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	W715912
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Actual Collection Date	2014 04 13
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Actual Collection Time	05:37
------------------------	-------

Specimen Condition	<hr/>
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Battery ID	RC9255
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Battery Name	CHEMISTRY PANEL
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Lab Test ID	RCT6
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1261

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (16)

Data signed: (hfarmer1) 30 Mar 2015 12:27:35

Generated On: 20 Jul 2016 22:42:34

Lab Test Name	UREA NITROGEN
Test ID	
Test Status	Done <input checked="" 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: 1261**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (16)

Data signed: (hfarmer1) 30 Mar 2015 12:27:35

Generated On: 20 Jul 2016 22:42:34

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (17)

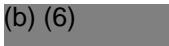
Data signed: (hfarmer1) 30 Mar 2015 12:27:35

Generated On: 20 Jul 2016 22:42:34

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	F
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Subject Date of Birth	(b) (6) 
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	W715912
--------------	---------

Actual Collection Date	2014 04 13
------------------------	------------

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

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: 1261

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (17)

Data signed: (hfarmer1) 30 Mar 2015 12:27:35

Generated On: 20 Jul 2016 22:42:34

Lab Test Name	MONOCYTES
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	0.80
Reported Numeric Result	0.80
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: 1261**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (17)

Data signed: (hfarmer1) 30 Mar 2015 12:27:35

Generated On: 20 Jul 2016 22:42:34

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (18)

Data signed: (hfarmer1) 30 Mar 2015 12:27:35

Generated On: 20 Jul 2016 22:42:34

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
----------------------	-------

Subject Sex	F
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Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	W715912
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Actual Collection Date	2014 04 13
------------------------	------------

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

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: 1261

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (18)

Data signed: (hfarmer1) 30 Mar 2015 12:27:35

Generated On: 20 Jul 2016 22:42:34

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (18)

Data signed: (hfarmer1) 30 Mar 2015 12:27:35

Generated On: 20 Jul 2016 22:42:34

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (19)

Data signed: (hfarmer1) 30 Mar 2015 12:27:35

Generated On: 20 Jul 2016 22:42:34

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

Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	W715912
--------------	---------

Actual Collection Date	2014 04 13
------------------------	------------

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

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: 1261

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (19)

Data signed: (hfarmer1) 30 Mar 2015 12:27:35

Generated On: 20 Jul 2016 22:42:34

Lab Test Name	MCHC
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	34
Reported Numeric Result	34
Reference Range low	31
Reference Range high	38
Range Units	G/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (19)

Data signed: (hfarmer1) 30 Mar 2015 12:27:35

Generated On: 20 Jul 2016 22:42:34

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1261

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (20)

Data signed: (hfarmer1) 30 Mar 2015 12:27:35

Generated On: 20 Jul 2016 22:42:34

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	F
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Subject Date of Birth	(b) (6) <div></div>
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	W715912
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Actual Collection Date	2014 04 13
------------------------	------------

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

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: 1261**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (20)

Data signed: (hfarmer1) 30 Mar 2015 12:27:35

Generated On: 20 Jul 2016 22:42:34

Lab Test Name	EOSINOPHILS
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	0.57
Reported Numeric Result	0.57
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: 1261**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (20)

Data signed: (hfarmer1) 30 Mar 2015 12:27:35

Generated On: 20 Jul 2016 22:42:34

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (21)

Data signed: (hfarmer1) 30 Mar 2015 12:27:35

Generated On: 20 Jul 2016 22:42:34

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	F
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Subject Date of Birth	(b) (6) 
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	W715912
--------------	---------

Actual Collection Date	2014 04 13
------------------------	------------

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

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: 1261

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (21)

Data signed: (hfarmer1) 30 Mar 2015 12:27:35

Generated On: 20 Jul 2016 22:42:34

Lab Test Name	BASOPHILS
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	0.03
Reported Numeric Result	0.03
Reference Range low	0.00
Reference Range high	0.20
Range Units	X10^3/UL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (21)

Data signed: (hfarmer1) 30 Mar 2015 12:27:35

Generated On: 20 Jul 2016 22:42:34

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1261

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (22)

Data signed: (hfarmer1) 30 Mar 2015 12:27:35

Generated On: 20 Jul 2016 22:42:34

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

Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	W715912
--------------	---------

Actual Collection Date	2014 04 13
------------------------	------------

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

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: 1261**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (22)

Data signed: (hfarmer1) 30 Mar 2015 12:27:35

Generated On: 20 Jul 2016 22:42:34

Lab Test Name	PLATELETS
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	239
Reported Numeric Result	239
Reference Range low	140
Reference Range high	400
Range Units	X10^3/UL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (22)

Data signed: (hfarmer1) 30 Mar 2015 12:27:35

Generated On: 20 Jul 2016 22:42:34

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (23)

Data signed: (hfarmer1) 30 Mar 2015 12:27:35

Generated On: 20 Jul 2016 22:42:34

Transmission Type Cumulative ☐

Subject ID or Number _____

Subject Sex F

Subject Date of Birth (b) (6) 

Visit Name _____

Visit Type Scheduled ☐

Accession ID W715912

Actual Collection Date 2014 04 13

Actual Collection Time 05:37

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: 1261

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (23)

Data signed: (hfarmer1) 30 Mar 2015 12:27:35

Generated On: 20 Jul 2016 22:42:34

Lab Test Name	NEUTROPHILS (%)
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	57.7
Reported Numeric Result	57.7
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: 1261**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (23)

Data signed: (hfarmer1) 30 Mar 2015 12:27:35

Generated On: 20 Jul 2016 22:42:34

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (24)

Data signed: (hfarmer1) 30 Mar 2015 12:27:35

Generated On: 20 Jul 2016 22:42:34

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	F
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Subject Date of Birth	(b) (6) 
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	W715912
--------------	---------

Actual Collection Date	2014 04 13
------------------------	------------

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

Specimen Condition	<hr/>
--------------------	-------

Battery ID	HM1604
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Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
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Lab Test ID	HMT16
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1261

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (24)

Data signed: (hfarmer1) 30 Mar 2015 12:27:35

Generated On: 20 Jul 2016 22:42:34

Lab Test Name	LYMPHOCYTES (%)
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	29.5
Reported Numeric Result	29.5
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: 1261**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (24)

Data signed: (hfarmer1) 30 Mar 2015 12:27:35

Generated On: 20 Jul 2016 22:42:34

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (25)

Data signed: (hfarmer1) 30 Mar 2015 12:27:35

Generated On: 20 Jul 2016 22:42:34

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
----------------------	-------

Subject Sex	F
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Subject Date of Birth	(b) (6) 
-----------------------	---

Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	W715912
--------------	---------

Actual Collection Date	2014 04 13
------------------------	------------

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

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: 1261

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (25)

Data signed: (hfarmer1) 30 Mar 2015 12:27:35

Generated On: 20 Jul 2016 22:42:34

Lab Test Name	MONOCYTES (%)
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	7.3
Reported Numeric Result	7.3
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: 1261**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (25)

Data signed: (hfarmer1) 30 Mar 2015 12:27:35

Generated On: 20 Jul 2016 22:42:34

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1261

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (26)

Data signed: (hfarmer1) 30 Mar 2015 12:27:35

Generated On: 20 Jul 2016 22:42:34

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

Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	W715912
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Actual Collection Date	2014 04 13
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Actual Collection Time	05:37
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Specimen Condition	<hr/>
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Battery ID	HM1604
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Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
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Lab Test ID	HMT18
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1261

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (26)

Data signed: (hfarmer1) 30 Mar 2015 12:27:35

Generated On: 20 Jul 2016 22:42:34

Lab Test Name	EOSINOPHILS (%)
Test ID	
Test Status	Done <input checked="" type="checkbox"/>
Reported Text Result	5.2
Reported Numeric Result	5.2
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: 1261**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (26)

Data signed: (hfarmer1) 30 Mar 2015 12:27:35

Generated On: 20 Jul 2016 22:42:34

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (27)

Data signed: (hfarmer1) 30 Mar 2015 12:27:35

Generated On: 20 Jul 2016 22:42:34

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	F
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Subject Date of Birth	(b) (6)
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	W715912
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Actual Collection Date	2014 04 13
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Actual Collection Time	05:37
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Specimen Condition	<hr/>
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Battery ID	HM1604
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Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
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Lab Test ID	HMT19
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1261

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (27)

Data signed: (hfarmer1) 30 Mar 2015 12:27:35

Generated On: 20 Jul 2016 22:42:34

Lab Test Name	BASOPHILS (%)
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	0.2
Reported Numeric Result	0.2
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: 1261**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (27)

Data signed: (hfarmer1) 30 Mar 2015 12:27:35

Generated On: 20 Jul 2016 22:42:34

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1261

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (28)

Data signed: (hfarmer1) 30 Mar 2015 12:27:35

Generated On: 20 Jul 2016 22:42:34

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	F
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Subject Date of Birth	(b) (6)
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	W715912
--------------	---------

Actual Collection Date	2014 04 13
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Actual Collection Time	05:37
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Specimen Condition	<hr/>
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Battery ID	HM1604
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Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
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Lab Test ID	HMT2
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1261

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (28)

Data signed: (hfarmer1) 30 Mar 2015 12:27:35

Generated On: 20 Jul 2016 22:42:34

Lab Test Name	HEMATOCRIT
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	43
Reported Numeric Result	43
Reference Range low	34
Reference Range high	48
Range Units	%
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (28)

Data signed: (hfarmer1) 30 Mar 2015 12:27:35

Generated On: 20 Jul 2016 22:42:34

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (29)

Data signed: (hfarmer1) 30 Mar 2015 12:27:35

Generated On: 20 Jul 2016 22:42:34

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	<hr/>
----------------------	-------

Subject Sex	F
-------------	---

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

Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	W715912
--------------	---------

Actual Collection Date	2014 04 13
------------------------	------------

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

Specimen Condition	<hr/>
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Battery ID	HM1604
------------	--------

Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
--------------	-----------------------------------

Lab Test ID	HMT3
-------------	------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1261

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (29)

Data signed: (hfarmer1) 30 Mar 2015 12:27:35

Generated On: 20 Jul 2016 22:42:34

Lab Test Name	RBC
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	4.8
Reported Numeric Result	4.8
Reference Range low	4.1
Reference Range high	5.6
Range Units	X10^6/UL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (29)

Data signed: (hfarmer1) 30 Mar 2015 12:27:35

Generated On: 20 Jul 2016 22:42:34

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (30)

Data signed: (hfarmer1) 30 Mar 2015 12:27:35

Generated On: 20 Jul 2016 22:42:34

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	<hr/>
----------------------	-------

Subject Sex	F
-------------	---

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

Visit Name	<hr/>
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	W715912
--------------	---------

Actual Collection Date	2014 04 13
------------------------	------------

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

Specimen Condition	<hr/>
--------------------	-------

Battery ID	HM1604
------------	--------

Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
--------------	-----------------------------------

Lab Test ID	HMT4
-------------	------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1261

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (30)

Data signed: (hfarmer1) 30 Mar 2015 12:27:35

Generated On: 20 Jul 2016 22:42:34

Lab Test Name	MCV
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	90
Reported Numeric Result	90
Reference Range low	79
Reference Range high	98
Range Units	FL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (30)

Data signed: (hfarmer1) 30 Mar 2015 12:27:35

Generated On: 20 Jul 2016 22:42:34

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (31)

Data signed: (hfarmer1) 30 Mar 2015 12:27:35

Generated On: 20 Jul 2016 22:42:34

Transmission Type	Cumulative <input type="radio"/>
-------------------	----------------------------------

Subject ID or Number	<hr/>
----------------------	-------

Subject Sex	F
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Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
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Visit Type	Scheduled <input type="radio"/>
------------	---------------------------------

Accession ID	W715912
--------------	---------

Actual Collection Date	2014 04 13
------------------------	------------

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

Specimen Condition	<hr/>
--------------------	-------

Battery ID	HM1604
------------	--------

Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
--------------	-----------------------------------

Lab Test ID	HMT40
-------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (31)

Data signed: (hfarmer1) 30 Mar 2015 12:27:35

Generated On: 20 Jul 2016 22:42:34

Lab Test Name	HEMOGLOBIN
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	14.5
Reported Numeric Result	14.5
Reference Range low	11.6
Reference Range high	16.4
Range Units	G/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (31)

Data signed: (hfarmer1) 30 Mar 2015 12:27:35

Generated On: 20 Jul 2016 22:42:34

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1261

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (32)

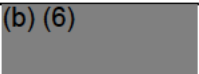
Data signed: (hfarmer1) 30 Mar 2015 12:27:35

Generated On: 20 Jul 2016 22:42:34

Transmission Type Cumulative ☐

Subject ID or Number _____

Subject Sex F

Subject Date of Birth (b) (6) 

Visit Name _____

Visit Type Scheduled ☐

Accession ID W715912

Actual Collection Date 2014 04 13

Actual Collection Time 05:37

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: 1261**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (32)

Data signed: (hfarmer1) 30 Mar 2015 12:27:35

Generated On: 20 Jul 2016 22:42:34

Lab Test Name	WBC
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	10.85
Reported Numeric Result	10.85
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: 1261**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (32)

Data signed: (hfarmer1) 30 Mar 2015 12:27:35

Generated On: 20 Jul 2016 22:42:34

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

High ☒

Clinically Significant?

No ☒

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (33)

Data signed: (hfarmer1) 30 Mar 2015 12:27:35

Generated On: 20 Jul 2016 22:42:34

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	<hr/>
----------------------	-------

Subject Sex	F
-------------	---

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

Visit Name	<hr/>
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	W715912
--------------	---------

Actual Collection Date	2014 04 13
------------------------	------------

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

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: 1261

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (33)

Data signed: (hfarmer1) 30 Mar 2015 12:27:35


Generated On: 20 Jul 2016 22:42:34

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: 1261**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (33)

Data signed: (hfarmer1) 30 Mar 2015 12:27:35

Generated On: 20 Jul 2016 22:42:34

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1261

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (34)

Data signed: (hfarmer1) 30 Mar 2015 12:27:35

Generated On: 20 Jul 2016 22:42:34

Transmission Type Cumulative ☐

Subject ID or Number _____

Subject Sex F

Subject Date of Birth (b) (6) 

Visit Name _____

Visit Type Scheduled ☐

Accession ID W715912

Actual Collection Date 2014 04 13

Actual Collection Time 05:37

Specimen Condition _____

Battery ID HM1604

Battery Name HEMATOLOGY
&DIFFERENTIAL PANEL

Lab Test ID HMT8

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (34)

Data signed: (hfarmer1) 30 Mar 2015 12:27:35

Generated On: 20 Jul 2016 22:42:34

Lab Test Name	NEUTROPHILS
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	6.26
Reported Numeric Result	6.26
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: 1261**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (34)

Data signed: (hfarmer1) 30 Mar 2015 12:27:35

Generated On: 20 Jul 2016 22:42:34

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (35)

Data signed: (hfarmer1) 30 Mar 2015 12:27:35

Generated On: 20 Jul 2016 22:42:34

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex F

Subject Date of Birth (b) (6)

Visit Name _____

Visit Type Scheduled ☒

Accession ID W715912

Actual Collection Date 2014 04 13

Actual Collection Time 05:37

Specimen Condition _____

Battery ID HM1604

Battery Name HEMATOLOGY
&DIFFERENTIAL PANEL

Lab Test ID HMT9

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (35)

Data signed: (hfarmer1) 30 Mar 2015 12:27:35

Generated On: 20 Jul 2016 22:42:34

Lab Test Name	LYMPHOCYTES
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	3.20
Reported Numeric Result	3.20
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: 1261**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (35)

Data signed: (hfarmer1) 30 Mar 2015 12:27:35

Generated On: 20 Jul 2016 22:42:34

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (36)

Data signed: (hfarmer1) 30 Mar 2015 12:27:35

Generated On: 20 Jul 2016 22:42:34

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex F

Subject Date of Birth (b) (6) 

Visit Name _____

Visit Type Scheduled ☒

Accession ID W715912

Actual Collection Date 2014 04 13

Actual Collection Time 05:37

Specimen Condition _____

Battery ID UA1538

Battery Name URINE MACRO PANEL

Lab Test ID UAT10

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1261

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (36)

Data signed: (hfarmer1) 30 Mar 2015 12:27:35


Generated On: 20 Jul 2016 22:42:34

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: 1261**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (36)

Data signed: (hfarmer1) 30 Mar 2015 12:27:35

Generated On: 20 Jul 2016 22:42:34

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (37)

Data signed: (hfarmer1) 30 Mar 2015 12:27:35

Generated On: 20 Jul 2016 22:42:34

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex F

Subject Date of Birth (b) (6)

Visit Name _____

Visit Type Scheduled ☒

Accession ID W715912

Actual Collection Date 2014 04 13

Actual Collection Time 05:37

Specimen Condition _____

Battery ID UA1538

Battery Name URINE MACRO PANEL

Lab Test ID UAT2

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1261

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (37)

Data signed: (hfarmer1) 30 Mar 2015 12:27:35

Generated On: 20 Jul 2016 22:42:34

Lab Test Name	UR SPECIFIC GRAVITY
Test ID	
Test Status	Done <input type="checkbox"/>
Reported Text Result	1.019
Reported Numeric Result	1.019
Reference Range low	1.003
Reference Range high	1.035
Range Units	
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (37)

Data signed: (hfarmer1) 30 Mar 2015 12:27:35

Generated On: 20 Jul 2016 22:42:34

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (38)

Data signed: (hfarmer1) 30 Mar 2015 12:27:35

Generated On: 20 Jul 2016 22:42:34

Transmission Type Cumulative ☐

Subject ID or Number _____

Subject Sex F

Subject Date of Birth (b) (6)

Visit Name _____

Visit Type Scheduled ☐

Accession ID W715912

Actual Collection Date 2014 04 13

Actual Collection Time 05:37

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: 1261**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (38)

Data signed: (hfarmer1) 30 Mar 2015 12:27:35

Generated On: 20 Jul 2016 22:42:34

Lab Test Name	UR PH
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	6.0
Reported Numeric Result	6.0
Reference Range low	5.0
Reference Range high	8.0
Range Units	
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (38)

Data signed: (hfarmer1) 30 Mar 2015 12:27:35

Generated On: 20 Jul 2016 22:42:34

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (39)

Data signed: (hfarmer1) 30 Mar 2015 12:27:35

Generated On: 20 Jul 2016 22:42:34

Transmission Type Cumulative ☐

Subject ID or Number _____

Subject Sex F

Subject Date of Birth (b) (6) 

Visit Name _____

Visit Type Scheduled ☐

Accession ID W715912

Actual Collection Date 2014 04 13

Actual Collection Time 05:37

Specimen Condition _____

Battery ID UA1538

Battery Name URINE MACRO PANEL

Lab Test ID UAT43

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (39)

Data signed: (hfarmer1) 30 Mar 2015 12:27:35


Generated On: 20 Jul 2016 22:42:34

Lab Test Name

UR BLOOD

Test ID

Test Status

Done 

Reported Text Result

+3

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: 1261**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (39)

Data signed: (hfarmer1) 30 Mar 2015 12:27:35

Generated On: 20 Jul 2016 22:42:34

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

High ☒

Clinically Significant?

No ☒

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (40)

Data signed: (hfarmer1) 30 Mar 2015 12:27:35

Generated On: 20 Jul 2016 22:42:34

Transmission Type Cumulative ☐

Subject ID or Number _____

Subject Sex F

Subject Date of Birth (b) (6)

Visit Name _____

Visit Type Scheduled ☐

Accession ID W715912

Actual Collection Date 2014 04 13

Actual Collection Time 05:37

Specimen Condition _____

Battery ID UA1538

Battery Name URINE MACRO PANEL

Lab Test ID UAT49

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1261

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (40)

Data signed: (hfarmer1) 30 Mar 2015 12:27:35

Generated On: 20 Jul 2016 22:42:34

Lab Test Name	UR PROTEIN
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	+1
Reported Numeric Result	
Reference Range low	
Reference Range high	
Range Units	
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (40)

Data signed: (hfarmer1) 30 Mar 2015 12:27:35

Generated On: 20 Jul 2016 22:42:34

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

High ☒

Clinically Significant?

No ☒

Comment

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1261

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (41)

Data signed: (hfarmer1) 30 Mar 2015 12:27:35

Generated On: 20 Jul 2016 22:42:34

Transmission Type Cumulative ☐

Subject ID or Number _____

Subject Sex F

Subject Date of Birth (b) (6) 

Visit Name _____

Visit Type Scheduled ☐

Accession ID W715912

Actual Collection Date 2014 04 13

Actual Collection Time 05:37

Specimen Condition _____

Battery ID UA1538

Battery Name URINE MACRO PANEL

Lab Test ID UAT5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (41)

Data signed: (hfarmer1) 30 Mar 2015 12:27:35


Generated On: 20 Jul 2016 22:42:34

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: 1261**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (41)

Data signed: (hfarmer1) 30 Mar 2015 12:27:35

Generated On: 20 Jul 2016 22:42:34

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (42)

Data signed: (hfarmer1) 30 Mar 2015 12:27:35

Generated On: 20 Jul 2016 22:42:34

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

Visit Name	<hr/>
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	W715912
--------------	---------

Actual Collection Date	2014 04 13
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Actual Collection Time	05:37
------------------------	-------

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: 1261

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (42)

Data signed: (hfarmer1) 30 Mar 2015 12:27:35


Generated On: 20 Jul 2016 22:42:34

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: 1261**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (42)

Data signed: (hfarmer1) 30 Mar 2015 12:27:35

Generated On: 20 Jul 2016 22:42:34

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day 0)

Form: Oxysterol results (1)

Generated On: 20 Jul 2016 22:42:34

Sample Accession number	3271591239
-------------------------	------------

Analyte	22(R)-HYDROXYCHOLESTERO L
---------	------------------------------

Analyte code	22RHCRL
--------------	---------

Result	
--------	--

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

Comment	NOT ANALYSED, INCOMPLETE SAMPLE SET
---------	--

Lower limit of quantification	9.46
-------------------------------	------

Date of Collection DD MMM YYYY	
-----------------------------------	--

Collection time hh:mm 24 hour clock	
--	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day 0)

Form: Oxysterol results (2)

Generated On: 20 Jul 2016 22:42:34

Sample Accession number	3271591239
-------------------------	------------

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: 1261**

Folder: Baseline (Day 0)

Form: Oxysterol results (3)

Generated On: 20 Jul 2016 22:42:34

Sample Accession number	3271591239
-------------------------	------------

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: 1261**

Folder: Baseline (Day 0)

Form: Oxysterol results (4)

Generated On: 20 Jul 2016 22:42:34

Sample Accession number	3271591239
-------------------------	------------

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: 1261**

Folder: Baseline (Day 0)

Form: Oxysterol results (5)

Generated On: 20 Jul 2016 22:42:34

Sample Accession number	3271591239
-------------------------	------------

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: 1261**

Folder: Baseline (Day 0)

Form: Oxysterol results (6)

Generated On: 20 Jul 2016 22:42:34

Sample Accession number	3271591239
-------------------------	------------

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: 1261**

Folder: Baseline (Day 0)

Form: Oxysterol results (7)

Generated On: 20 Jul 2016 22:42:34

Sample Accession number	3271591239
-------------------------	------------

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: 1261**

Folder: Baseline (Day 0)

Form: Oxysterol results (8)

Generated On: 20 Jul 2016 22:42:34

Sample Accession number	3271591239
-------------------------	------------

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: 1261**

Folder: Baseline (Day 0)

Form: Oxysterol results (9)

Generated On: 20 Jul 2016 22:42:34

Sample Accession number	3271591239
-------------------------	------------

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: 1261**

Folder: Baseline (Day 0)

Form: Oxysterol results (10)

Generated On: 20 Jul 2016 22:42:34

Sample Accession number	3271591239
-------------------------	------------

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: 1261**

Folder: Baseline (Day 0)

Form: Oxysterol results (11)

Generated On: 20 Jul 2016 22:42:34

Sample Accession number	3271591239
-------------------------	------------

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: 1261**

Folder: Baseline (Day 0)

Form: Oxysterol results (12)

Generated On: 20 Jul 2016 22:42:34

Sample Accession number	3271591239
-------------------------	------------

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: 1261**

Folder: Baseline (Day 0)

Form: Lab_BU_COHB (1)

Data signed: (hfarmer1) 30 Mar 2015 12:27:49

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05115150004274
----------------	----------------

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

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

Result	4.00
--------	------

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

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

Sample comment	
----------------	--

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

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

Planned time point (Hour)	6
---------------------------	---

Day of Visit	0
--------------	---

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

Date of Collection	2014-APR-13
--------------------	-------------

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day 0)

Form: Lab_BU_COHB (1)

Data signed: (hfarmer1) 30 Mar 2015 12:27:49

Generated On: 20 Jul 2016 22:42:34

Start Day (24 hour urine only) _____

End Day (24 hour Urine Only) _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day 0)

Form: Lab_BU_COHB (2)

Data signed: (hfarmer1) 30 Mar 2015 12:27:49

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05115150004275
----------------	----------------

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

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

Result	6.30
--------	------

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

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

Sample comment	
----------------	--

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

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

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

Day of Visit	0
--------------	---

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

Date of Collection	2014-APR-13
--------------------	-------------

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day 0)

Form: Lab_BU_COHB (2)

Data signed: (hfarmer1) 30 Mar 2015 12:27:49

Generated On: 20 Jul 2016 22:42:34

Start Day (24 hour urine only) _____

End Day (24 hour Urine Only) _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day 0)

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)

Data signed: (hfarmer1) 30 Mar 2015 12:27:28

Generated On: 20 Jul 2016 22:42:34

Date of Birth

(b) (6)

Date of assessment

2014 APR 13

DD/MMM/YYYY

DD/MMM/YYYY

Time of assessment

20:05

hour:min 24-hour clock

Assessment Status

Completed ☒

1. Was smoking satisfying?

Not at all ☐

2. Did cigarettes taste good?

Not at all ☐

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

Not at all ☐

4. Did smoking calm you down?

Not at all ☐

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?

Very little ☐

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day 0)

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)

Data signed: (hfarmer1) 30 Mar 2015 12:27:28

Generated On: 20 Jul 2016 22:42:34

9. Did smoking make you dizzy? Not at all ☐

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

11. Did smoking immediately relieve your craving for a
cigarette? Not at all ☐

12. Did you enjoy smoking? Little ☐

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1261

Folder: Baseline (Day 0)

Form: Human Smoking Topography Questionnaire

Data signed: (hfarmer1) 30 Mar 2015 12:27:28

Generated On: 20 Jul 2016 22:42:34

Type	HUMAN SMOKING TOPOGRAPHY QUESTIONNAIRE
------	--

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

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

Date of assessment	13 APR 2014 DD/MMM/YYYY
--------------------	----------------------------

Time of assessment	21:07 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 :	THE CIGARETTE IS STRONGER
---	------------------------------

2. You enjoy smoking with the device as much as without it.	Neither agree nor disagree <input type="radio"/>
---	--

If you disagree or strongly disagree, please describe :	<hr/>
---	-------

3. The taste of the conventional cigarettes/products is different with the device.	Neither agree nor disagree <input type="radio"/>
--	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day 0)

Form: Human Smoking Topography Questionnaire

Data signed: (hfarmer1) 30 Mar 2015 12:27:28

Generated On: 20 Jul 2016 22:42:34

If you agree or strongly agree, please describe : _____

4. The device is easy to use.

Agree ☒

If you disagree or strongly disagree, please describe : _____

5. Your smoking is disturbed by the device.

Disagree ☒

If you agree or strongly agree, please describe : _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day 0)

Form: Questionnaire on smoking urges (QSU)

Data signed: (hfarmer1) 30 Mar 2015 12:27:29

Generated On: 20 Jul 2016 22:42:34

Type	QSU
------	-----

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

Date of assessment	2014 APR 13
--------------------	-------------

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

2. Nothing would be better than smoking a cigarette right now	Strongly 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	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	Do not agree or disagree <input type="radio"/>
-----------------------------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day 0)

Form: Questionnaire on smoking urges (QSU)

Data signed: (hfarmer1) 30 Mar 2015 12:27:29

Generated On: 20 Jul 2016 22:42:34

7. A cigarette would taste good now Do not agree or 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 Somewhat disagree ☐

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1261

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (1)

Data signed: (hfarmer1) 30 Mar 2015 12:27:29

Generated On: 20 Jul 2016 22:42:34

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	1261
----------------------	------

Subject Sex	F
-------------	---

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

Visit Name	DAY0
------------	------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	W715912
--------------	---------

Actual Collection Date	2014 04 13
------------------------	------------

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

Specimen Condition	
--------------------	--

Battery ID	HM1054
------------	--------

Battery Name	HEMOGLOBIN A1C
--------------	----------------

Lab Test ID	HMT370
-------------	--------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1261

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (1)

Data signed: (hfarmer1) 30 Mar 2015 12:27:29

Generated On: 20 Jul 2016 22:42:34

Lab Test Name

HEMOGLOBIN
A1C,VARIANT(-70)

Test ID

Test Status

Done ☒

Reported Text Result

5.2

Reported Numeric Result

5.2

Reference Range low

Reference Range high

<6.5

Range Units

%

Conventional Text Result

Conventional Numeric Result

Conventional Reference Range Low

Conventional Reference Range High

Conventional Units

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (1)

Data signed: (hfarmer1) 30 Mar 2015 12:27:29

Generated On: 20 Jul 2016 22:42:34

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: 1261**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (2)

Data signed: (hfarmer1) 30 Mar 2015 12:27:29

Generated On: 20 Jul 2016 22:42:34

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	1261
----------------------	------

Subject Sex	F
-------------	---

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

Visit Name	DAY0
------------	------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	W715912
--------------	---------

Actual Collection Date	2014 04 13
------------------------	------------

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

Specimen Condition	
--------------------	--

Battery ID	RC6871
------------	--------

Battery Name	HDL
--------------	-----

Lab Test ID	RCT1684
-------------	---------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (2)

Data signed: (hfarmer1) 30 Mar 2015 12:27:29

Generated On: 20 Jul 2016 22:42:34

Lab Test Name	DIRECT HDL-C 3RD GENERATION
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	42
Reported Numeric Result	42
Reference Range low	36
Reference Range high	77
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: 1261**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (2)

Data signed: (hfarmer1) 30 Mar 2015 12:27:29

Generated On: 20 Jul 2016 22:42:34

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: 1261

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (3)

Data signed: (hfarmer1) 30 Mar 2015 12:27:29

Generated On: 20 Jul 2016 22:42:34

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	1261
----------------------	------

Subject Sex	F
-------------	---

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

Visit Name	DAY0
------------	------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	W715912
--------------	---------

Actual Collection Date	2014 04 13
------------------------	------------

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

Specimen Condition	
--------------------	--

Battery ID	SC3249
------------	--------

Battery Name	HS-CRP
--------------	--------

Lab Test ID	SCT1528
-------------	---------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1261

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (3)

Data signed: (hfarmer1) 30 Mar 2015 12:27:29

Generated On: 20 Jul 2016 22:42:34

Lab Test Name	C-REACTIVE PROTEIN (NHS)-QT
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	0.054
Reported Numeric Result	0.054
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: 1261**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (3)

Data signed: (hfarmer1) 30 Mar 2015 12:27:29

Generated On: 20 Jul 2016 22:42:34

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: 1261

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (4)

Data signed: (hfarmer1) 30 Mar 2015 12:27:29

Generated On: 20 Jul 2016 22:42:34

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	1261
----------------------	------

Subject Sex	F
-------------	---

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

Visit Name	DAY0
------------	------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	W715912
--------------	---------

Actual Collection Date	2014 04 13
------------------------	------------

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

Specimen Condition	
--------------------	--

Battery ID	SC3582
------------	--------

Battery Name	APOLIPOPROTEIN
--------------	----------------

Lab Test ID	SCT3639
-------------	---------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (4)

Data signed: (hfarmer1) 30 Mar 2015 12:27:29

Generated On: 20 Jul 2016 22:42:34

Lab Test Name	APOLIPOPROTEIN A1, RAND
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	134
Reported Numeric Result	134
Reference Range low	125
Reference Range high	215
Range Units	MG/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (4)

Data signed: (hfarmer1) 30 Mar 2015 12:27:29

Generated On: 20 Jul 2016 22:42:34

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: 1261

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (5)

Data signed: (hfarmer1) 30 Mar 2015 12:27:29

Generated On: 20 Jul 2016 22:42:34

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	1261
----------------------	------

Subject Sex	F
-------------	---

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

Visit Name	DAY0
------------	------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	W715912
--------------	---------

Actual Collection Date	2014 04 13
------------------------	------------

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

Specimen Condition	
--------------------	--

Battery ID	SC3582
------------	--------

Battery Name	APOLIPOPROTEIN
--------------	----------------

Lab Test ID	SCT3643
-------------	---------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1261

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (5)

Data signed: (hfarmer1) 30 Mar 2015 12:27:29

Generated On: 20 Jul 2016 22:42:34

Lab Test Name	APOLIPOPROTEIN B, RAND
Test ID	
Test Status	Done <input checked="" type="checkbox"/>
Reported Text Result	102
Reported Numeric Result	102
Reference Range low	55
Reference Range high	125
Range Units	MG/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (5)

Data signed: (hfarmer1) 30 Mar 2015 12:27:29

Generated On: 20 Jul 2016 22:42:34

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: 1261

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (6)

Data signed: (hfarmer1) 30 Mar 2015 12:27:29

Generated On: 20 Jul 2016 22:42:34

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	1261
----------------------	------

Subject Sex	F
-------------	---

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

Visit Name	DAY0
------------	------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	W715912
--------------	---------

Actual Collection Date	2014 04 13
------------------------	------------

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

Specimen Condition	
--------------------	--

Battery ID	CG267
------------	-------

Battery Name	FIBRINOGEN
--------------	------------

Lab Test ID	CGT285
-------------	--------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1261

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (6)

Data signed: (hfarmer1) 30 Mar 2015 12:27:29

Generated On: 20 Jul 2016 22:42:34

Lab Test Name	FIBRINOGEN
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	313
Reported Numeric Result	313
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: 1261**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (6)

Data signed: (hfarmer1) 30 Mar 2015 12:27:29

Generated On: 20 Jul 2016 22:42:34

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: 1261

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (7)

Data signed: (hfarmer1) 30 Mar 2015 12:27:29

Generated On: 20 Jul 2016 22:42:34

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	1261
----------------------	------

Subject Sex	F
-------------	---

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

Visit Name	DAY0
------------	------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	W715912
--------------	---------

Actual Collection Date	2014 04 13
------------------------	------------

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

Specimen Condition	
--------------------	--

Battery ID	CN236
------------	-------

Battery Name	HOMOCYSTEINE
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Lab Test ID	CNT145
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1261

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (7)

Data signed: (hfarmer1) 30 Mar 2015 12:27:29

Generated On: 20 Jul 2016 22:42:34

Lab Test Name	HOMOCYSTEINE, EDTAPL
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	12.76
Reported Numeric Result	12.76
Reference Range low	3.70
Reference Range high	13.90
Range Units	UMOL/L
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (7)

Data signed: (hfarmer1) 30 Mar 2015 12:27:29

Generated On: 20 Jul 2016 22:42:34

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: 1261

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (8)

Data signed: (hfarmer1) 30 Mar 2015 12:27:29

Generated On: 20 Jul 2016 22:42:34

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	1261
----------------------	------

Subject Sex	F
-------------	---

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

Visit Name	DAY0
------------	------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	W715912
--------------	---------

Actual Collection Date	2014 04 13
------------------------	------------

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

Specimen Condition	
--------------------	--

Battery ID	IM2293
------------	--------

Battery Name	SICAM-1
--------------	---------

Lab Test ID	IMT1768
-------------	---------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1261

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (8)

Data signed: (hfarmer1) 30 Mar 2015 12:27:29

Generated On: 20 Jul 2016 22:42:34

Lab Test Name	SICAM-1-RUO
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	241.6
Reported Numeric Result	241.6
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: 1261**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (8)

Data signed: (hfarmer1) 30 Mar 2015 12:27:29

Generated On: 20 Jul 2016 22:42:34

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: 1261**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (9)

Data signed: (hfarmer1) 30 Mar 2015 12:27:29

Generated On: 20 Jul 2016 22:42:34

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	1261
----------------------	------

Subject Sex	F
-------------	---

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

Visit Name	DAY0
------------	------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	W715912
--------------	---------

Actual Collection Date	2014 04 13
------------------------	------------

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

Specimen Condition	
--------------------	--

Battery ID	RC9267
------------	--------

Battery Name	LDL
--------------	-----

Lab Test ID	RCT2394
-------------	---------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1261

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (9)

Data signed: (hfarmer1) 30 Mar 2015 12:27:29

Generated On: 20 Jul 2016 22:42:34

Lab Test Name	DIRECT LDL-C 2ND GEN (-70)
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Test ID	<hr/>
---------	-------

Test Status	Done <input checked="" type="radio"/>
-------------	---------------------------------------

Reported Text Result	132
----------------------	-----

Reported Numeric Result	132
-------------------------	-----

Reference Range low	67
---------------------	----

Reference Range high	150
----------------------	-----

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: 1261**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (9)

Data signed: (hfarmer1) 30 Mar 2015 12:27:29

Generated On: 20 Jul 2016 22:42:34

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: 1261**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (CEMA, HPMa, HBMA)

Data signed: (hfarmer1) 30 Mar 2015 12:27:51

Generated On: 20 Jul 2016 22:42:34

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (1)

Data signed: (hfarmer1) 30 Mar 2015 12:27:51

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05112450002925
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Analyte	HPMA
---------	------

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

Result	550
--------	-----

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

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

Sample comment	
----------------	--

Detection method	LC-MS/MS
------------------	----------

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

Day of Visit	0
--------------	---

Celerion Study Number	AA99128-03
-----------------------	------------

Date of Collection	2014-APR-13
--------------------	-------------

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

Urine Start Day	0
-----------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (CEMA, HPMa, HBMA) (1)

Data signed: (hfarmer1) 30 Mar 2015 12:27:51

Generated On: 20 Jul 2016 22:42:34

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (CEMA, HPMa, HBMA) (2)

Data signed: (hfarmer1) 30 Mar 2015 12:27:51

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05112450002925
Analyte	CEMA
Sample type	URINE
Result	78.6
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	0
Celerion Study Number	AA99128-03
Date of Collection	2014-APR-13
Timepoint-minutes	
Urine Start Day	0

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (CEMA, HPMa, HBMA) (2)

Data signed: (hfarmer1) 30 Mar 2015 12:27:51

Generated On: 20 Jul 2016 22:42:34

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (3)

Data signed: (hfarmer1) 30 Mar 2015 12:27:51

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05112450002925
----------------	----------------

Analyte	HBMA
---------	------

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

Result	270
--------	-----

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

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

Sample comment	
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Detection method	LC-MS/MS
------------------	----------

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

Day of Visit	0
--------------	---

Celerion Study Number	AA99128-03
-----------------------	------------

Date of Collection	2014-APR-13
--------------------	-------------

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

Urine Start Day	0
-----------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (CEMA, HPMa, HBMA) (3)

Data signed: (hfarmer1) 30 Mar 2015 12:27:51

Generated On: 20 Jul 2016 22:42:34

Urine End Day	1
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (NNN, NNAL)

Data signed: (hfarmer1) 30 Mar 2015 12:27:50

Generated On: 20 Jul 2016 22:42:34

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (NNN, NNAL) (1)

Data signed: (hfarmer1) 30 Mar 2015 12:27:50

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05112460003512
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Analyte	NNAL
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Sample type	URINE
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Result	299
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Result Unit	PG/ML
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Lab Status	OK
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Sample comment	
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Detection method	LC-MS/MS
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Planned time point (Hour)	0
---------------------------	---

Day of Visit	0
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Celerion Study Number	AA99128-04
-----------------------	------------

Date of Collection	2014-APR-13
--------------------	-------------

Timepoint-minutes	
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Urine Start Day	0
-----------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (NNN, NNAL) (1)

Data signed: (hfarmer1) 30 Mar 2015 12:27:50

Generated On: 20 Jul 2016 22:42:34

Urine End Day	1
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (NNN, NNAL) (2)

Data signed: (hfarmer1) 30 Mar 2015 12:27:50

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05112460003512
Analyte	NNN
Sample type	URINE
Result	12.2
Result Unit	PG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	0
Celerion Study Number	AA99128-04
Date of Collection	2014-APR-13
Timepoint-minutes	
Urine Start Day	0

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (NNN, NNAL) (2)

Data signed: (hfarmer1) 30 Mar 2015 12:27:50

Generated On: 20 Jul 2016 22:42:34

Urine End Day

1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (HEMA)

Data signed: (hfarmer1) 30 Mar 2015 12:27:50

Generated On: 20 Jul 2016 22:42:34

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (HEMA) (1)

Data signed: (hfarmer1) 30 Mar 2015 12:27:50

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05112470001752
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Analyte	HEMA
---------	------

Sample type	URINE
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Result	10.4
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Result Unit	NG/ML
-------------	-------

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

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

Day of Visit	0
--------------	---

Celerion Study Number	AA99128-05
-----------------------	------------

Date of Collection	2014-APR-13
--------------------	-------------

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

Urine Start Day	0
-----------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (HEMA) (1)

Data signed: (hfarmer1) 30 Mar 2015 12:27:50

Generated On: 20 Jul 2016 22:42:34

Urine End Day	1
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day 0)

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

Data signed: (hfarmer1) 30 Mar 2015 12:27:51

Generated On: 20 Jul 2016 22:42:34

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day 0)

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

Data signed: (hfarmer1) 30 Mar 2015 12:27:51

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05112480001158
----------------	----------------

Analyte	COT
---------	-----

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

Result	1270
--------	------

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

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

Sample comment	
----------------	--

Detection method	LC-MS/MS
------------------	----------

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

Day of Visit	0
--------------	---

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

Date of Collection	2014-APR-14
--------------------	-------------

Timepoint-minutes	
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day 0)

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

Data signed: (hfarmer1) 30 Mar 2015 12:27:51

Generated On: 20 Jul 2016 22:42:34

Urine Start Day	0
<hr/>	
Urine End Day	1
<hr/>	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day 0)

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

Data signed: (hfarmer1) 30 Mar 2015 12:27:51

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05112480001158
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Analyte	COT-GLUC
---------	----------

Sample type	URINE
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Result	3880
--------	------

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

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

Sample comment	
----------------	--

Detection method	LC-MS/MS
------------------	----------

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

Day of Visit	0
--------------	---

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

Date of Collection	2014-APR-14
--------------------	-------------

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day 0)

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

Data signed: (hfarmer1) 30 Mar 2015 12:27:51

Generated On: 20 Jul 2016 22:42:34

Urine Start Day	0
<hr/>	
Urine End Day	1
<hr/>	

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1261

Folder: Baseline (Day 0)

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

Data signed: (hfarmer1) 30 Mar 2015 12:27:51

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05112480001158
Analyte	NIC
Sample type	URINE
Result	359
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	0
Celerion Study Number	AA99128-06
Date of Collection	2014-APR-14
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day 0)

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

Data signed: (hfarmer1) 30 Mar 2015 12:27:51

Generated On: 20 Jul 2016 22:42:34

Urine Start Day	0
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Urine End Day	1
---------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day 0)

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

Data signed: (hfarmer1) 30 Mar 2015 12:27:51

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05112480001158
----------------	----------------

Analyte	NIC-GLUC
---------	----------

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

Result	811
--------	-----

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

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

Sample comment	
----------------	--

Detection method	LC-MS/MS
------------------	----------

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

Day of Visit	0
--------------	---

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

Date of Collection	2014-APR-14
--------------------	-------------

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day 0)

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

Data signed: (hfarmer1) 30 Mar 2015 12:27:51

Generated On: 20 Jul 2016 22:42:34

Urine Start Day	0
<hr/>	
Urine End Day	1
<hr/>	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day 0)

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

Data signed: (hfarmer1) 30 Mar 2015 12:27:51

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05112480001158
----------------	----------------

Analyte	THCOT
---------	-------

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

Result	2110
--------	------

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

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

Sample comment	
----------------	--

Detection method	LC-MS/MS
------------------	----------

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

Day of Visit	0
--------------	---

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

Date of Collection	2014-APR-14
--------------------	-------------

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day 0)

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

Data signed: (hfarmer1) 30 Mar 2015 12:27:51

Generated On: 20 Jul 2016 22:42:34

Urine Start Day	0
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Urine End Day	1
---------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day 0)

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

Data signed: (hfarmer1) 30 Mar 2015 12:27:51

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05112480001158
Analyte	THCOT-GLUC
Sample type	URINE
Result	742
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	0
Celerion Study Number	AA99128-06
Date of Collection	2014-APR-14
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day 0)

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

Data signed: (hfarmer1) 30 Mar 2015 12:27:51

Generated On: 20 Jul 2016 22:42:34

Urine Start Day	0
-----------------	---

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (3-OH BaP)

Data signed: (hfarmer1) 30 Mar 2015 12:27:52

Generated On: 20 Jul 2016 22:42:34

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (3-OH BaP) (1)

Data signed: (hfarmer1) 30 Mar 2015 12:27:52

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05112490001752
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Analyte	3-OH BAP
---------	----------

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

Result	297
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Result Unit	FG/ML
-------------	-------

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

Sample comment	
----------------	--

Detection method	LC-MS/MS
------------------	----------

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

Day of Visit	0
--------------	---

Celerion Study Number	AA99128-07
-----------------------	------------

Date of Collection	2014-APR-13
--------------------	-------------

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

Urine Start Day	0
-----------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (3-OH BaP) (1)

Data signed: (hfarmer1) 30 Mar 2015 12:27:52

Generated On: 20 Jul 2016 22:42:34

Urine End Day

1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day 0)

Form: Biomarker-Plasma (Caffeine, Paraxanthine)

Generated On: 20 Jul 2016 22:42:34

Sample type

PLASMA

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day 0)

Form: Biomarker-Plasma (Caffeine, Paraxanthine) (1)

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05112500000478
----------------	----------------

Analyte	CAFFEINE
---------	----------

Sample type	PLASMA
-------------	--------

Result	646
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Result Unit	NG/ML
-------------	-------

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

Sample comment	
----------------	--

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	6
---------------------------	---

Day of Visit	0
--------------	---

Celerion Study Number	AA99128-08
-----------------------	------------

Date of Collection	2014-APR-13
--------------------	-------------

Timepoint-minutes	0
-------------------	---

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day 0)

Form: Biomarker-Plasma (Caffeine, Paraxanthine) (1)

Generated On: 20 Jul 2016 22:42:34

Urine End Day	0
---------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day 0)

Form: Biomarker-Plasma (Caffeine, Paraxanthine) (2)

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05112500000478
----------------	----------------

Analyte	PARAXANTHINE
---------	--------------

Sample type	PLASMA
-------------	--------

Result	1160
--------	------

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

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

Sample comment	
----------------	--

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	6
---------------------------	---

Day of Visit	0
--------------	---

Celerion Study Number	AA99128-08
-----------------------	------------

Date of Collection	2014-APR-13
--------------------	-------------

Timepoint-minutes	0
-------------------	---

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day 0)

Form: Biomarker-Plasma (Caffeine, Paraxanthine) (2)

Generated On: 20 Jul 2016 22:42:34

Urine End Day	0
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day 0)

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

Data signed: (hfarmer1) 30 Mar 2015 12:27:52

Generated On: 20 Jul 2016 22:42:34

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day 0)

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

Data signed: (hfarmer1) 30 Mar 2015 12:27:52

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05112510001774
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Analyte	1-NA
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Sample type	URINE
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Result	32.8
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Result Unit	PG/ML
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Lab Status	OK
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Sample comment	
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Detection method	LC-MS/MS
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Planned time point (Hour)	0
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Day of Visit	0
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Celerion Study Number	AA99128-09
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Date of Collection	2014-APR-13
--------------------	-------------

Timepoint-minutes	
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Urine Start Day	0
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day 0)

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

Data signed: (hfarmer1) 30 Mar 2015 12:27:52

Generated On: 20 Jul 2016 22:42:34

Urine End Day	1
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day 0)

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

Data signed: (hfarmer1) 30 Mar 2015 12:27:52

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05112510001774
Analyte	2-NA
Sample type	URINE
Result	13.5
Result Unit	PG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	0
Celerion Study Number	AA99128-09
Date of Collection	2014-APR-13
Timepoint-minutes	
Urine Start Day	0

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day 0)

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

Data signed: (hfarmer1) 30 Mar 2015 12:27:52

Generated On: 20 Jul 2016 22:42:34

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

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1261

Folder: Baseline (Day 0)

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (3)

Data signed: (hfarmer1) 30 Mar 2015 12:27:52

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05112510001774
Analyte	4-ABP
Sample type	URINE
Result	8.66
Result Unit	PG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	0
Celerion Study Number	AA99128-09
Date of Collection	2014-APR-13
Timepoint-minutes	
Urine Start Day	0

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (3)

Data signed: (hfarmer1) 30 Mar 2015 12:27:52

Generated On: 20 Jul 2016 22:42:34

Urine End Day	1
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day 0)

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

Data signed: (hfarmer1) 30 Mar 2015 12:27:52

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05112510001774
Analyte	O-TOL
Sample type	URINE
Result	80.0
Result Unit	PG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	0
Celerion Study Number	AA99128-09
Date of Collection	2014-APR-13
Timepoint-minutes	
Urine Start Day	0

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day 0)

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

Data signed: (hfarmer1) 30 Mar 2015 12:27:52

Generated On: 20 Jul 2016 22:42:34

Urine End Day	1
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (11-dTXb2)

Data signed: (hfarmer1) 30 Mar 2015 12:27:50

Generated On: 20 Jul 2016 22:42:34

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (11-dTXb2) (1)

Data signed: (hfarmer1) 30 Mar 2015 12:27:50

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05112530000556
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Analyte	11-DTXB2
---------	----------

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

Result	498
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Result Unit	PG/ML
-------------	-------

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

Day of Visit	0
--------------	---

Celerion Study Number	AA99128-11
-----------------------	------------

Date of Collection	2014-APR-13
--------------------	-------------

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

Urine Start Day	0
-----------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (11-dTXb2) (1)

Data signed: (hfarmer1) 30 Mar 2015 12:27:50

Generated On: 20 Jul 2016 22:42:34

Urine End Day

1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (iPF2a-III)

Data signed: (hfarmer1) 30 Mar 2015 12:27:50

Generated On: 20 Jul 2016 22:42:34

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (iPF2a-III) (1)

Data signed: (hfarmer1) 30 Mar 2015 12:27:50

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05112540000549
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Analyte	IPF2A-III
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Sample type	URINE
-------------	-------

Result	137
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Result Unit	PG/ML
-------------	-------

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

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

Day of Visit	0
--------------	---

Celerion Study Number	AA99128-12
-----------------------	------------

Date of Collection	2014-APR-13
--------------------	-------------

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

Urine Start Day	0
-----------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (iPF2a-III) (1)

Data signed: (hfarmer1) 30 Mar 2015 12:27:50

Generated On: 20 Jul 2016 22:42:34

Urine End Day

1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (Ames)

Data signed: (hfarmer1) 30 Mar 2015 12:27:52

Generated On: 20 Jul 2016 22:42:34

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (Ames) (1)

Data signed: (hfarmer1) 30 Mar 2015 12:27:52

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05113320000238
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Analyte	AMES
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Sample type	URINE
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Result	1.03
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Result Unit	REV/ML
-------------	--------

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

Sample comment	
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Detection method	COUNT
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Planned time point (Hour)	0
---------------------------	---

Day of Visit	0
--------------	---

Celerion Study Number	AA99128-15
-----------------------	------------

Date of Collection	2014-APR-13
--------------------	-------------

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

Urine Start Day	0
-----------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (Ames) (1)

Data signed: (hfarmer1) 30 Mar 2015 12:27:52

Generated On: 20 Jul 2016 22:42:34

Urine End Day	1
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (1-OHP)

Data signed: (hfarmer1) 30 Mar 2015 12:27:52

Generated On: 20 Jul 2016 22:42:34

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day 0)

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

Data signed: (hfarmer1) 30 Mar 2015 12:27:52

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05115190003776
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Analyte	1-OHP
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Sample type	URINE
-------------	-------

Result	225
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Result Unit	PG/ML
-------------	-------

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

Sample comment	
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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-APR-13
--------------------	-------------

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

Urine Start Day	0
-----------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day 0)

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

Data signed: (hfarmer1) 30 Mar 2015 12:27:52

Generated On: 20 Jul 2016 22:42:34

Urine End Day

1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (SPMA, SBMA)

Data signed: (hfarmer1) 30 Mar 2015 12:27:50

Generated On: 20 Jul 2016 22:42:34

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day 0)

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

Data signed: (hfarmer1) 30 Mar 2015 12:27:50

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05115170003767
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Analyte	SBMA
---------	------

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

Result	2.07
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Result Unit	NG/ML
-------------	-------

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

Sample comment	
----------------	--

Detection method	LC-MS/MS
------------------	----------

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

Day of Visit	0
--------------	---

Celerion Study Number	AA99598-01
-----------------------	------------

Date of Collection	2014-APR-13
--------------------	-------------

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

Urine Start Day	0
-----------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day 0)

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

Data signed: (hfarmer1) 30 Mar 2015 12:27:50

Generated On: 20 Jul 2016 22:42:34

Urine End Day

1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (SPMA, SBMA) (2)

Data signed: (hfarmer1) 30 Mar 2015 12:27:50

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05115170003767
----------------	----------------

Analyte	SPMA
---------	------

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

Result	2.69
--------	------

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

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

Sample comment	
----------------	--

Detection method	LC-MS/MS
------------------	----------

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

Day of Visit	0
--------------	---

Celerion Study Number	AA99598-01
-----------------------	------------

Date of Collection	2014-APR-13
--------------------	-------------

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

Urine Start Day	0
-----------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (SPMA, SBMA) (2)

Data signed: (hfarmer1) 30 Mar 2015 12:27:50

Generated On: 20 Jul 2016 22:42:34

Urine End Day

1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (MHBMA)

Data signed: (hfarmer1) 30 Mar 2015 12:27:50

Generated On: 20 Jul 2016 22:42:34

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (MHBMA) (1)

Data signed: (hfarmer1) 30 Mar 2015 12:27:50

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05115180003776
----------------	----------------

Analyte	MHBMA
---------	-------

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

Result	1.51
--------	------

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

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

Sample comment	
----------------	--

Detection method	LC-MS/MS
------------------	----------

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

Day of Visit	0
--------------	---

Celerion Study Number	AA99598-02
-----------------------	------------

Date of Collection	2014-APR-13
--------------------	-------------

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

Urine Start Day	0
-----------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (MHBMA) (1)

Data signed: (hfarmer1) 30 Mar 2015 12:27:50

Generated On: 20 Jul 2016 22:42:34

Urine End Day

1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (Creatinine)

Data signed: (hfarmer1) 30 Mar 2015 12:27:52

Generated On: 20 Jul 2016 22:42:34

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (Creatinine) (1)

Data signed: (hfarmer1) 30 Mar 2015 12:27:52

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05115160001752
----------------	----------------

Analyte	CREATININE
---------	------------

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

Result	65.3
--------	------

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

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

Sample comment	
----------------	--

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

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

Day of Visit	0
--------------	---

Celerion Study Number	AA99128-14
-----------------------	------------

Date of Collection	2014-APR-13
--------------------	-------------

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

Urine Start Day	0
-----------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (Creatinine) (1)

Data signed: (hfarmer1) 30 Mar 2015 12:27:52

Generated On: 20 Jul 2016 22:42:34

Urine End Day	1
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day 0)

Form: Biomarker-Plasma (Nic, Cot, tHCot)

Data signed: (hfarmer1) 30 Mar 2015 12:27:50

Generated On: 20 Jul 2016 22:42:34

Sample type

PLASMA

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day 0)

Form: Biomarker-Plasma (Nic, Cot, tHCot) (1)

Data signed: (hfarmer1) 30 Mar 2015 12:27:50

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05112430001996
----------------	----------------

Analyte	COT
---------	-----

Sample type	PLASMA
-------------	--------

Result	207
--------	-----

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

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

Sample comment	
----------------	--

Detection method	LC-MS/MS
------------------	----------

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

Day of Visit	0
--------------	---

Celerion Study Number	AA99128-01
-----------------------	------------

Date of Collection	2014-APR-13
--------------------	-------------

Timepoint-minutes	0
-------------------	---

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day 0)

Form: Biomarker-Plasma (Nic, Cot, tHCot) (1)

Data signed: (hfarmer1) 30 Mar 2015 12:27:50

Generated On: 20 Jul 2016 22:42:34

Urine End Day	0
---------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day 0)

Form: Biomarker-Plasma (Nic, Cot, tHCot) (2)

Data signed: (hfarmer1) 30 Mar 2015 12:27:50

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05112430001996
----------------	----------------

Analyte	NIC
---------	-----

Sample type	PLASMA
-------------	--------

Result	18.2
--------	------

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

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

Sample comment	
----------------	--

Detection method	LC-MS/MS
------------------	----------

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

Day of Visit	0
--------------	---

Celerion Study Number	AA99128-01
-----------------------	------------

Date of Collection	2014-APR-13
--------------------	-------------

Timepoint-minutes	0
-------------------	---

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day 0)

Form: Biomarker-Plasma (Nic, Cot, tHCot) (2)

Data signed: (hfarmer1) 30 Mar 2015 12:27:50

Generated On: 20 Jul 2016 22:42:34

Urine End Day	0
---------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day 0)

Form: Biomarker-Plasma (Nic, Cot, tHCot) (3)

Data signed: (hfarmer1) 30 Mar 2015 12:27:50

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05112520000478
----------------	----------------

Analyte	COT
---------	-----

Sample type	PLASMA
-------------	--------

Result	218
--------	-----

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

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

Sample comment	
----------------	--

Detection method	LC-MS/MS
------------------	----------

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

Day of Visit	0
--------------	---

Celerion Study Number	AA99128-10
-----------------------	------------

Date of Collection	2014-APR-13
--------------------	-------------

Timepoint-minutes	0
-------------------	---

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day 0)

Form: Biomarker-Plasma (Nic, Cot, tHCot) (3)

Data signed: (hfarmer1) 30 Mar 2015 12:27:50

Generated On: 20 Jul 2016 22:42:34

Urine End Day	0
---------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day 0)

Form: Biomarker-Plasma (Nic, Cot, tHCot) (4)

Data signed: (hfarmer1) 30 Mar 2015 12:27:50

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05112520000478
----------------	----------------

Analyte	THCOT
---------	-------

Sample type	PLASMA
-------------	--------

Result	58.1
--------	------

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

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

Sample comment	
----------------	--

Detection method	LC-MS/MS
------------------	----------

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

Day of Visit	0
--------------	---

Celerion Study Number	AA99128-10
-----------------------	------------

Date of Collection	2014-APR-13
--------------------	-------------

Timepoint-minutes	0
-------------------	---

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Baseline (Day 0)

Form: Biomarker-Plasma (Nic, Cot, tHCot) (4)

Data signed: (hfarmer1) 30 Mar 2015 12:27:50

Generated On: 20 Jul 2016 22:42:34

Urine End Day	0
---------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 1

Form: Date of Visit

Data signed: (hfarmer1) 30 Mar 2015 12:27:52

Generated On: 20 Jul 2016 22:42:34

Date of Visit

14 APR 2014
DD/MMM/YYYY

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 1

Form: Vital Signs

Data signed: (hfarmer1) 30 Mar 2015 12:27:52

Generated On: 20 Jul 2016 22:42:34

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 08:46
hour:min 24-hour clock

Pulse rate 68
beats per minute

Respiratory rate 16
breaths per minute

Blood Pressure (systolic) 113
mmHg

Blood Pressure (diastolic) 76
mmHg

Vital Signs Position of Subject Supine ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 1

Form: Plasma Nicotine Sample

Data signed: (hfarmer1) 30 Mar 2015 12:27:52

Generated On: 20 Jul 2016 22:42:34

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	14 APR 2014
---------------------	-------------

Time hour:min 24-hour clock	20:09
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 1

Form: Plasma Cotinine Sample

Data signed: (hfarmer1) 30 Mar 2015 12:27:52

Generated On: 20 Jul 2016 22:42:34

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	14 APR 2014
---------------------	-------------

Time hour:min 24-hour clock	20:09
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 1

Form: CoHb Blood Sample

Data signed: (hfarmer1) 30 Mar 2015 12:27:52

Generated On: 20 Jul 2016 22:42:34

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	14 APR 2014
---------------------	-------------

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

Time hour:min 24-hour clock	20:09
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 1

Form: CO Breath Test (1)

Data signed: (hfarmer1) 30 Mar 2015 12:27:53

Generated On: 20 Jul 2016 22:42:34

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	06:41
---	-------

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 1

Form: CO Breath Test (2)

Data signed: (hfarmer1) 30 Mar 2015 12:27:53

Generated On: 20 Jul 2016 22:42:34

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	12:22
---	-------

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 1

Form: CO Breath Test (3)

Data signed: (hfarmer1) 30 Mar 2015 12:27:53

Generated On: 20 Jul 2016 22:42:34

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

If Not Done, please specify the reason: _____

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

Actual Time of Assessment hour:min 24-hour clock	16:03
---	-------

Result(ppm)	13
-------------	----

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 1

Form: CO Breath Test (4)

Data signed: (hfarmer1) 30 Mar 2015 12:27:53

Generated On: 20 Jul 2016 22:42:34

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	20:16
---	-------

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 1

Form: 24 hour urine collections

Data signed: (hfarmer1) 30 Mar 2015 12:27:52

Generated On: 20 Jul 2016 22:42:34

Start Time	06:08
	hour:min 24-hour clock

End Date	15 APR 2014
	DD/MMM/YYYY

End Time	06:04
	hour:min 24-hour clock

Volume	1974
	mL

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 1

Form: Sample Urine Collection

Data signed: (hfarmer1) 30 Mar 2015 12:27:52

Generated On: 20 Jul 2016 22:42:34

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: 1261**

Folder: Day 1

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Data signed: (hfarmer1) 30 Mar 2015 12:27:53

Generated On: 20 Jul 2016 22:42:34

Date of Birth

(b) (6)

Date of assessment
DD/MMM/YYYY

2014 APR 14
DD/MMM/YYYY

Time of assessment

06:19
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: 1261**

Folder: Day 1

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Data signed: (hfarmer1) 30 Mar 2015 12:27:53

Generated On: 20 Jul 2016 22:42:34

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

5. Difficulty concentrating

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

6. Increased appetite, hungry, weight gain

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

7. Insomnia, sleep problems, awakening at night

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

8. Restless

How have you been feeling over the past 24 hours? 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: 1261**

Folder: Day 1

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Data signed: (hfarmer1) 30 Mar 2015 12:27:53

Generated On: 20 Jul 2016 22:42:34

How have you been feeling over the past 24 hours?

Slight ☒

13. Dreaming or nightmares

How have you been feeling over the past 24 hours?

None ☒

14. Nausea

How have you been feeling over the past 24 hours?

None ☒

15. Sore Throat

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 1

Form: Cough Assessment

Data signed: (hfarmer1) 30 Mar 2015 12:27:53

Generated On: 20 Jul 2016 22:42:34

Date of Birth

(b) (6)

Date of assessment
DD/MMM/YYYY

2014 APR 14
DD/MMM/YYYY

Time of assessment

06:17
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: 1261**

Folder: Day 1

Form: Lab_BU_COHB (1)

Data signed: (hfarmer1) 30 Mar 2015 12:27:53

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05115150004276
----------------	----------------

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

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

Result	6.20
--------	------

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

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

Sample comment	
----------------	--

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

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

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

Day of Visit	1
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Celerion Study Number	AA99128-16
-----------------------	------------

Date of Collection	2014-APR-14
--------------------	-------------

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 1

Form: Lab_BU_COHB (1)

Data signed: (hfarmer1) 30 Mar 2015 12:27:53

Generated On: 20 Jul 2016 22:42:34

Start Day (24 hour urine only) _____

End Day (24 hour Urine Only) _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 1

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)

Data signed: (hfarmer1) 30 Mar 2015 12:27:53

Generated On: 20 Jul 2016 22:42:34

Date of Birth

(b) (6)

Date of assessment

2014 APR 14

DD/MMM/YYYY

DD/MMM/YYYY

Time of assessment

20:03

hour:min 24-hour clock

Assessment Status

Completed ☒

1. Was smoking satisfying?

A lot ☒

2. Did cigarettes taste good?

Extremely ☒

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

Little ☒

4. Did smoking calm you down?

Not at all ☒

5. Did smoking make you feel more awake?

Moderately ☒

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?

Little ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 1

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)

Data signed: (hfarmer1) 30 Mar 2015 12:27:53

Generated On: 20 Jul 2016 22:42:34

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? A lot ☐

12. Did you enjoy smoking? A lot ☐

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 1

Form: Questionnaire on smoking urges (QSU)

Data signed: (hfarmer1) 30 Mar 2015 12:27:53

Generated On: 20 Jul 2016 22:42:34

Type	QSU
------	-----

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

Date of assessment	2014 APR 14
--------------------	-------------

DD/MMM/YYYY

Time of assessment	20:01
--------------------	-------

hour:min 24-hour clock

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

1. I have a desire for a cigarette right now	Do not agree or disagree <input checked="" type="radio"/>
--	---

2. Nothing would be better than smoking a cigarette right now	Strongly agree <input checked="" type="radio"/>
---	---

3. If it were possible I would probably smoke now	Strongly agree <input checked="" type="radio"/>
---	---

4. I could control things better right now if I could smoke	Strongly disagree <input checked="" type="radio"/>
---	--

5. All I want right now is a cigarette	Do not agree or disagree <input checked="" type="radio"/>
--	---

6. I have an urge for a cigarette	Do not agree or disagree <input checked="" type="radio"/>
-----------------------------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 1

Form: Questionnaire on smoking urges (QSU)

Data signed: (hfarmer1) 30 Mar 2015 12:27:53

Generated On: 20 Jul 2016 22:42:34

7. A cigarette would taste good now Do not agree or disagree ☐

8. I would do almost anything for a cigarette now Do not agree or disagree ☐

9. Smoking would make me less depressed Strongly disagree ☐

10. I am going to smoke as soon as possible Do not agree or disagree ☐

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 1

Form: Biomarker-Urine (CEMA, HPMa, HBMA)

Data signed: (hfarmer1) 30 Mar 2015 12:27:54

Generated On: 20 Jul 2016 22:42:34

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 1

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (1)

Data signed: (hfarmer1) 30 Mar 2015 12:27:54

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05112450002926
----------------	----------------

Analyte	HPMA
---------	------

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

Result	556
--------	-----

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

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

Sample comment	
----------------	--

Detection method	LC-MS/MS
------------------	----------

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

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

Celerion Study Number	AA99128-03
-----------------------	------------

Date of Collection	2014-APR-14
--------------------	-------------

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

Urine Start Day	1
-----------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 1

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (1)

Data signed: (hfarmer1) 30 Mar 2015 12:27:54

Generated On: 20 Jul 2016 22:42:34

Urine End Day

2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 1

Form: Biomarker-Urine (CEMA, HPMa, HBMA) (2)

Data signed: (hfarmer1) 30 Mar 2015 12:27:54

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05112450002926
----------------	----------------

Analyte	CEMA
---------	------

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

Result	86.9
--------	------

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

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

Sample comment	
----------------	--

Detection method	LC-MS/MS
------------------	----------

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

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

Celerion Study Number	AA99128-03
-----------------------	------------

Date of Collection	2014-APR-14
--------------------	-------------

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

Urine Start Day	1
-----------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 1

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (2)

Data signed: (hfarmer1) 30 Mar 2015 12:27:54

Generated On: 20 Jul 2016 22:42:34

Urine End Day

2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 1

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (3)

Data signed: (hfarmer1) 30 Mar 2015 12:27:54

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05112450002926
----------------	----------------

Analyte	HBMA
---------	------

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

Result	337
--------	-----

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

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

Sample comment	
----------------	--

Detection method	LC-MS/MS
------------------	----------

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

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

Celerion Study Number	AA99128-03
-----------------------	------------

Date of Collection	2014-APR-14
--------------------	-------------

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

Urine Start Day	1
-----------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 1

Form: Biomarker-Urine (CEMA, HPMa, HBMA) (3)

Data signed: (hfarmer1) 30 Mar 2015 12:27:54

Generated On: 20 Jul 2016 22:42:34

Urine End Day

2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 1

Form: Biomarker-Urine (NNN, NNAL)

Data signed: (hfarmer1) 30 Mar 2015 12:27:54

Generated On: 20 Jul 2016 22:42:34

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 1

Form: Biomarker-Urine (NNN, NNAL) (1)

Data signed: (hfarmer1) 30 Mar 2015 12:27:54

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05112460003513
----------------	----------------

Analyte	NNAL
---------	------

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

Result	289
--------	-----

Result Unit	PG/ML
-------------	-------

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

Sample comment	
----------------	--

Detection method	LC-MS/MS
------------------	----------

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

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

Celerion Study Number	AA99128-04
-----------------------	------------

Date of Collection	2014-APR-14
--------------------	-------------

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

Urine Start Day	1
-----------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 1

Form: Biomarker-Urine (NNN, NNAL) (1)

Data signed: (hfarmer1) 30 Mar 2015 12:27:54

Generated On: 20 Jul 2016 22:42:34

Urine End Day

2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 1

Form: Biomarker-Urine (NNN, NNAL) (2)

Data signed: (hfarmer1) 30 Mar 2015 12:27:54

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05112460003513
----------------	----------------

Analyte	NNN
---------	-----

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

Result	12.6
--------	------

Result Unit	PG/ML
-------------	-------

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

Sample comment	
----------------	--

Detection method	LC-MS/MS
------------------	----------

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

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

Celerion Study Number	AA99128-04
-----------------------	------------

Date of Collection	2014-APR-14
--------------------	-------------

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

Urine Start Day	1
-----------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 1

Form: Biomarker-Urine (NNN, NNAL) (2)

Data signed: (hfarmer1) 30 Mar 2015 12:27:54

Generated On: 20 Jul 2016 22:42:34

Urine End Day

2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 1

Form: Biomarker-Urine (HEMA)

Data signed: (hfarmer1) 30 Mar 2015 12:27:54

Generated On: 20 Jul 2016 22:42:34

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 1

Form: Biomarker-Urine (HEMA) (1)

Data signed: (hfarmer1) 30 Mar 2015 12:27:54

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05112470001753
----------------	----------------

Analyte	HEMA
---------	------

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

Result	10.5
--------	------

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

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

Sample comment	
----------------	--

Detection method	LC-MS/MS
------------------	----------

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

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

Celerion Study Number	AA99128-05
-----------------------	------------

Date of Collection	2014-APR-14
--------------------	-------------

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

Urine Start Day	1
-----------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 1

Form: Biomarker-Urine (HEMA) (1)

Data signed: (hfarmer1) 30 Mar 2015 12:27:54

Generated On: 20 Jul 2016 22:42:34

Urine End Day

2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 1

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

Data signed: (hfarmer1) 30 Mar 2015 12:27:55

Generated On: 20 Jul 2016 22:42:34

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 1

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

Data signed: (hfarmer1) 30 Mar 2015 12:27:55

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05112480001159
Analyte	COT
Sample type	URINE
Result	1200
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	1
Celerion Study Number	AA99128-06
Date of Collection	2014-APR-15
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 1

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

Data signed: (hfarmer1) 30 Mar 2015 12:27:55

Generated On: 20 Jul 2016 22:42:34

Urine Start Day	1
-----------------	---

Urine End Day	2
---------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 1

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

Data signed: (hfarmer1) 30 Mar 2015 12:27:55

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05112480001159
----------------	----------------

Analyte	COT-GLUC
---------	----------

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

Result	4200
--------	------

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

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

Sample comment	
----------------	--

Detection method	LC-MS/MS
------------------	----------

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

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

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

Date of Collection	2014-APR-15
--------------------	-------------

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 1

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

Data signed: (hfarmer1) 30 Mar 2015 12:27:55

Generated On: 20 Jul 2016 22:42:34

Urine Start Day	1
-----------------	---

Urine End Day	2
---------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 1

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

Data signed: (hfarmer1) 30 Mar 2015 12:27:55

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05112480001159
Analyte	NIC
Sample type	URINE
Result	359
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	1
Celerion Study Number	AA99128-06
Date of Collection	2014-APR-15
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 1

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

Data signed: (hfarmer1) 30 Mar 2015 12:27:55

Generated On: 20 Jul 2016 22:42:34

Urine Start Day	1
-----------------	---

Urine End Day	2
---------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 1

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

Data signed: (hfarmer1) 30 Mar 2015 12:27:55

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05112480001159
Analyte	NIC-GLUC
Sample type	URINE
Result	955
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	1
Celerion Study Number	AA99128-06
Date of Collection	2014-APR-15
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 1

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

Data signed: (hfarmer1) 30 Mar 2015 12:27:55

Generated On: 20 Jul 2016 22:42:34

Urine Start Day	1
-----------------	---

Urine End Day	2
---------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 1

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

Data signed: (hfarmer1) 30 Mar 2015 12:27:55

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05112480001159
----------------	----------------

Analyte	THCOT
---------	-------

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

Result	2140
--------	------

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

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

Sample comment	
----------------	--

Detection method	LC-MS/MS
------------------	----------

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

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

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

Date of Collection	2014-APR-15
--------------------	-------------

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 1

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

Data signed: (hfarmer1) 30 Mar 2015 12:27:55

Generated On: 20 Jul 2016 22:42:34

Urine Start Day	1
-----------------	---

Urine End Day	2
---------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 1

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

Data signed: (hfarmer1) 30 Mar 2015 12:27:55

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05112480001159
----------------	----------------

Analyte	THCOT-GLUC
---------	------------

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

Result	683
--------	-----

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

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

Sample comment	
----------------	--

Detection method	LC-MS/MS
------------------	----------

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

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

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

Date of Collection	2014-APR-15
--------------------	-------------

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 1

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

Data signed: (hfarmer1) 30 Mar 2015 12:27:55

Generated On: 20 Jul 2016 22:42:34

Urine Start Day	1
-----------------	---

Urine End Day	2
---------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 1

Form: Biomarker-Urine (3-OH BaP)

Data signed: (hfarmer1) 30 Mar 2015 12:27:57

Generated On: 20 Jul 2016 22:42:34

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 1

Form: Biomarker-Urine (3-OH BaP) (1)

Data signed: (hfarmer1) 30 Mar 2015 12:27:57

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05112490001753
----------------	----------------

Analyte	3-OH BAP
---------	----------

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

Result	190
--------	-----

Result Unit	FG/ML
-------------	-------

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

Sample comment	
----------------	--

Detection method	LC-MS/MS
------------------	----------

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

Day of Visit	1
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Celerion Study Number	AA99128-07
-----------------------	------------

Date of Collection	2014-APR-14
--------------------	-------------

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

Urine Start Day	1
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 1

Form: Biomarker-Urine (3-OH BaP) (1)

Data signed: (hfarmer1) 30 Mar 2015 12:27:57

Generated On: 20 Jul 2016 22:42:34

Urine End Day

2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 1

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

Data signed: (hfarmer1) 30 Mar 2015 12:27:57

Generated On: 20 Jul 2016 22:42:34

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 1

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

Data signed: (hfarmer1) 30 Mar 2015 12:27:57

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05112510001775
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Analyte	1-NA
---------	------

Sample type	URINE
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Result	44.4
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Result Unit	PG/ML
-------------	-------

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

Sample comment	
----------------	--

Detection method	LC-MS/MS
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Planned time point (Hour)	0
---------------------------	---

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

Celerion Study Number	AA99128-09
-----------------------	------------

Date of Collection	2014-APR-14
--------------------	-------------

Timepoint-minutes	
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Urine Start Day	1
-----------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 1

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

Data signed: (hfarmer1) 30 Mar 2015 12:27:57

Generated On: 20 Jul 2016 22:42:34

Urine End Day

2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 1

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

Data signed: (hfarmer1) 30 Mar 2015 12:27:57

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05112510001775
Analyte	2-NA
Sample type	URINE
Result	17.8
Result Unit	PG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	1
Celerion Study Number	AA99128-09
Date of Collection	2014-APR-14
Timepoint-minutes	
Urine Start Day	1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 1

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

Data signed: (hfarmer1) 30 Mar 2015 12:27:57

Generated On: 20 Jul 2016 22:42:34

Urine End Day

2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 1

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (3)

Data signed: (hfarmer1) 30 Mar 2015 12:27:57

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05112510001775
----------------	----------------

Analyte	4-ABP
---------	-------

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

Result	12.8
--------	------

Result Unit	PG/ML
-------------	-------

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

Sample comment	
----------------	--

Detection method	LC-MS/MS
------------------	----------

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

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

Celerion Study Number	AA99128-09
-----------------------	------------

Date of Collection	2014-APR-14
--------------------	-------------

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

Urine Start Day	1
-----------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 1

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (3)

Data signed: (hfarmer1) 30 Mar 2015 12:27:57

Generated On: 20 Jul 2016 22:42:34

Urine End Day

2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 1

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

Data signed: (hfarmer1) 30 Mar 2015 12:27:57

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05112510001775
Analyte	O-TOL
Sample type	URINE
Result	109
Result Unit	PG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	1
Celerion Study Number	AA99128-09
Date of Collection	2014-APR-14
Timepoint-minutes	
Urine Start Day	1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 1

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

Data signed: (hfarmer1) 30 Mar 2015 12:27:57

Generated On: 20 Jul 2016 22:42:34

Urine End Day

2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 1

Form: Biomarker-Urine (1-OHP)

Data signed: (hfarmer1) 30 Mar 2015 12:27:58

Generated On: 20 Jul 2016 22:42:34

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 1

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

Data signed: (hfarmer1) 30 Mar 2015 12:27:58

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05115190003777
----------------	----------------

Analyte	1-OHP
---------	-------

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

Result	189
--------	-----

Result Unit	PG/ML
-------------	-------

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

Sample comment	
----------------	--

Detection method	LC-MS/MS
------------------	----------

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

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

Celerion Study Number	AA99598-03
-----------------------	------------

Date of Collection	2014-APR-14
--------------------	-------------

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

Urine Start Day	1
-----------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 1

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

Data signed: (hfarmer1) 30 Mar 2015 12:27:58

Generated On: 20 Jul 2016 22:42:34

Urine End Day

2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 1

Form: Biomarker-Urine (SPMA, SBMA)

Data signed: (hfarmer1) 30 Mar 2015 12:27:54

Generated On: 20 Jul 2016 22:42:34

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 1

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

Data signed: (hfarmer1) 30 Mar 2015 12:27:54

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05115170003768
----------------	----------------

Analyte	SBMA
---------	------

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

Result	2.75
--------	------

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

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

Sample comment	
----------------	--

Detection method	LC-MS/MS
------------------	----------

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

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

Celerion Study Number	AA99598-01
-----------------------	------------

Date of Collection	2014-APR-14
--------------------	-------------

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

Urine Start Day	1
-----------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 1

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

Data signed: (hfarmer1) 30 Mar 2015 12:27:54

Generated On: 20 Jul 2016 22:42:34

Urine End Day

2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 1

Form: Biomarker-Urine (SPMA, SBMA) (2)

Data signed: (hfarmer1) 30 Mar 2015 12:27:54

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05115170003768
----------------	----------------

Analyte	SPMA
---------	------

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

Result	2.54
--------	------

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

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

Sample comment	
----------------	--

Detection method	LC-MS/MS
------------------	----------

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

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

Celerion Study Number	AA99598-01
-----------------------	------------

Date of Collection	2014-APR-14
--------------------	-------------

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

Urine Start Day	1
-----------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 1

Form: Biomarker-Urine (SPMA, SBMA) (2)

Data signed: (hfarmer1) 30 Mar 2015 12:27:54

Generated On: 20 Jul 2016 22:42:34

Urine End Day

2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 1

Form: Biomarker-Urine (MHBMA)

Data signed: (hfarmer1) 30 Mar 2015 12:27:54

Generated On: 20 Jul 2016 22:42:34

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 1

Form: Biomarker-Urine (MHBMA) (1)

Data signed: (hfarmer1) 30 Mar 2015 12:27:54

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05115180003777
----------------	----------------

Analyte	MHBMA
---------	-------

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

Result	1.66
--------	------

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

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

Sample comment	
----------------	--

Detection method	LC-MS/MS
------------------	----------

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

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

Celerion Study Number	AA99598-02
-----------------------	------------

Date of Collection	2014-APR-14
--------------------	-------------

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

Urine Start Day	1
-----------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 1

Form: Biomarker-Urine (MHBMA) (1)

Data signed: (hfarmer1) 30 Mar 2015 12:27:54

Generated On: 20 Jul 2016 22:42:34

Urine End Day

2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 1

Form: Biomarker-Urine (Creatinine)

Data signed: (hfarmer1) 30 Mar 2015 12:27:58

Generated On: 20 Jul 2016 22:42:34

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 1

Form: Biomarker-Urine (Creatinine) (1)

Data signed: (hfarmer1) 30 Mar 2015 12:27:58

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05115160001753
----------------	----------------

Analyte	CREATININE
---------	------------

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

Result	77.2
--------	------

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

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

Sample comment	
----------------	--

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

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

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

Celerion Study Number	AA99128-14
-----------------------	------------

Date of Collection	2014-APR-14
--------------------	-------------

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

Urine Start Day	1
-----------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 1

Form: Biomarker-Urine (Creatinine) (1)

Data signed: (hfarmer1) 30 Mar 2015 12:27:58

Generated On: 20 Jul 2016 22:42:34

Urine End Day

2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 1

Form: Biomarker-Plasma (Nic, Cot, tHCot)

Data signed: (hfarmer1) 30 Mar 2015 12:27:54

Generated On: 20 Jul 2016 22:42:34

Sample type

PLASMA

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 1

Form: Biomarker-Plasma (Nic, Cot, tHCot) (1)

Data signed: (hfarmer1) 30 Mar 2015 12:27:54

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05112430001997
----------------	----------------

Analyte	COT
---------	-----

Sample type	PLASMA
-------------	--------

Result	208
--------	-----

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

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

Sample comment	
----------------	--

Detection method	LC-MS/MS
------------------	----------

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

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

Celerion Study Number	AA99128-01
-----------------------	------------

Date of Collection	2014-APR-14
--------------------	-------------

Timepoint-minutes	0
-------------------	---

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 1

Form: Biomarker-Plasma (Nic, Cot, tHCot) (1)

Data signed: (hfarmer1) 30 Mar 2015 12:27:54

Generated On: 20 Jul 2016 22:42:34

Urine End Day

1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 1

Form: Biomarker-Plasma (Nic, Cot, tHCot) (2)

Data signed: (hfarmer1) 30 Mar 2015 12:27:54

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05112430001997
----------------	----------------

Analyte	NIC
---------	-----

Sample type	PLASMA
-------------	--------

Result	18.7
--------	------

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

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

Sample comment	
----------------	--

Detection method	LC-MS/MS
------------------	----------

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

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

Celerion Study Number	AA99128-01
-----------------------	------------

Date of Collection	2014-APR-14
--------------------	-------------

Timepoint-minutes	0
-------------------	---

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 1

Form: Biomarker-Plasma (Nic, Cot, tHCot) (2)

Data signed: (hfarmer1) 30 Mar 2015 12:27:54

Generated On: 20 Jul 2016 22:42:34

Urine End Day

1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 2

Form: Date of Visit

Data signed: (hfarmer1) 30 Mar 2015 12:27:58

Generated On: 20 Jul 2016 22:42:34

Date of Visit

15 APR 2014
DD/MMM/YYYY

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 2

Form: Vital Signs

Data signed: (hfarmer1) 30 Mar 2015 12:27:58

Generated On: 20 Jul 2016 22:42:34

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 09:47
hour:min 24-hour clock

Pulse rate 64
beats per minute

Respiratory rate 16
breaths per minute

Blood Pressure (systolic) 112
mmHg

Blood Pressure (diastolic) 74
mmHg

Vital Signs Position of Subject Supine ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 2

Form: Plasma Nicotine Sample

Data signed: (hfarmer1) 30 Mar 2015 12:27:58

Generated On: 20 Jul 2016 22:42:34

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

If Not Done, please specify the reason: _____

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

Time hour:min 24-hour clock	20:09
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 2

Form: Plasma Cotinine Sample

Data signed: (hfarmer1) 30 Mar 2015 12:27:58

Generated On: 20 Jul 2016 22:42:34

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

If Not Done, please specify the reason: _____

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

Time hour:min 24-hour clock	20:09
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 2

Form: CoHb Blood Sample

Data signed: (hfarmer1) 30 Mar 2015 12:27:58

Generated On: 20 Jul 2016 22:42:34

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

If Not Done, please specify the reason: _____

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

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

Time hour:min 24-hour clock	20:09
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 2

Form: CO Breath Test (1)

Data signed: (hfarmer1) 30 Mar 2015 12:27:58

Generated On: 20 Jul 2016 22:42:34

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

If Not Done, please specify the reason: _____

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

Actual Time of Assessment hour:min 24-hour clock	06:31
---	-------

Result(ppm)	12
-------------	----

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 2

Form: CO Breath Test (2)

Data signed: (hfarmer1) 30 Mar 2015 12:27:58

Generated On: 20 Jul 2016 22:42:34

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	12:19
---	-------

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 2

Form: CO Breath Test (3)

Data signed: (hfarmer1) 30 Mar 2015 12:27:58

Generated On: 20 Jul 2016 22:42:34

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	16:49
---	-------

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 2

Form: CO Breath Test (4)

Data signed: (hfarmer1) 30 Mar 2015 12:27:58

Generated On: 20 Jul 2016 22:42:34

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	20:12
---	-------

Result(ppm)	23
-------------	----

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 2

Form: 24 hour urine collections

Data signed: (hfarmer1) 30 Mar 2015 12:27:58

Generated On: 20 Jul 2016 22:42:34

Start Time	06:04
	hour:min 24-hour clock

End Date	16 APR 2014
	DD/MMM/YYYY

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

Volume	1527
	mL

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 2

Form: Sample Urine Collection

Data signed: (hfarmer1) 30 Mar 2015 12:27:58

Generated On: 20 Jul 2016 22:42:34

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: 1261**

Folder: Day 2

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Data signed: (hfarmer1) 30 Mar 2015 12:27:59

Generated On: 20 Jul 2016 22:42:34

Date of Birth

(b) (6)

Date of assessment
DD/MMM/YYYY

2014 APR 15
DD/MMM/YYYY

Time of assessment

06:03
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: 1261**

Folder: Day 2

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Data signed: (hfarmer1) 30 Mar 2015 12:27:59

Generated On: 20 Jul 2016 22:42:34

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

5. Difficulty concentrating

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

6. Increased appetite, hungry, weight gain

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

7. Insomnia, sleep problems, awakening at night

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

8. Restless

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

9. Impatient

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

10. Constipation

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

11. Dizziness

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

12. Coughing

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 2

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Data signed: (hfarmer1) 30 Mar 2015 12:27:59

Generated On: 20 Jul 2016 22:42:34

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: 1261

Folder: Day 2

Form: Cough Assessment

Data signed: (hfarmer1) 30 Mar 2015 12:27:59

Generated On: 20 Jul 2016 22:42:34

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

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

Time of assessment	06:01 hour:min 24-hour clock
--------------------	---------------------------------

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

Have you experienced a regular need to cough e.g. coughing several times in the last 24 hrs?	No <input checked="" type="radio"/>
--	-------------------------------------

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

Third Question: Cough Frequency Scale: How frequently do you normally have to cough each day?	Not Applicable <input checked="" type="radio"/>
--	---

Fourth Question: Sputum Production To what extent do you produce sputum when coughing?	Not Applicable <input checked="" type="radio"/>
---	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 2

Form: Lab_BU_COHB (1)

Data signed: (hfarmer1) 30 Mar 2015 12:27:59

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05115150004277
----------------	----------------

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

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

Result	7.30
--------	------

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-APR-15
--------------------	-------------

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 2

Form: Lab_BU_COHB (1)

Data signed: (hfarmer1) 30 Mar 2015 12:27:59

Generated On: 20 Jul 2016 22:42:34

Start Day (24 hour urine only)

End Day (24 hour Urine Only)

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 2

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)

Data signed: (hfarmer1) 30 Mar 2015 12:27:59

Generated On: 20 Jul 2016 22:42:34

Date of Birth	(b) (6)
Date of assessment DD/MMM/YYYY	2014 APR 15 DD/MMM/YYYY
Time of assessment	20:02 hour:min 24-hour clock
Assessment Status	Completed
1. Was smoking satisfying?	A lot
2. Did cigarettes taste good?	Extremely
3. Did you enjoy the sensation in your throat and chest?	A lot
4. Did smoking calm you down?	Little
5. Did smoking make you feel more awake?	Not at all
6. Did smoking make you feel less irritable?	Little
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: 1261**

Folder: Day 2

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)

Data signed: (hfarmer1) 30 Mar 2015 12:27:59

Generated On: 20 Jul 2016 22:42:34

9. Did smoking make you dizzy? Not at all ☐

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

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

12. Did you enjoy smoking? Extremely ☐

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 2

Form: Questionnaire on smoking urges (QSU)

Data signed: (hfarmer1) 30 Mar 2015 12:27:59

Generated On: 20 Jul 2016 22:42:34

Type	QSU
------	-----

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

Date of assessment	2014 APR 15
--------------------	-------------

DD/MMM/YYYY

Time of assessment	20:01
--------------------	-------

hour:min 24-hour clock

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

1. I have a desire for a cigarette right now	Strongly agree <input checked="" type="radio"/>
--	---

2. Nothing would be better than smoking a cigarette right now	Strongly agree <input checked="" type="radio"/>
---	---

3. If it were possible I would probably smoke now	Strongly agree <input checked="" type="radio"/>
---	---

4. I could control things better right now if I could smoke	Strongly disagree <input checked="" type="radio"/>
---	--

5. All I want right now is a cigarette	Strongly agree <input checked="" type="radio"/>
--	---

6. I have an urge for a cigarette	Strongly agree <input checked="" type="radio"/>
-----------------------------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 2

Form: Questionnaire on smoking urges (QSU)

Data signed: (hfarmer1) 30 Mar 2015 12:27:59

Generated On: 20 Jul 2016 22:42:34

7. A cigarette would taste good now Strongly agree ☐

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

9. Smoking would make me less depressed Strongly disagree ☐

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 2

Form: Biomarker-Urine (CEMA, HPMa, HBMA)

Data signed: (hfarmer1) 30 Mar 2015 12:28:01

Generated On: 20 Jul 2016 22:42:34

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 2

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (1)

Data signed: (hfarmer1) 30 Mar 2015 12:28:01

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05112450002927
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Analyte	HPMA
---------	------

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

Result	580
--------	-----

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

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

Sample comment	
----------------	--

Detection method	LC-MS/MS
------------------	----------

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

Day of Visit	2
--------------	---

Celerion Study Number	AA99128-03
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Date of Collection	2014-APR-15
--------------------	-------------

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

Urine Start Day	2
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 2

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (1)

Data signed: (hfarmer1) 30 Mar 2015 12:28:01

Generated On: 20 Jul 2016 22:42:34

Urine End Day

3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 2

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (2)

Data signed: (hfarmer1) 30 Mar 2015 12:28:01

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05112450002927
----------------	----------------

Analyte	CEMA
---------	------

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

Result	104
--------	-----

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

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

Sample comment	
----------------	--

Detection method	LC-MS/MS
------------------	----------

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

Day of Visit	2
--------------	---

Celerion Study Number	AA99128-03
-----------------------	------------

Date of Collection	2014-APR-15
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Timepoint-minutes	
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Urine Start Day	2
-----------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 2

Form: Biomarker-Urine (CEMA, HPMa, HBMA) (2)

Data signed: (hfarmer1) 30 Mar 2015 12:28:01

Generated On: 20 Jul 2016 22:42:34

Urine End Day

3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 2

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (3)

Data signed: (hfarmer1) 30 Mar 2015 12:28:01

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05112450002927
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Analyte	HBMA
---------	------

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

Result	251
--------	-----

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

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

Sample comment	
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Detection method	LC-MS/MS
------------------	----------

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

Day of Visit	2
--------------	---

Celerion Study Number	AA99128-03
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Date of Collection	2014-APR-15
--------------------	-------------

Timepoint-minutes	
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Urine Start Day	2
-----------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 2

Form: Biomarker-Urine (CEMA, HPMa, HBMA) (3)

Data signed: (hfarmer1) 30 Mar 2015 12:28:01

Generated On: 20 Jul 2016 22:42:34

Urine End Day

3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 2

Form: Biomarker-Urine (NNN, NNAL)

Data signed: (hfarmer1) 30 Mar 2015 12:28:00

Generated On: 20 Jul 2016 22:42:34

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 2

Form: Biomarker-Urine (NNN, NNAL) (1)

Data signed: (hfarmer1) 30 Mar 2015 12:28:00

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05112460003514
Analyte	NNAL
Sample type	URINE
Result	395
Result Unit	PG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	2
Celerion Study Number	AA99128-04
Date of Collection	2014-APR-15
Timepoint-minutes	
Urine Start Day	2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 2

Form: Biomarker-Urine (NNN, NNAL) (1)

Data signed: (hfarmer1) 30 Mar 2015 12:28:00

Generated On: 20 Jul 2016 22:42:34

Urine End Day

3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 2

Form: Biomarker-Urine (NNN, NNAL) (2)

Data signed: (hfarmer1) 30 Mar 2015 12:28:00

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05112460003514
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Analyte	NNN
---------	-----

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

Result	16.0
--------	------

Result Unit	PG/ML
-------------	-------

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

Sample comment	
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Detection method	LC-MS/MS
------------------	----------

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

Day of Visit	2
--------------	---

Celerion Study Number	AA99128-04
-----------------------	------------

Date of Collection	2014-APR-15
--------------------	-------------

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

Urine Start Day	2
-----------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 2

Form: Biomarker-Urine (NNN, NNAL) (2)

Data signed: (hfarmer1) 30 Mar 2015 12:28:00

Generated On: 20 Jul 2016 22:42:34

Urine End Day

3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 2

Form: Biomarker-Urine (HEMA)

Data signed: (hfarmer1) 30 Mar 2015 12:28:01

Generated On: 20 Jul 2016 22:42:34

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 2

Form: Biomarker-Urine (HEMA) (1)

Data signed: (hfarmer1) 30 Mar 2015 12:28:01

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05112470001754
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Analyte	HEMA
---------	------

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

Result	8.09
--------	------

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

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

Sample comment	
----------------	--

Detection method	LC-MS/MS
------------------	----------

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

Day of Visit	2
--------------	---

Celerion Study Number	AA99128-05
-----------------------	------------

Date of Collection	2014-APR-15
--------------------	-------------

Timepoint-minutes	
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Urine Start Day	2
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 2

Form: Biomarker-Urine (HEMA) (1)

Data signed: (hfarmer1) 30 Mar 2015 12:28:01

Generated On: 20 Jul 2016 22:42:34

Urine End Day

3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 2

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

Data signed: (hfarmer1) 30 Mar 2015 12:28:02

Generated On: 20 Jul 2016 22:42:34

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 2

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

Data signed: (hfarmer1) 30 Mar 2015 12:28:02

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05112480001160
Analyte	COT
Sample type	URINE
Result	1410
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	2
Celerion Study Number	AA99128-06
Date of Collection	2014-APR-16
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 2

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

Data signed: (hfarmer1) 30 Mar 2015 12:28:02

Generated On: 20 Jul 2016 22:42:34

Urine Start Day	2
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Urine End Day	3
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 2

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

Data signed: (hfarmer1) 30 Mar 2015 12:28:02

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05112480001160
Analyte	COT-GLUC
Sample type	URINE
Result	5180
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	2
Celerion Study Number	AA99128-06
Date of Collection	2014-APR-16
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 2

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

Data signed: (hfarmer1) 30 Mar 2015 12:28:02

Generated On: 20 Jul 2016 22:42:34

Urine Start Day	2
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Urine End Day	3
---------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 2

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

Data signed: (hfarmer1) 30 Mar 2015 12:28:02

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05112480001160
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Analyte	NIC
---------	-----

Sample type	URINE
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Result	381
--------	-----

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

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

Sample comment	
----------------	--

Detection method	LC-MS/MS
------------------	----------

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

Day of Visit	2
--------------	---

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

Date of Collection	2014-APR-16
--------------------	-------------

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 2

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

Data signed: (hfarmer1) 30 Mar 2015 12:28:02

Generated On: 20 Jul 2016 22:42:34

Urine Start Day	2
-----------------	---

Urine End Day	3
---------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 2

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

Data signed: (hfarmer1) 30 Mar 2015 12:28:02

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05112480001160
Analyte	NIC-GLUC
Sample type	URINE
Result	1110
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	2
Celerion Study Number	AA99128-06
Date of Collection	2014-APR-16
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 2

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

Data signed: (hfarmer1) 30 Mar 2015 12:28:02

Generated On: 20 Jul 2016 22:42:34

Urine Start Day	2
-----------------	---

Urine End Day	3
---------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 2

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

Data signed: (hfarmer1) 30 Mar 2015 12:28:02

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05112480001160
Analyte	THCOT
Sample type	URINE
Result	2590
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	2
Celerion Study Number	AA99128-06
Date of Collection	2014-APR-16
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 2

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

Data signed: (hfarmer1) 30 Mar 2015 12:28:02

Generated On: 20 Jul 2016 22:42:34

Urine Start Day	2
-----------------	---

Urine End Day	3
---------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 2

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

Data signed: (hfarmer1) 30 Mar 2015 12:28:02

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05112480001160
Analyte	THCOT-GLUC
Sample type	URINE
Result	889
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	2
Celerion Study Number	AA99128-06
Date of Collection	2014-APR-16
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 2

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

Data signed: (hfarmer1) 30 Mar 2015 12:28:02

Generated On: 20 Jul 2016 22:42:34

Urine Start Day	2
-----------------	---

Urine End Day	3
---------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 2

Form: Biomarker-Urine (3-OH BaP)

Data signed: (hfarmer1) 30 Mar 2015 12:28:02

Generated On: 20 Jul 2016 22:42:34

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 2

Form: Biomarker-Urine (3-OH BaP) (1)

Data signed: (hfarmer1) 30 Mar 2015 12:28:02

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05112490001754
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Analyte	3-OH BAP
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Sample type	URINE
-------------	-------

Result	131
--------	-----

Result Unit	FG/ML
-------------	-------

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

Sample comment	
----------------	--

Detection method	LC-MS/MS
------------------	----------

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

Day of Visit	2
--------------	---

Celerion Study Number	AA99128-07
-----------------------	------------

Date of Collection	2014-APR-15
--------------------	-------------

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

Urine Start Day	2
-----------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 2

Form: Biomarker-Urine (3-OH BaP) (1)

Data signed: (hfarmer1) 30 Mar 2015 12:28:02

Generated On: 20 Jul 2016 22:42:34

Urine End Day

3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 2

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

Data signed: (hfarmer1) 30 Mar 2015 12:28:02

Generated On: 20 Jul 2016 22:42:34

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 2

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

Data signed: (hfarmer1) 30 Mar 2015 12:28:02

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05112510001776
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Analyte	1-NA
---------	------

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

Result	58.6
--------	------

Result Unit	PG/ML
-------------	-------

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

Sample comment	
----------------	--

Detection method	LC-MS/MS
------------------	----------

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

Day of Visit	2
--------------	---

Celerion Study Number	AA99128-09
-----------------------	------------

Date of Collection	2014-APR-15
--------------------	-------------

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

Urine Start Day	2
-----------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 2

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

Data signed: (hfarmer1) 30 Mar 2015 12:28:02

Generated On: 20 Jul 2016 22:42:34

Urine End Day

3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 2

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

Data signed: (hfarmer1) 30 Mar 2015 12:28:02

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05112510001776
----------------	----------------

Analyte	2-NA
---------	------

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

Result	20.9
--------	------

Result Unit	PG/ML
-------------	-------

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

Sample comment	
----------------	--

Detection method	LC-MS/MS
------------------	----------

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

Day of Visit	2
--------------	---

Celerion Study Number	AA99128-09
-----------------------	------------

Date of Collection	2014-APR-15
--------------------	-------------

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

Urine Start Day	2
-----------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 2

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

Data signed: (hfarmer1) 30 Mar 2015 12:28:02

Generated On: 20 Jul 2016 22:42:34

Urine End Day

3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 2

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (3)

Data signed: (hfarmer1) 30 Mar 2015 12:28:02

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05112510001776
Analyte	4-ABP
Sample type	URINE
Result	14.0
Result Unit	PG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	2
Celerion Study Number	AA99128-09
Date of Collection	2014-APR-15
Timepoint-minutes	
Urine Start Day	2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 2

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (3)

Data signed: (hfarmer1) 30 Mar 2015 12:28:02

Generated On: 20 Jul 2016 22:42:34

Urine End Day

3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 2

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

Data signed: (hfarmer1) 30 Mar 2015 12:28:02

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05112510001776
Analyte	O-TOL
Sample type	URINE
Result	108
Result Unit	PG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	2
Celerion Study Number	AA99128-09
Date of Collection	2014-APR-15
Timepoint-minutes	
Urine Start Day	2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 2

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

Data signed: (hfarmer1) 30 Mar 2015 12:28:02

Generated On: 20 Jul 2016 22:42:34

Urine End Day

3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 2

Form: Biomarker-Urine (1-OHP)

Data signed: (hfarmer1) 30 Mar 2015 12:28:02

Generated On: 20 Jul 2016 22:42:34

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 2

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

Data signed: (hfarmer1) 30 Mar 2015 12:28:02

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05115190003778
----------------	----------------

Analyte	1-OHP
---------	-------

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

Result	241
--------	-----

Result Unit	PG/ML
-------------	-------

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

Sample comment	
----------------	--

Detection method	LC-MS/MS
------------------	----------

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

Day of Visit	2
--------------	---

Celerion Study Number	AA99598-03
-----------------------	------------

Date of Collection	2014-APR-15
--------------------	-------------

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

Urine Start Day	2
-----------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 2

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

Data signed: (hfarmer1) 30 Mar 2015 12:28:02

Generated On: 20 Jul 2016 22:42:34

Urine End Day

3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 2

Form: Biomarker-Urine (SPMA, SBMA)

Data signed: (hfarmer1) 30 Mar 2015 12:28:01

Generated On: 20 Jul 2016 22:42:34

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 2

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

Data signed: (hfarmer1) 30 Mar 2015 12:28:01

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05115170003769
Analyte	SBMA
Sample type	URINE
Result	2.11
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	2
Celerion Study Number	AA99598-01
Date of Collection	2014-APR-15
Timepoint-minutes	
Urine Start Day	2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 2

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

Data signed: (hfarmer1) 30 Mar 2015 12:28:01

Generated On: 20 Jul 2016 22:42:34

Urine End Day

3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 2

Form: Biomarker-Urine (SPMA, SBMA) (2)

Data signed: (hfarmer1) 30 Mar 2015 12:28:01

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05115170003769
----------------	----------------

Analyte	SPMA
---------	------

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

Result	3.10
--------	------

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

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

Sample comment	
----------------	--

Detection method	LC-MS/MS
------------------	----------

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

Day of Visit	2
--------------	---

Celerion Study Number	AA99598-01
-----------------------	------------

Date of Collection	2014-APR-15
--------------------	-------------

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

Urine Start Day	2
-----------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 2

Form: Biomarker-Urine (SPMA, SBMA) (2)

Data signed: (hfarmer1) 30 Mar 2015 12:28:01

Generated On: 20 Jul 2016 22:42:34

Urine End Day

3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 2

Form: Biomarker-Urine (MHBMA)

Data signed: (hfarmer1) 30 Mar 2015 12:28:01

Generated On: 20 Jul 2016 22:42:34

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 2

Form: Biomarker-Urine (MHBMA) (1)

Data signed: (hfarmer1) 30 Mar 2015 12:28:01

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05115180003778
----------------	----------------

Analyte	MHBMA
---------	-------

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

Result	1.80
--------	------

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

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

Sample comment	
----------------	--

Detection method	LC-MS/MS
------------------	----------

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

Day of Visit	2
--------------	---

Celerion Study Number	AA99598-02
-----------------------	------------

Date of Collection	2014-APR-15
--------------------	-------------

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

Urine Start Day	2
-----------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 2

Form: Biomarker-Urine (MHBMA) (1)

Data signed: (hfarmer1) 30 Mar 2015 12:28:01

Generated On: 20 Jul 2016 22:42:34

Urine End Day

3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 2

Form: Biomarker-Urine (Creatinine)

Data signed: (hfarmer1) 30 Mar 2015 12:28:02

Generated On: 20 Jul 2016 22:42:34

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 2

Form: Biomarker-Urine (Creatinine) (1)

Data signed: (hfarmer1) 30 Mar 2015 12:28:02

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05115160001754
----------------	----------------

Analyte	CREATININE
---------	------------

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

Result	89.9
--------	------

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

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

Sample comment	
----------------	--

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

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

Day of Visit	2
--------------	---

Celerion Study Number	AA99128-14
-----------------------	------------

Date of Collection	2014-APR-15
--------------------	-------------

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

Urine Start Day	2
-----------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 2

Form: Biomarker-Urine (Creatinine) (1)

Data signed: (hfarmer1) 30 Mar 2015 12:28:02

Generated On: 20 Jul 2016 22:42:34

Urine End Day

3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 2

Form: Biomarker-Plasma (Nic, Cot, tHCot)

Data signed: (hfarmer1) 30 Mar 2015 12:28:01

Generated On: 20 Jul 2016 22:42:34

Sample type

PLASMA

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 2

Form: Biomarker-Plasma (Nic, Cot, tHCot) (1)

Data signed: (hfarmer1) 30 Mar 2015 12:28:01

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05112430001998
----------------	----------------

Analyte	COT
---------	-----

Sample type	PLASMA
-------------	--------

Result	234
--------	-----

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

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

Sample comment	
----------------	--

Detection method	LC-MS/MS
------------------	----------

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

Day of Visit	2
--------------	---

Celerion Study Number	AA99128-01
-----------------------	------------

Date of Collection	2014-APR-15
--------------------	-------------

Timepoint-minutes	0
-------------------	---

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 2

Form: Biomarker-Plasma (Nic, Cot, tHCot) (1)

Data signed: (hfarmer1) 30 Mar 2015 12:28:01

Generated On: 20 Jul 2016 22:42:34

Urine End Day

2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 2

Form: Biomarker-Plasma (Nic, Cot, tHCot) (2)

Data signed: (hfarmer1) 30 Mar 2015 12:28:01

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05112430001998
----------------	----------------

Analyte	NIC
---------	-----

Sample type	PLASMA
-------------	--------

Result	24.5
--------	------

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

Lab Status	OK
------------	----

Sample comment	
----------------	--

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	2
--------------	---

Celerion Study Number	AA99128-01
-----------------------	------------

Date of Collection	2014-APR-15
--------------------	-------------

Timepoint-minutes	0
-------------------	---

Urine Start Day	
-----------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 2

Form: Biomarker-Plasma (Nic, Cot, tHCot) (2)

Data signed: (hfarmer1) 30 Mar 2015 12:28:01

Generated On: 20 Jul 2016 22:42:34

Urine End Day

2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 3

Form: Date of Visit

Data signed: (hfarmer1) 30 Mar 2015 12:28:03

Generated On: 20 Jul 2016 22:42:34

Date of Visit

16 APR 2014
DD/MMM/YYYY

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 3

Form: Vital Signs

Data signed: (hfarmer1) 30 Mar 2015 12:28:03

Generated On: 20 Jul 2016 22:42:34

Were Vitals Signs assessed?

Yes ☒

If No, please specify the reason: _____

Has the subject smoked within 15 minutes prior to
assessment

No ☒

Time of assessment

10:15
hour:min 24-hour clock

Pulse rate

77
beats per minute

Respiratory rate

16
breaths per minute

Blood Pressure (systolic)

118
mmHg

Blood Pressure (diastolic)

79
mmHg

Vital Signs Position of Subject

Supine ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 3

Form: Plasma Nicotine Sample

Data signed: (hfarmer1) 30 Mar 2015 12:28:02

Generated On: 20 Jul 2016 22:42:34

Not Done	False
----------	-------

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	16 APR 2014
---------------------	-------------

Time hour:min 24-hour clock	20:15
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 3

Form: Plasma Cotinine Sample

Data signed: (hfarmer1) 30 Mar 2015 12:28:02

Generated On: 20 Jul 2016 22:42:34

Not Done	False
----------	-------

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	16 APR 2014
---------------------	-------------

Time hour:min 24-hour clock	20:15
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 3

Form: CoHb Blood Sample

Data signed: (hfarmer1) 30 Mar 2015 12:28:02

Generated On: 20 Jul 2016 22:42:34

Not Done	False
----------	-------

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	16 APR 2014
---------------------	-------------

Timepoint	20:00 - 21:30 <input checked="" type="radio"/>
-----------	--

Time hour:min 24-hour clock	20:15
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 3

Form: CO Breath Test (1)

Data signed: (hfarmer1) 30 Mar 2015 12:28:03

Generated On: 20 Jul 2016 22:42:34

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	06:27
---	-------

Result(ppm)	10
-------------	----

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 3

Form: CO Breath Test (2)

Data signed: (hfarmer1) 30 Mar 2015 12:28:03

Generated On: 20 Jul 2016 22:42:34

Assessment not done	False
---------------------	-------

If Not Done, please specify the reason: _____

Scheduled Time	12:00 - 13:30 
----------------	---

Actual Time of Assessment hour:min 24-hour clock	12:06
---	-------

Result(ppm)	25
-------------	----

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 3

Form: CO Breath Test (3)

Data signed: (hfarmer1) 30 Mar 2015 12:28:03

Generated On: 20 Jul 2016 22:42:34

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	16:09
---	-------

Result(ppm)	20
-------------	----

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 3

Form: CO Breath Test (4)

Data signed: (hfarmer1) 30 Mar 2015 12:28:03

Generated On: 20 Jul 2016 22:42:34

Assessment not done	False
---------------------	-------

If Not Done, please specify the reason: _____

Scheduled Time	20:00 - 21:30 <input checked="" type="radio"/>
----------------	--

Actual Time of Assessment hour:min 24-hour clock	20:12
---	-------

Result(ppm)	22
-------------	----

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 3

Form: 24 hour urine collections

Data signed: (hfarmer1) 30 Mar 2015 12:28:03

Generated On: 20 Jul 2016 22:42:34

Start Time	06:06
	hour:min 24-hour clock

End Date	17 APR 2014
	DD/MMM/YYYY

End Time	06:10
	hour:min 24-hour clock

Volume	1677
	mL

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 3

Form: Sample Urine Collection

Data signed: (hfarmer1) 30 Mar 2015 12:28:02

Generated On: 20 Jul 2016 22:42:34

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: 1261**

Folder: Day 3

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Data signed: (hfarmer1) 30 Mar 2015 12:28:03

Generated On: 20 Jul 2016 22:42:34

Date of Birth

(b) (6)

Date of assessment
DD/MMM/YYYY

2014 APR 16
DD/MMM/YYYY

Time of assessment

06:02
hour:min 24-hour clock

Assessment Status

Completed ☒

Please indicate for each of the items below, how you have been feeling over the past 24 hours

How have you been feeling over the past 24 hours?

Slight ☒

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: 1261**

Folder: Day 3

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Data signed: (hfarmer1) 30 Mar 2015 12:28:03

Generated On: 20 Jul 2016 22:42:34

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? Mild ☐

9. Impatient

How have you been feeling over the past 24 hours? None ☐

10. Constipation

How have you been feeling over the past 24 hours? None ☐

11. Dizziness

How have you been feeling over the past 24 hours? None ☐

12. Coughing

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 3

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Data signed: (hfarmer1) 30 Mar 2015 12:28:03

Generated On: 20 Jul 2016 22:42:34

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: 1261**

Folder: Day 3

Form: Cough Assessment

Data signed: (hfarmer1) 30 Mar 2015 12:28:03

Generated On: 20 Jul 2016 22:42:34

Date of Birth	(b) (6)
---------------	---------

Date of assessment DD/MMM/YYYY	2014 APR 16 DD/MMM/YYYY
-----------------------------------	----------------------------

Time of assessment	06:00 hour:min 24-hour clock
--------------------	---------------------------------

Assessment Status	Completed <input checked="" type="radio"/>
-------------------	--

Have you experienced a regular need to cough e.g. coughing several times in the last 24 hrs?	No <input checked="" type="radio"/>
---	-------------------------------------

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 <input checked="" type="radio"/>
---	---

Third Question: Cough Frequency Scale: How frequently do you normally have to cough each day?	Not Applicable <input checked="" type="radio"/>
---	---

Fourth Question: Sputum Production To what extent do you produce sputum when coughing?	Not Applicable <input checked="" type="radio"/>
---	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 3

Form: Lab_BU_COHB (1)

Data signed: (hfarmer1) 30 Mar 2015 12:28:03

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05115150004278
----------------	----------------

Analyte	CARBOXYHEMOGLOBIN
---------	-------------------

Sample type	BLOOD
-------------	-------

Result	6.90
--------	------

Result Unit	%
-------------	---

Lab Status	OK
------------	----

Sample comment	
----------------	--

Detection method	SPECTROPHOTOMETRIC
------------------	--------------------

Lower limit of quantification	0.500
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Planned time point (Hour)	20
---------------------------	----

Day of Visit	3
--------------	---

Celerion Study Number	AA99128-16
-----------------------	------------

Date of Collection	2014-APR-16
--------------------	-------------

Timepoint-minutes	
-------------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 3

Form: Lab_BU_COHB (1)

Data signed: (hfarmer1) 30 Mar 2015 12:28:03

Generated On: 20 Jul 2016 22:42:34

Start Day (24 hour urine only)

End Day (24 hour Urine Only)

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 3

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)

Data signed: (hfarmer1) 30 Mar 2015 12:28:03

Generated On: 20 Jul 2016 22:42:34

Date of Birth

(b) (6)

Date of assessment

2014 APR 16

DD/MMM/YYYY

DD/MMM/YYYY

Time of assessment

20:02

hour:min 24-hour clock

Assessment Status

Completed

1. Was smoking satisfying?

A lot

2. Did cigarettes taste good?

Extremely

3. Did you enjoy the sensation in your throat and chest?

A lot

4. Did smoking calm you down?

Not at all

5. Did smoking make you feel more awake?

Not at all

6. Did smoking make you feel less irritable?

Little

7. Did smoking help you concentrate?

Not at all

8. Did smoking reduce your hunger for food?

Little

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 3

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)

Data signed: (hfarmer1) 30 Mar 2015 12:28:03

Generated On: 20 Jul 2016 22:42:34

9. Did smoking make you dizzy? Not at all ☐

10. Did smoking make you nauseous? Not at all ☐

11. Did smoking immediately relieve your craving for a
cigarette? Extremely ☐

12. Did you enjoy smoking? Extremely ☐

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 3

Form: Questionnaire on smoking urges (QSU)

Data signed: (hfarmer1) 30 Mar 2015 12:28:03

Generated On: 20 Jul 2016 22:42:34

Type	QSU
------	-----

Date of Birth	(b) (6)
---------------	---------

Date of assessment	2014 APR 16
--------------------	-------------

DD/MMM/YYYY

Time of assessment	20:01
--------------------	-------

hour:min 24-hour clock

Assessment Status	Completed <input checked="" type="radio"/>
-------------------	--

1. I have a desire for a cigarette right now	Do not agree or disagree <input checked="" type="radio"/>
--	---

2. Nothing would be better than smoking a cigarette right now	Do not agree or disagree <input checked="" type="radio"/>
---	---

3. If it were possible I would probably smoke now	Do not agree or disagree <input checked="" type="radio"/>
---	---

4. I could control things better right now if I could smoke	Strongly disagree <input checked="" type="radio"/>
---	--

5. All I want right now is a cigarette	Do not agree or disagree <input checked="" type="radio"/>
--	---

6. I have an urge for a cigarette	Do not agree or disagree <input checked="" type="radio"/>
-----------------------------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 3

Form: Questionnaire on smoking urges (QSU)

Data signed: (hfarmer1) 30 Mar 2015 12:28:03

Generated On: 20 Jul 2016 22:42:34

7. A cigarette would taste good now Do not agree or disagree ☐

8. I would do almost anything for a cigarette now Do not agree or disagree ☐

9. Smoking would make me less depressed Strongly disagree ☐

10. I am going to smoke as soon as possible Do not agree or disagree ☐

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 3

Form: Biomarker-Urine (CEMA, HPMA, HBMA)

Data signed: (hfarmer1) 30 Mar 2015 12:28:04

Generated On: 20 Jul 2016 22:42:34

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 3

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (1)

Data signed: (hfarmer1) 30 Mar 2015 12:28:04

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05112450002928
----------------	----------------

Analyte	HPMA
---------	------

Sample type	URINE
-------------	-------

Result	765
--------	-----

Result Unit	NG/ML
-------------	-------

Lab Status	OK
------------	----

Sample comment	
----------------	--

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	3
--------------	---

Celerion Study Number	AA99128-03
-----------------------	------------

Date of Collection	2014-APR-16
--------------------	-------------

Timepoint-minutes	
-------------------	--

Urine Start Day	3
-----------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 3

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (1)

Data signed: (hfarmer1) 30 Mar 2015 12:28:04

Generated On: 20 Jul 2016 22:42:34

Urine End Day

4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 3

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (2)

Data signed: (hfarmer1) 30 Mar 2015 12:28:04

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05112450002928
----------------	----------------

Analyte	CEMA
---------	------

Sample type	URINE
-------------	-------

Result	125
--------	-----

Result Unit	NG/ML
-------------	-------

Lab Status	OK
------------	----

Sample comment	
----------------	--

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	3
--------------	---

Celerion Study Number	AA99128-03
-----------------------	------------

Date of Collection	2014-APR-16
--------------------	-------------

Timepoint-minutes	
-------------------	--

Urine Start Day	3
-----------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 3

Form: Biomarker-Urine (CEMA, HPMa, HBMA) (2)

Data signed: (hfarmer1) 30 Mar 2015 12:28:04

Generated On: 20 Jul 2016 22:42:34

Urine End Day

4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 3

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (3)

Data signed: (hfarmer1) 30 Mar 2015 12:28:04

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05112450002928
----------------	----------------

Analyte	HBMA
---------	------

Sample type	URINE
-------------	-------

Result	448
--------	-----

Result Unit	NG/ML
-------------	-------

Lab Status	OK
------------	----

Sample comment	
----------------	--

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	3
--------------	---

Celerion Study Number	AA99128-03
-----------------------	------------

Date of Collection	2014-APR-16
--------------------	-------------

Timepoint-minutes	
-------------------	--

Urine Start Day	3
-----------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 3

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (3)

Data signed: (hfarmer1) 30 Mar 2015 12:28:04

Generated On: 20 Jul 2016 22:42:34

Urine End Day

4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 3

Form: Biomarker-Urine (NNN, NNAL)

Data signed: (hfarmer1) 30 Mar 2015 12:28:03

Generated On: 20 Jul 2016 22:42:34

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 3

Form: Biomarker-Urine (NNN, NNAL) (1)

Data signed: (hfarmer1) 30 Mar 2015 12:28:03

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05112460003515
----------------	----------------

Analyte	NNAL
---------	------

Sample type	URINE
-------------	-------

Result	300
--------	-----

Result Unit	PG/ML
-------------	-------

Lab Status	OK
------------	----

Sample comment	
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Detection method	LC-MS/MS
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Planned time point (Hour)	0
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Day of Visit	3
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Celerion Study Number	AA99128-04
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Date of Collection	2014-APR-16
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Timepoint-minutes	
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Urine Start Day	3
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 3

Form: Biomarker-Urine (NNN, NNAL) (1)

Data signed: (hfarmer1) 30 Mar 2015 12:28:03

Generated On: 20 Jul 2016 22:42:34

Urine End Day

4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 3

Form: Biomarker-Urine (NNN, NNAL) (2)

Data signed: (hfarmer1) 30 Mar 2015 12:28:03

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05112460003515
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Analyte	NNN
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Sample type	URINE
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Result	11.5
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Result Unit	PG/ML
-------------	-------

Lab Status	OK
------------	----

Sample comment	
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Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
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Day of Visit	3
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Celerion Study Number	AA99128-04
-----------------------	------------

Date of Collection	2014-APR-16
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Timepoint-minutes	
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Urine Start Day	3
-----------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 3

Form: Biomarker-Urine (NNN, NNAL) (2)

Data signed: (hfarmer1) 30 Mar 2015 12:28:03

Generated On: 20 Jul 2016 22:42:34

Urine End Day

4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 3

Form: Biomarker-Urine (HEMA)

Data signed: (hfarmer1) 30 Mar 2015 12:28:03

Generated On: 20 Jul 2016 22:42:34

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 3

Form: Biomarker-Urine (HEMA) (1)

Data signed: (hfarmer1) 30 Mar 2015 12:28:03

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05112470001755
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Analyte	HEMA
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Sample type	URINE
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Result	16.5
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Result Unit	NG/ML
-------------	-------

Lab Status	OK
------------	----

Sample comment	
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Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	3
--------------	---

Celerion Study Number	AA99128-05
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Date of Collection	2014-APR-16
--------------------	-------------

Timepoint-minutes	
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Urine Start Day	3
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 3

Form: Biomarker-Urine (HEMA) (1)

Data signed: (hfarmer1) 30 Mar 2015 12:28:03

Generated On: 20 Jul 2016 22:42:34

Urine End Day

4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 3

Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)

Data signed: (hfarmer1) 30 Mar 2015 12:28:04

Generated On: 20 Jul 2016 22:42:34

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 3

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(1)**

Data signed: (hfarmer1) 30 Mar 2015 12:28:04

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05112480001161
Analyte	COT
Sample type	URINE
Result	1560
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	3
Celerion Study Number	AA99128-06
Date of Collection	2014-APR-17
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 3

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(1)**

Data signed: (hfarmer1) 30 Mar 2015 12:28:04

Generated On: 20 Jul 2016 22:42:34

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: 1261**

Folder: Day 3

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(2)**

Data signed: (hfarmer1) 30 Mar 2015 12:28:04

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05112480001161
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Analyte	COT-GLUC
---------	----------

Sample type	URINE
-------------	-------

Result	5560
--------	------

Result Unit	NG/ML
-------------	-------

Lab Status	OK
------------	----

Sample comment	
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Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	3
--------------	---

Celerion Study Number	AA99128-06
-----------------------	------------

Date of Collection	2014-APR-17
--------------------	-------------

Timepoint-minutes	
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 3

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(2)**

Data signed: (hfarmer1) 30 Mar 2015 12:28:04

Generated On: 20 Jul 2016 22:42:34

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: 1261**

Folder: Day 3

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(3)**

Data signed: (hfarmer1) 30 Mar 2015 12:28:04

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05112480001161
Analyte	NIC
Sample type	URINE
Result	142
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	3
Celerion Study Number	AA99128-06
Date of Collection	2014-APR-17
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 3

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(3)**

Data signed: (hfarmer1) 30 Mar 2015 12:28:04

Generated On: 20 Jul 2016 22:42:34

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: 1261**

Folder: Day 3

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(4)**

Data signed: (hfarmer1) 30 Mar 2015 12:28:04

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05112480001161
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Analyte	NIC-GLUC
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Sample type	URINE
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Result	1190
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Result Unit	NG/ML
-------------	-------

Lab Status	OK
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Sample comment	
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Detection method	LC-MS/MS
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Planned time point (Hour)	0
---------------------------	---

Day of Visit	3
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Celerion Study Number	AA99128-06
-----------------------	------------

Date of Collection	2014-APR-17
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Timepoint-minutes	
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 3

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(4)**

Data signed: (hfarmer1) 30 Mar 2015 12:28:04

Generated On: 20 Jul 2016 22:42:34

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: 1261**

Folder: Day 3

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(5)**

Data signed: (hfarmer1) 30 Mar 2015 12:28:04

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05112480001161
Analyte	THCOT
Sample type	URINE
Result	3340
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	3
Celerion Study Number	AA99128-06
Date of Collection	2014-APR-17
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 3

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(5)**

Data signed: (hfarmer1) 30 Mar 2015 12:28:04

Generated On: 20 Jul 2016 22:42:34

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: 1261**

Folder: Day 3

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(6)**

Data signed: (hfarmer1) 30 Mar 2015 12:28:04

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05112480001161
Analyte	THCOT-GLUC
Sample type	URINE
Result	1110
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	3
Celerion Study Number	AA99128-06
Date of Collection	2014-APR-17
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 3

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(6)**

Data signed: (hfarmer1) 30 Mar 2015 12:28:04

Generated On: 20 Jul 2016 22:42:34

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: 1261**

Folder: Day 3

Form: Biomarker-Urine (3-OH BaP)

Data signed: (hfarmer1) 30 Mar 2015 12:28:04

Generated On: 20 Jul 2016 22:42:34

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 3

Form: Biomarker-Urine (3-OH BaP) (1)

Data signed: (hfarmer1) 30 Mar 2015 12:28:04

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05112490001755
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Analyte	3-OH BAP
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Sample type	URINE
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Result	164
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Result Unit	FG/ML
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Lab Status	OK
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Sample comment	
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Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	3
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Celerion Study Number	AA99128-07
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Date of Collection	2014-APR-16
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Timepoint-minutes	
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Urine Start Day	3
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 3

Form: Biomarker-Urine (3-OH BaP) (1)

Data signed: (hfarmer1) 30 Mar 2015 12:28:04

Generated On: 20 Jul 2016 22:42:34

Urine End Day

4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 3

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP)

Data signed: (hfarmer1) 30 Mar 2015 12:28:04

Generated On: 20 Jul 2016 22:42:34

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 3

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (1)

Data signed: (hfarmer1) 30 Mar 2015 12:28:04

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05112510001777
Analyte	1-NA
Sample type	URINE
Result	83.5
Result Unit	PG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	3
Celerion Study Number	AA99128-09
Date of Collection	2014-APR-16
Timepoint-minutes	
Urine Start Day	3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 3

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (1)

Data signed: (hfarmer1) 30 Mar 2015 12:28:04

Generated On: 20 Jul 2016 22:42:34

Urine End Day

4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 3

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (2)

Data signed: (hfarmer1) 30 Mar 2015 12:28:04

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05112510001777
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Analyte	2-NA
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Sample type	URINE
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Result	23.4
--------	------

Result Unit	PG/ML
-------------	-------

Lab Status	OK
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Sample comment	
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Detection method	LC-MS/MS
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Planned time point (Hour)	0
---------------------------	---

Day of Visit	3
--------------	---

Celerion Study Number	AA99128-09
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Date of Collection	2014-APR-16
--------------------	-------------

Timepoint-minutes	
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Urine Start Day	3
-----------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 3

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (2)

Data signed: (hfarmer1) 30 Mar 2015 12:28:04

Generated On: 20 Jul 2016 22:42:34

Urine End Day

4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 3

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (3)

Data signed: (hfarmer1) 30 Mar 2015 12:28:04

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05112510001777
Analyte	4-ABP
Sample type	URINE
Result	18.2
Result Unit	PG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	3
Celerion Study Number	AA99128-09
Date of Collection	2014-APR-16
Timepoint-minutes	
Urine Start Day	3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 3

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (3)

Data signed: (hfarmer1) 30 Mar 2015 12:28:04

Generated On: 20 Jul 2016 22:42:34

Urine End Day

4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 3

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (4)

Data signed: (hfarmer1) 30 Mar 2015 12:28:04

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05112510001777
Analyte	O-TOL
Sample type	URINE
Result	135
Result Unit	PG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	3
Celerion Study Number	AA99128-09
Date of Collection	2014-APR-16
Timepoint-minutes	
Urine Start Day	3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 3

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (4)

Data signed: (hfarmer1) 30 Mar 2015 12:28:04

Generated On: 20 Jul 2016 22:42:34

Urine End Day

4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 3

Form: Biomarker-Urine (1-OHP)

Data signed: (hfarmer1) 30 Mar 2015 12:28:04

Generated On: 20 Jul 2016 22:42:34

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 3

Form: Biomarker-Urine (1-OHP) (1)

Data signed: (hfarmer1) 30 Mar 2015 12:28:04

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05115190003779
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Analyte	1-OHP
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Sample type	URINE
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Result	224
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Result Unit	PG/ML
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Lab Status	OK
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Sample comment	
----------------	--

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	3
--------------	---

Celerion Study Number	AA99598-03
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Date of Collection	2014-APR-16
--------------------	-------------

Timepoint-minutes	
-------------------	--

Urine Start Day	3
-----------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 3

Form: Biomarker-Urine (1-OHP) (1)

Data signed: (hfarmer1) 30 Mar 2015 12:28:04

Generated On: 20 Jul 2016 22:42:34

Urine End Day

4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 3

Form: Biomarker-Urine (SPMA, SBMA)

Data signed: (hfarmer1) 30 Mar 2015 12:28:03

Generated On: 20 Jul 2016 22:42:34

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 3

Form: Biomarker-Urine (SPMA, SBMA) (1)

Data signed: (hfarmer1) 30 Mar 2015 12:28:03

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05115170003770
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Analyte	SBMA
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Sample type	URINE
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Result	2.00
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Result Unit	NG/ML
-------------	-------

Lab Status	OK
------------	----

Sample comment	
----------------	--

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	3
--------------	---

Celerion Study Number	AA99598-01
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Date of Collection	2014-APR-16
--------------------	-------------

Timepoint-minutes	
-------------------	--

Urine Start Day	3
-----------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 3

Form: Biomarker-Urine (SPMA, SBMA) (1)

Data signed: (hfarmer1) 30 Mar 2015 12:28:03

Generated On: 20 Jul 2016 22:42:34

Urine End Day

4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 3

Form: Biomarker-Urine (SPMA, SBMA) (2)

Data signed: (hfarmer1) 30 Mar 2015 12:28:03

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05115170003770
----------------	----------------

Analyte	SPMA
---------	------

Sample type	URINE
-------------	-------

Result	3.53
--------	------

Result Unit	NG/ML
-------------	-------

Lab Status	OK
------------	----

Sample comment	
----------------	--

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	3
--------------	---

Celerion Study Number	AA99598-01
-----------------------	------------

Date of Collection	2014-APR-16
--------------------	-------------

Timepoint-minutes	
-------------------	--

Urine Start Day	3
-----------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 3

Form: Biomarker-Urine (SPMA, SBMA) (2)

Data signed: (hfarmer1) 30 Mar 2015 12:28:03

Generated On: 20 Jul 2016 22:42:34

Urine End Day

4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 3

Form: Biomarker-Urine (MHBMA)

Data signed: (hfarmer1) 30 Mar 2015 12:28:04

Generated On: 20 Jul 2016 22:42:34

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 3

Form: Biomarker-Urine (MHBMA) (1)

Data signed: (hfarmer1) 30 Mar 2015 12:28:04

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05115180003779
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Analyte	MHBMA
---------	-------

Sample type	URINE
-------------	-------

Result	2.63
--------	------

Result Unit	NG/ML
-------------	-------

Lab Status	OK
------------	----

Sample comment	
----------------	--

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	3
--------------	---

Celerion Study Number	AA99598-02
-----------------------	------------

Date of Collection	2014-APR-16
--------------------	-------------

Timepoint-minutes	
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Urine Start Day	3
-----------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 3

Form: Biomarker-Urine (MHBMA) (1)

Data signed: (hfarmer1) 30 Mar 2015 12:28:04

Generated On: 20 Jul 2016 22:42:34

Urine End Day

4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 3

Form: Biomarker-Urine (Creatinine)

Data signed: (hfarmer1) 30 Mar 2015 12:28:04

Generated On: 20 Jul 2016 22:42:34

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 3

Form: Biomarker-Urine (Creatinine) (1)

Data signed: (hfarmer1) 30 Mar 2015 12:28:04

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05115160001755
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Analyte	CREATININE
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Sample type	URINE
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Result	82.3
--------	------

Result Unit	MG/DL
-------------	-------

Lab Status	OK
------------	----

Sample comment	
----------------	--

Detection method	SPECTROPHOTOMETRIC
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Planned time point (Hour)	0
---------------------------	---

Day of Visit	3
--------------	---

Celerion Study Number	AA99128-14
-----------------------	------------

Date of Collection	2014-APR-16
--------------------	-------------

Timepoint-minutes	
-------------------	--

Urine Start Day	3
-----------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 3

Form: Biomarker-Urine (Creatinine) (1)

Data signed: (hfarmer1) 30 Mar 2015 12:28:04

Generated On: 20 Jul 2016 22:42:34

Urine End Day

4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 3

Form: Biomarker-Plasma (Nic, Cot, tHCot)

Data signed: (hfarmer1) 30 Mar 2015 12:28:04

Generated On: 20 Jul 2016 22:42:34

Sample type

PLASMA

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 3

Form: Biomarker-Plasma (Nic, Cot, tHCot) (1)

Data signed: (hfarmer1) 30 Mar 2015 12:28:04

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05112430001999
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Analyte	COT
---------	-----

Sample type	PLASMA
-------------	--------

Result	236
--------	-----

Result Unit	NG/ML
-------------	-------

Lab Status	OK
------------	----

Sample comment	
----------------	--

Detection method	LC-MS/MS
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Planned time point (Hour)	0
---------------------------	---

Day of Visit	3
--------------	---

Celerion Study Number	AA99128-01
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Date of Collection	2014-APR-16
--------------------	-------------

Timepoint-minutes	0
-------------------	---

Urine Start Day	
-----------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 3

Form: Biomarker-Plasma (Nic, Cot, tHCot) (1)

Data signed: (hfarmer1) 30 Mar 2015 12:28:04

Generated On: 20 Jul 2016 22:42:34

Urine End Day

3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 3

Form: Biomarker-Plasma (Nic, Cot, tHCot) (2)

Data signed: (hfarmer1) 30 Mar 2015 12:28:04

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05112430001999
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Analyte	NIC
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Sample type	PLASMA
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Result	23.4
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Result Unit	NG/ML
-------------	-------

Lab Status	OK
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Sample comment	
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Detection method	LC-MS/MS
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Planned time point (Hour)	0
---------------------------	---

Day of Visit	3
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Celerion Study Number	AA99128-01
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Date of Collection	2014-APR-16
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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: 1261**

Folder: Day 3

Form: Biomarker-Plasma (Nic, Cot, tHCot) (2)

Data signed: (hfarmer1) 30 Mar 2015 12:28:04

Generated On: 20 Jul 2016 22:42:34

Urine End Day

3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 4

Form: Date of Visit

Data signed: (hfarmer1) 30 Mar 2015 12:28:05

Generated On: 20 Jul 2016 22:42:34

Date of Visit

17 APR 2014
DD/MMM/YYYY

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 4

Form: Vital Signs

Data signed: (hfarmer1) 30 Mar 2015 12:28:05

Generated On: 20 Jul 2016 22:42:34

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 10:27
hour:min 24-hour clock

Pulse rate 72
beats per minute

Respiratory rate 16
breaths per minute

Blood Pressure (systolic) 113
mmHg

Blood Pressure (diastolic) 72
mmHg

Vital Signs Position of Subject Supine ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 4

Form: Socio-Economic Status

Data signed: (hfarmer1) 30 Mar 2015 12:28:05

Generated On: 20 Jul 2016 22:42:34

Was paper questionnaire used? Yes ☒

Reason not done _____

Date 17 APR 2014
DD/MMM/YYYY

Time 06:29
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? Other ☒

SPECIFY SELF EMPLOYED

Q3. How many people are currently living in your household, including yourself? 02

Q4. Of these people, how many are children? 00

Q5. Of these people, how many are adults? 02

Q6. Of the adults, how many bring income into the household? 02

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 4

Form: Socio-Economic Status

Data signed: (hfarmer1) 30 Mar 2015 12:28:05

Generated On: 20 Jul 2016 22:42:34

Q7. Which of these categories best describes your total combined family income for the past 12 months? This should include income (before taxes) from all sources, wages, rent from properties, social security, disability and/or veteran's benefits, unemployment benefits, workman's compensation, help from relatives (including child payments and alimony), and so on.

Less than \$10,000 ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 4

Form: Plasma Nicotine Sample

Data signed: (hfarmer1) 30 Mar 2015 12:28:04

Generated On: 20 Jul 2016 22:42:34

Not Done	False
----------	-------

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	17 APR 2014
---------------------	-------------

Time hour:min 24-hour clock	20:21
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 4

Form: Plasma Cotinine Sample

Data signed: (hfarmer1) 30 Mar 2015 12:28:04

Generated On: 20 Jul 2016 22:42:34

Not Done	False
----------	-------

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	17 APR 2014
---------------------	-------------

Time hour:min 24-hour clock	20:21
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 4

Form: CoHb Blood Sample

Data signed: (hfarmer1) 30 Mar 2015 12:28:04

Generated On: 20 Jul 2016 22:42:34

Not Done	False
----------	-------

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	17 APR 2014
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Timepoint	20:00 - 21:30 <input checked="" type="radio"/>
-----------	--

Time hour:min 24-hour clock	20:21
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 4

Form: CO Breath Test (1)

Data signed: (hfarmer1) 30 Mar 2015 12:28:05

Generated On: 20 Jul 2016 22:42:34

Assessment not done	False
---------------------	-------

If Not Done, please specify the reason: _____

Scheduled Time	Within 15 min prior to smoking <input checked="" type="radio"/>
----------------	---

Actual Time of Assessment hour:min 24-hour clock	06:28
---	-------

Result(ppm)	10
-------------	----

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 4

Form: CO Breath Test (2)

Data signed: (hfarmer1) 30 Mar 2015 12:28:05

Generated On: 20 Jul 2016 22:42:34

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	12:13
---	-------

Result(ppm)	13
-------------	----

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 4

Form: CO Breath Test (3)

Data signed: (hfarmer1) 30 Mar 2015 12:28:05

Generated On: 20 Jul 2016 22:42:34

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)	16
-------------	----

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 4

Form: CO Breath Test (4)

Data signed: (hfarmer1) 30 Mar 2015 12:28:05

Generated On: 20 Jul 2016 22:42:34

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	20:19
---	-------

Result(ppm)	18
-------------	----

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 4

Form: 24 hour urine collections

Data signed: (hfarmer1) 30 Mar 2015 12:28:05

Generated On: 20 Jul 2016 22:42:34

Start Time	06:10
	hour:min 24-hour clock

End Date	18 APR 2014
	DD/MMM/YYYY

End Time	06:08
	hour:min 24-hour clock

Volume	1360
	mL

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 4

Form: Sample Urine Collection

Data signed: (hfarmer1) 30 Mar 2015 12:28:04

Generated On: 20 Jul 2016 22:42:34

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: 1261**

Folder: Day 4

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Data signed: (hfarmer1) 30 Mar 2015 12:28:05

Generated On: 20 Jul 2016 22:42:34

Date of Birth	(b) (6)
---------------	---------

Date of assessment DD/MMM/YYYY	2014 APR 17 DD/MMM/YYYY
-----------------------------------	----------------------------

Time of assessment	06:04 hour:min 24-hour clock
--------------------	---------------------------------

Assessment Status	Completed <input 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?	None <input type="radio"/>
---	----------------------------

4. Desire or craving to smoke

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 4

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Data signed: (hfarmer1) 30 Mar 2015 12:28:05

Generated On: 20 Jul 2016 22:42:34

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: 1261**

Folder: Day 4

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Data signed: (hfarmer1) 30 Mar 2015 12:28:05

Generated On: 20 Jul 2016 22:42:34

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: 1261

Folder: Day 4

Form: Cough Assessment

Data signed: (hfarmer1) 30 Mar 2015 12:28:05

Generated On: 20 Jul 2016 22:42:34

Date of Birth

(b) (6)

Date of assessment
DD/MMM/YYYY

2014 APR 17
DD/MMM/YYYY

Time of assessment

06:04
hour:min 24-hour clock

Assessment Status

Completed ☒

Have you experienced a regular need to cough e.g.
coughing several times in the last 24 hrs?

Yes ☒

If YES, please answer the following questions:

First Question: Cough Impact Scale
How much is your cough bothering you?

5

Second Question: Cough Intensity Scale:
How intense is your cough?

Very mild ☒

Third Question: Cough Frequency Scale:
How frequently do you normally have to cough each
day?

Rarely ☒

Fourth Question: Sputum Production
To what extent do you produce sputum when coughing?

No sputum ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 4

Form: Lab_BU_COHB (1)

Data signed: (hfarmer1) 30 Mar 2015 12:28:05

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05115150004279
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Analyte	CARBOXYHEMOGLOBIN
---------	-------------------

Sample type	BLOOD
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Result	6.50
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Result Unit	%
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Lab Status	OK
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Sample comment	
----------------	--

Detection method	SPECTROPHOTOMETRIC
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Lower limit of quantification	0.500
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Planned time point (Hour)	20
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Day of Visit	4
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Celerion Study Number	AA99128-16
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Date of Collection	2014-APR-17
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Timepoint-minutes	
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 4

Form: Lab_BU_COHB (1)

Data signed: (hfarmer1) 30 Mar 2015 12:28:05

Generated On: 20 Jul 2016 22:42:34

Start Day (24 hour urine only)

End Day (24 hour Urine Only)

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 4

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)

Data signed: (hfarmer1) 30 Mar 2015 12:28:05

Generated On: 20 Jul 2016 22:42:34

Date of Birth

(b) (6)

Date of assessment

2014 APR 17

DD/MMM/YYYY

DD/MMM/YYYY

Time of assessment

20:03

hour:min 24-hour clock

Assessment Status

Completed

1. Was smoking satisfying?

Extremely

2. Did cigarettes taste good?

Extremely

3. Did you enjoy the sensation in your throat and chest?

Extremely

4. Did smoking calm you down?

Extremely

5. Did smoking make you feel more awake?

Extremely

6. Did smoking make you feel less irritable?

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: 1261**

Folder: Day 4

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)

Data signed: (hfarmer1) 30 Mar 2015 12:28:05

Generated On: 20 Jul 2016 22:42:34

9. Did smoking make you dizzy? Not at all ☐

10. Did smoking make you nauseous? Not at all ☐

11. Did smoking immediately relieve your craving for a
cigarette? Extremely ☐

12. Did you enjoy smoking? Extremely ☐

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1261

Folder: Day 4

Form: Human Smoking Topography Questionnaire

Data signed: (hfarmer1) 30 Mar 2015 12:28:05

Generated On: 20 Jul 2016 22:42:34

Type	HUMAN SMOKING TOPOGRAPHY QUESTIONNAIRE
------	--

Was paper questionnaire used?	Yes <input type="radio"/>
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Reason not done	<hr/>
-----------------	-------

Date of assessment	17 APR 2014 DD/MMM/YYYY
--------------------	----------------------------

Time of assessment	20:48 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 :	IT BURNS QUICKER.
---	-------------------

2. You enjoy smoking with the device as much as without it.	Neither agree nor disagree <input type="radio"/>
---	--

If you disagree or strongly disagree, please describe :	<hr/>
---	-------

3. The taste of the conventional cigarettes/products is different with the device.	Disagree <input type="radio"/>
--	--------------------------------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 4

Form: Human Smoking Topography Questionnaire

Data signed: (hfarmer1) 30 Mar 2015 12:28:05

Generated On: 20 Jul 2016 22:42:34

If you agree or strongly agree, please describe : _____

4. The device is easy to use.

Agree ☒

If you disagree or strongly disagree, please describe : _____

5. Your smoking is disturbed by the device.

Disagree ☒

If you agree or strongly agree, please describe : _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 4

Form: Questionnaire on smoking urges (QSU)

Data signed: (hfarmer1) 30 Mar 2015 12:28:05

Generated On: 20 Jul 2016 22:42:34

Type	QSU
Date of Birth	(b) (6)
Date of assessment DD/MMM/YYYY	2014 APR 17
Time of assessment hour:min 24-hour clock	20:02
Assessment Status	Completed <input checked="" type="radio"/>
1. I have a desire for a cigarette right now	Strongly agree <input checked="" type="radio"/>
2. Nothing would be better than smoking a cigarette right now	Strongly agree <input checked="" type="radio"/>
3. If it were possible I would probably smoke now	Strongly agree <input checked="" type="radio"/>
4. I could control things better right now if I could smoke	Strongly agree <input checked="" type="radio"/>
5. All I want right now is a cigarette	Strongly agree <input checked="" type="radio"/>
6. I have an urge for a cigarette	Strongly agree <input checked="" type="radio"/>

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 4

Form: Questionnaire on smoking urges (QSU)

Data signed: (hfarmer1) 30 Mar 2015 12:28:05

Generated On: 20 Jul 2016 22:42:34

7. A cigarette would taste good now Strongly agree ☐

8. I would do almost anything for a cigarette now Strongly agree ☐

9. Smoking would make me less depressed Disagree ☐

10. I am going to smoke as soon as possible Strongly agree ☐

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 4

Form: Biomarker-Urine (CEMA, HPMa, HBMA)

Data signed: (hfarmer1) 30 Mar 2015 12:28:07

Generated On: 20 Jul 2016 22:42:34

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 4

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (1)

Data signed: (hfarmer1) 30 Mar 2015 12:28:07

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05112450002929
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Analyte	HPMA
---------	------

Sample type	URINE
-------------	-------

Result	978
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Result Unit	NG/ML
-------------	-------

Lab Status	OK
------------	----

Sample comment	
----------------	--

Detection method	LC-MS/MS
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Planned time point (Hour)	0
---------------------------	---

Day of Visit	4
--------------	---

Celerion Study Number	AA99128-03
-----------------------	------------

Date of Collection	2014-APR-17
--------------------	-------------

Timepoint-minutes	
-------------------	--

Urine Start Day	4
-----------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 4

Form: Biomarker-Urine (CEMA, HPMa, HBMA) (1)

Data signed: (hfarmer1) 30 Mar 2015 12:28:07

Generated On: 20 Jul 2016 22:42:34

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 4

Form: Biomarker-Urine (CEMA, HPMa, HBMA) (2)

Data signed: (hfarmer1) 30 Mar 2015 12:28:07

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05112450002929
----------------	----------------

Analyte	CEMA
---------	------

Sample type	URINE
-------------	-------

Result	158
--------	-----

Result Unit	NG/ML
-------------	-------

Lab Status	OK
------------	----

Sample comment	
----------------	--

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	4
--------------	---

Celerion Study Number	AA99128-03
-----------------------	------------

Date of Collection	2014-APR-17
--------------------	-------------

Timepoint-minutes	
-------------------	--

Urine Start Day	4
-----------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 4

Form: Biomarker-Urine (CEMA, HPMa, HBMA) (2)

Data signed: (hfarmer1) 30 Mar 2015 12:28:07

Generated On: 20 Jul 2016 22:42:34

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 4

Form: Biomarker-Urine (CEMA, HPMa, HBMA) (3)

Data signed: (hfarmer1) 30 Mar 2015 12:28:07

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05112450002929
----------------	----------------

Analyte	HBMA
---------	------

Sample type	URINE
-------------	-------

Result	411
--------	-----

Result Unit	NG/ML
-------------	-------

Lab Status	OK
------------	----

Sample comment	
----------------	--

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	4
--------------	---

Celerion Study Number	AA99128-03
-----------------------	------------

Date of Collection	2014-APR-17
--------------------	-------------

Timepoint-minutes	
-------------------	--

Urine Start Day	4
-----------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 4

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (3)

Data signed: (hfarmer1) 30 Mar 2015 12:28:07

Generated On: 20 Jul 2016 22:42:34

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 4

Form: Biomarker-Urine (NNN, NNAL)

Data signed: (hfarmer1) 30 Mar 2015 12:28:05

Generated On: 20 Jul 2016 22:42:34

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 4

Form: Biomarker-Urine (NNN, NNAL) (1)

Data signed: (hfarmer1) 30 Mar 2015 12:28:05

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05112460003516
----------------	----------------

Analyte	NNAL
---------	------

Sample type	URINE
-------------	-------

Result	462
--------	-----

Result Unit	PG/ML
-------------	-------

Lab Status	OK
------------	----

Sample comment	
----------------	--

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	4
--------------	---

Celerion Study Number	AA99128-04
-----------------------	------------

Date of Collection	2014-APR-17
--------------------	-------------

Timepoint-minutes	
-------------------	--

Urine Start Day	4
-----------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 4

Form: Biomarker-Urine (NNN, NNAL) (1)

Data signed: (hfarmer1) 30 Mar 2015 12:28:05

Generated On: 20 Jul 2016 22:42:34

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 4

Form: Biomarker-Urine (NNN, NNAL) (2)

Data signed: (hfarmer1) 30 Mar 2015 12:28:05

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05112460003516
Analyte	NNN
Sample type	URINE
Result	17.5
Result Unit	PG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	4
Celerion Study Number	AA99128-04
Date of Collection	2014-APR-17
Timepoint-minutes	
Urine Start Day	4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 4

Form: Biomarker-Urine (NNN, NNAL) (2)

Data signed: (hfarmer1) 30 Mar 2015 12:28:05

Generated On: 20 Jul 2016 22:42:34

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 4

Form: Biomarker-Urine (HEMA)

Data signed: (hfarmer1) 30 Mar 2015 12:28:06

Generated On: 20 Jul 2016 22:42:34

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 4

Form: Biomarker-Urine (HEMA) (1)

Data signed: (hfarmer1) 30 Mar 2015 12:28:06

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05112470001756
----------------	----------------

Analyte	HEMA
---------	------

Sample type	URINE
-------------	-------

Result	16.2
--------	------

Result Unit	NG/ML
-------------	-------

Lab Status	OK
------------	----

Sample comment	
----------------	--

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	4
--------------	---

Celerion Study Number	AA99128-05
-----------------------	------------

Date of Collection	2014-APR-17
--------------------	-------------

Timepoint-minutes	
-------------------	--

Urine Start Day	4
-----------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 4

Form: Biomarker-Urine (HEMA) (1)

Data signed: (hfarmer1) 30 Mar 2015 12:28:06

Generated On: 20 Jul 2016 22:42:34

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 4

Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)

Data signed: (hfarmer1) 30 Mar 2015 12:28:07

Generated On: 20 Jul 2016 22:42:34

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 4

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(1)**

Data signed: (hfarmer1) 30 Mar 2015 12:28:07

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05112480001162
Analyte	COT
Sample type	URINE
Result	1750
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	4
Celerion Study Number	AA99128-06
Date of Collection	2014-APR-18
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 4

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(1)**

Data signed: (hfarmer1) 30 Mar 2015 12:28:07

Generated On: 20 Jul 2016 22:42:34

Urine Start Day	4
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Urine End Day	5
---------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 4

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(2)**

Data signed: (hfarmer1) 30 Mar 2015 12:28:07

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05112480001162
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Analyte	COT-GLUC
---------	----------

Sample type	URINE
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Result	6930
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Result Unit	NG/ML
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Lab Status	OK
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Sample comment	
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Detection method	LC-MS/MS
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Planned time point (Hour)	0
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Day of Visit	4
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Celerion Study Number	AA99128-06
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Date of Collection	2014-APR-18
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Timepoint-minutes	
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 4

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(2)**

Data signed: (hfarmer1) 30 Mar 2015 12:28:07

Generated On: 20 Jul 2016 22:42:34

Urine Start Day	4
-----------------	---

Urine End Day	5
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 4

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(3)**

Data signed: (hfarmer1) 30 Mar 2015 12:28:07

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05112480001162
Analyte	NIC
Sample type	URINE
Result	622
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	4
Celerion Study Number	AA99128-06
Date of Collection	2014-APR-18
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 4

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(3)**

Data signed: (hfarmer1) 30 Mar 2015 12:28:07

Generated On: 20 Jul 2016 22:42:34

Urine Start Day	4
-----------------	---

Urine End Day	5
---------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 4

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(4)**

Data signed: (hfarmer1) 30 Mar 2015 12:28:07

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05112480001162
Analyte	NIC-GLUC
Sample type	URINE
Result	1350
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	4
Celerion Study Number	AA99128-06
Date of Collection	2014-APR-18
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 4

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(4)**

Data signed: (hfarmer1) 30 Mar 2015 12:28:07

Generated On: 20 Jul 2016 22:42:34

Urine Start Day	4
-----------------	---

Urine End Day	5
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 4

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(5)**

Data signed: (hfarmer1) 30 Mar 2015 12:28:07

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05112480001162
----------------	----------------

Analyte	THCOT
---------	-------

Sample type	URINE
-------------	-------

Result	3920
--------	------

Result Unit	NG/ML
-------------	-------

Lab Status	OK
------------	----

Sample comment	
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Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	4
--------------	---

Celerion Study Number	AA99128-06
-----------------------	------------

Date of Collection	2014-APR-18
--------------------	-------------

Timepoint-minutes	
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 4

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(5)**

Data signed: (hfarmer1) 30 Mar 2015 12:28:07

Generated On: 20 Jul 2016 22:42:34

Urine Start Day	4
-----------------	---

Urine End Day	5
---------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 4

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(6)**

Data signed: (hfarmer1) 30 Mar 2015 12:28:07

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05112480001162
Analyte	THCOT-GLUC
Sample type	URINE
Result	1310
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	4
Celerion Study Number	AA99128-06
Date of Collection	2014-APR-18
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 4

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(6)**

Data signed: (hfarmer1) 30 Mar 2015 12:28:07

Generated On: 20 Jul 2016 22:42:34

Urine Start Day	4
-----------------	---

Urine End Day	5
---------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 4

Form: Biomarker-Urine (3-OH BaP)

Data signed: (hfarmer1) 30 Mar 2015 12:28:07

Generated On: 20 Jul 2016 22:42:34

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 4

Form: Biomarker-Urine (3-OH BaP) (1)

Data signed: (hfarmer1) 30 Mar 2015 12:28:07

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05112490001756
----------------	----------------

Analyte	3-OH BAP
---------	----------

Sample type	URINE
-------------	-------

Result	191
--------	-----

Result Unit	FG/ML
-------------	-------

Lab Status	OK
------------	----

Sample comment	
----------------	--

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	4
--------------	---

Celerion Study Number	AA99128-07
-----------------------	------------

Date of Collection	2014-APR-17
--------------------	-------------

Timepoint-minutes	
-------------------	--

Urine Start Day	4
-----------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 4

Form: Biomarker-Urine (3-OH BaP) (1)

Data signed: (hfarmer1) 30 Mar 2015 12:28:07

Generated On: 20 Jul 2016 22:42:34

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 4

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP)

Data signed: (hfarmer1) 30 Mar 2015 12:28:07

Generated On: 20 Jul 2016 22:42:34

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 4

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (1)

Data signed: (hfarmer1) 30 Mar 2015 12:28:07

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05112510001778
----------------	----------------

Analyte	1-NA
---------	------

Sample type	URINE
-------------	-------

Result	88.3
--------	------

Result Unit	PG/ML
-------------	-------

Lab Status	OK
------------	----

Sample comment	
----------------	--

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	4
--------------	---

Celerion Study Number	AA99128-09
-----------------------	------------

Date of Collection	2014-APR-17
--------------------	-------------

Timepoint-minutes	
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Urine Start Day	4
-----------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 4

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (1)

Data signed: (hfarmer1) 30 Mar 2015 12:28:07

Generated On: 20 Jul 2016 22:42:34

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 4

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (2)

Data signed: (hfarmer1) 30 Mar 2015 12:28:07

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05112510001778
----------------	----------------

Analyte	2-NA
---------	------

Sample type	URINE
-------------	-------

Result	28.2
--------	------

Result Unit	PG/ML
-------------	-------

Lab Status	OK
------------	----

Sample comment	
----------------	--

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	4
--------------	---

Celerion Study Number	AA99128-09
-----------------------	------------

Date of Collection	2014-APR-17
--------------------	-------------

Timepoint-minutes	
-------------------	--

Urine Start Day	4
-----------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 4

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (2)

Data signed: (hfarmer1) 30 Mar 2015 12:28:07

Generated On: 20 Jul 2016 22:42:34

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 4

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (3)

Data signed: (hfarmer1) 30 Mar 2015 12:28:07

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05112510001778
----------------	----------------

Analyte	4-ABP
---------	-------

Sample type	URINE
-------------	-------

Result	16.4
--------	------

Result Unit	PG/ML
-------------	-------

Lab Status	OK
------------	----

Sample comment	
----------------	--

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	4
--------------	---

Celerion Study Number	AA99128-09
-----------------------	------------

Date of Collection	2014-APR-17
--------------------	-------------

Timepoint-minutes	
-------------------	--

Urine Start Day	4
-----------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 4

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (3)

Data signed: (hfarmer1) 30 Mar 2015 12:28:07

Generated On: 20 Jul 2016 22:42:34

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 4

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (4)

Data signed: (hfarmer1) 30 Mar 2015 12:28:07

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05112510001778
Analyte	O-TOL
Sample type	URINE
Result	137
Result Unit	PG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	4
Celerion Study Number	AA99128-09
Date of Collection	2014-APR-17
Timepoint-minutes	
Urine Start Day	4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 4

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (4)

Data signed: (hfarmer1) 30 Mar 2015 12:28:07

Generated On: 20 Jul 2016 22:42:34

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 4

Form: Biomarker-Urine (1-OHP)

Data signed: (hfarmer1) 30 Mar 2015 12:28:08

Generated On: 20 Jul 2016 22:42:34

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 4

Form: Biomarker-Urine (1-OHP) (1)

Data signed: (hfarmer1) 30 Mar 2015 12:28:08

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05115190003780
----------------	----------------

Analyte	1-OHP
---------	-------

Sample type	URINE
-------------	-------

Result	241
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Result Unit	PG/ML
-------------	-------

Lab Status	OK
------------	----

Sample comment	
----------------	--

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	4
--------------	---

Celerion Study Number	AA99598-03
-----------------------	------------

Date of Collection	2014-APR-17
--------------------	-------------

Timepoint-minutes	
-------------------	--

Urine Start Day	4
-----------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 4

Form: Biomarker-Urine (1-OHP) (1)

Data signed: (hfarmer1) 30 Mar 2015 12:28:08

Generated On: 20 Jul 2016 22:42:34

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 4

Form: Biomarker-Urine (SPMA, SBMA)

Data signed: (hfarmer1) 30 Mar 2015 12:28:06

Generated On: 20 Jul 2016 22:42:34

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 4

Form: Biomarker-Urine (SPMA, SBMA) (1)

Data signed: (hfarmer1) 30 Mar 2015 12:28:06

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05115170003771
----------------	----------------

Analyte	SBMA
---------	------

Sample type	URINE
-------------	-------

Result	2.97
--------	------

Result Unit	NG/ML
-------------	-------

Lab Status	OK
------------	----

Sample comment	
----------------	--

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	4
--------------	---

Celerion Study Number	AA99598-01
-----------------------	------------

Date of Collection	2014-APR-17
--------------------	-------------

Timepoint-minutes	
-------------------	--

Urine Start Day	4
-----------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 4

Form: Biomarker-Urine (SPMA, SBMA) (1)

Data signed: (hfarmer1) 30 Mar 2015 12:28:06

Generated On: 20 Jul 2016 22:42:34

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 4

Form: Biomarker-Urine (SPMA, SBMA) (2)

Data signed: (hfarmer1) 30 Mar 2015 12:28:06

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05115170003771
----------------	----------------

Analyte	SPMA
---------	------

Sample type	URINE
-------------	-------

Result	4.38
--------	------

Result Unit	NG/ML
-------------	-------

Lab Status	OK
------------	----

Sample comment	
----------------	--

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	4
--------------	---

Celerion Study Number	AA99598-01
-----------------------	------------

Date of Collection	2014-APR-17
--------------------	-------------

Timepoint-minutes	
-------------------	--

Urine Start Day	4
-----------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 4

Form: Biomarker-Urine (SPMA, SBMA) (2)

Data signed: (hfarmer1) 30 Mar 2015 12:28:06

Generated On: 20 Jul 2016 22:42:34

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 4

Form: Biomarker-Urine (MHBMA)

Data signed: (hfarmer1) 30 Mar 2015 12:28:06

Generated On: 20 Jul 2016 22:42:34

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 4

Form: Biomarker-Urine (MHBMA) (1)

Data signed: (hfarmer1) 30 Mar 2015 12:28:06

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05115180003780
Analyte	MHBMA
Sample type	URINE
Result	3.11
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	4
Celerion Study Number	AA99598-02
Date of Collection	2014-APR-17
Timepoint-minutes	
Urine Start Day	4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 4

Form: Biomarker-Urine (MHBMA) (1)

Data signed: (hfarmer1) 30 Mar 2015 12:28:06

Generated On: 20 Jul 2016 22:42:34

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 4

Form: Biomarker-Urine (Creatinine)

Data signed: (hfarmer1) 30 Mar 2015 12:28:08

Generated On: 20 Jul 2016 22:42:34

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 4

Form: Biomarker-Urine (Creatinine) (1)

Data signed: (hfarmer1) 30 Mar 2015 12:28:08

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05115160001756
----------------	----------------

Analyte	CREATININE
---------	------------

Sample type	URINE
-------------	-------

Result	101
--------	-----

Result Unit	MG/DL
-------------	-------

Lab Status	OK
------------	----

Sample comment	
----------------	--

Detection method	SPECTROPHOTOMETRIC
------------------	--------------------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	4
--------------	---

Celerion Study Number	AA99128-14
-----------------------	------------

Date of Collection	2014-APR-17
--------------------	-------------

Timepoint-minutes	
-------------------	--

Urine Start Day	4
-----------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 4

Form: Biomarker-Urine (Creatinine) (1)

Data signed: (hfarmer1) 30 Mar 2015 12:28:08

Generated On: 20 Jul 2016 22:42:34

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 4

Form: Biomarker-Plasma (Nic, Cot, tHCot)

Data signed: (hfarmer1) 30 Mar 2015 12:28:06

Generated On: 20 Jul 2016 22:42:34

Sample type

PLASMA

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 4

Form: Biomarker-Plasma (Nic, Cot, tHCot) (1)

Data signed: (hfarmer1) 30 Mar 2015 12:28:06

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05112430002000
----------------	----------------

Analyte	COT
---------	-----

Sample type	PLASMA
-------------	--------

Result	234
--------	-----

Result Unit	NG/ML
-------------	-------

Lab Status	OK
------------	----

Sample comment	
----------------	--

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	4
--------------	---

Celerion Study Number	AA99128-01
-----------------------	------------

Date of Collection	2014-APR-17
--------------------	-------------

Timepoint-minutes	0
-------------------	---

Urine Start Day	
-----------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 4

Form: Biomarker-Plasma (Nic, Cot, tHCot) (1)

Data signed: (hfarmer1) 30 Mar 2015 12:28:06

Generated On: 20 Jul 2016 22:42:34

Urine End Day

4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 4

Form: Biomarker-Plasma (Nic, Cot, tHCot) (2)

Data signed: (hfarmer1) 30 Mar 2015 12:28:06

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05112430002000
----------------	----------------

Analyte	NIC
---------	-----

Sample type	PLASMA
-------------	--------

Result	13.0
--------	------

Result Unit	NG/ML
-------------	-------

Lab Status	OK
------------	----

Sample comment	
----------------	--

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	4
--------------	---

Celerion Study Number	AA99128-01
-----------------------	------------

Date of Collection	2014-APR-17
--------------------	-------------

Timepoint-minutes	0
-------------------	---

Urine Start Day	
-----------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 4

Form: Biomarker-Plasma (Nic, Cot, tHCot) (2)

Data signed: (hfarmer1) 30 Mar 2015 12:28:06

Generated On: 20 Jul 2016 22:42:34

Urine End Day

4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 5

Form: Date of Visit

Data signed: (hfarmer1) 30 Mar 2015 12:28:10

Generated On: 20 Jul 2016 22:42:34

Date of Visit

18 APR 2014
DD/MMM/YYYY

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 5

Form: Vital Signs

Data signed: (hfarmer1) 30 Mar 2015 12:28:10

Generated On: 20 Jul 2016 22:42:34

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

09:12
hour:min 24-hour clock

Pulse rate

76
beats per minute

Respiratory rate

20
breaths per minute

Blood Pressure (systolic)

110
mmHg

Blood Pressure (diastolic)

71
mmHg

Vital Signs Position of Subject

Supine ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 5

Form: Plasma Nicotine Samples <Day 5> (1)

Data signed: (hfarmer1) 30 Mar 2015 12:28:11

Generated On: 20 Jul 2016 22:42:34

Not Done	False
----------	-------

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	18 APR 2014
---------------------	-------------

Scheduled Time	T0 -15 min <input checked="" type="radio"/>
----------------	---

Time hour:min 24-hour clock	06:28
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 5

Form: Plasma Nicotine Samples <Day 5> (2)

Data signed: (hfarmer1) 30 Mar 2015 12:28:11

Generated On: 20 Jul 2016 22:42:34

Not Done	False
----------	-------

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	18 APR 2014
---------------------	-------------

Scheduled Time	T1 <input checked="" type="radio"/>
----------------	-------------------------------------

Time hour:min 24-hour clock	08:36
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 5

Form: Plasma Nicotine Samples <Day 5> (3)

Data signed: (hfarmer1) 30 Mar 2015 12:28:11

Generated On: 20 Jul 2016 22:42:34

Not Done	False
----------	-------

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	18 APR 2014
---------------------	-------------

Scheduled Time	T2 <input checked="" type="radio"/>
----------------	-------------------------------------

Time hour:min 24-hour clock	10:34
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 5

Form: Plasma Nicotine Samples <Day 5> (4)

Data signed: (hfarmer1) 30 Mar 2015 12:28:11

Generated On: 20 Jul 2016 22:42:34

Not Done	False
----------	-------

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	18 APR 2014
---------------------	-------------

Scheduled Time	T3 <input checked="" type="radio"/>
----------------	-------------------------------------

Time hour:min 24-hour clock	12:36
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 5

Form: Plasma Nicotine Samples <Day 5> (5)

Data signed: (hfarmer1) 30 Mar 2015 12:28:11

Generated On: 20 Jul 2016 22:42:34

Not Done	False
----------	-------

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	18 APR 2014
---------------------	-------------

Scheduled Time	T4 <input checked="" type="radio"/>
----------------	-------------------------------------

Time hour:min 24-hour clock	14:34
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 5

Form: Plasma Nicotine Samples <Day 5> (6)

Data signed: (hfarmer1) 30 Mar 2015 12:28:11

Generated On: 20 Jul 2016 22:42:34

Not Done	False
----------	-------

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	18 APR 2014
---------------------	-------------

Scheduled Time	T5 <input checked="" type="radio"/>
----------------	-------------------------------------

Time hour:min 24-hour clock	16:34
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 5

Form: Plasma Nicotine Samples <Day 5> (7)

Data signed: (hfarmer1) 30 Mar 2015 12:28:11

Generated On: 20 Jul 2016 22:42:34

Not Done	False
----------	-------

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	18 APR 2014
---------------------	-------------

Scheduled Time	T6 <input checked="" type="radio"/>
----------------	-------------------------------------

Time hour:min 24-hour clock	18:34
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 5

Form: Plasma Nicotine Samples <Day 5> (8)

Data signed: (hfarmer1) 30 Mar 2015 12:28:11

Generated On: 20 Jul 2016 22:42:34

Not Done	False
----------	-------

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	18 APR 2014
---------------------	-------------

Scheduled Time	T7 <input checked="" type="radio"/>
----------------	-------------------------------------

Time hour:min 24-hour clock	20:34
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 5

Form: Plasma Nicotine Samples <Day 5> (9)

Data signed: (hfarmer1) 30 Mar 2015 12:28:11

Generated On: 20 Jul 2016 22:42:34

Not Done	False
----------	-------

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	18 APR 2014
---------------------	-------------

Scheduled Time	T8 <input checked="" type="radio"/>
----------------	-------------------------------------

Time hour:min 24-hour clock	22:34
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 5

Form: Plasma Cotinine Samples <Day 5> (1)

Data signed: (hfarmer1) 30 Mar 2015 12:28:10

Generated On: 20 Jul 2016 22:42:34

Not Done	False
----------	-------

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	18 APR 2014
---------------------	-------------

Scheduled Time	T0 -15 min <input checked="" type="radio"/>
----------------	---

Time hour:min 24-hour clock	06:28
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 5

Form: Plasma Cotinine Samples <Day 5> (2)

Data signed: (hfarmer1) 30 Mar 2015 12:28:10

Generated On: 20 Jul 2016 22:42:34

Not Done	False
----------	-------

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	18 APR 2014
---------------------	-------------

Scheduled Time	T1 <input checked="" type="radio"/>
----------------	-------------------------------------

Time hour:min 24-hour clock	08:36
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 5

Form: Plasma Cotinine Samples <Day 5> (3)

Data signed: (hfarmer1) 30 Mar 2015 12:28:10

Generated On: 20 Jul 2016 22:42:34

Not Done	False
----------	-------

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	18 APR 2014
---------------------	-------------

Scheduled Time	T2 <input checked="" type="radio"/>
----------------	-------------------------------------

Time hour:min 24-hour clock	10:34
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 5

Form: Plasma Cotinine Samples <Day 5> (4)

Data signed: (hfarmer1) 30 Mar 2015 12:28:10

Generated On: 20 Jul 2016 22:42:34

Not Done	False
----------	-------

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	18 APR 2014
---------------------	-------------

Scheduled Time	T3 <input checked="" type="radio"/>
----------------	-------------------------------------

Time hour:min 24-hour clock	12:36
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 5

Form: Plasma Cotinine Samples <Day 5> (5)

Data signed: (hfarmer1) 30 Mar 2015 12:28:10

Generated On: 20 Jul 2016 22:42:34

Not Done	False
----------	-------

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	18 APR 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: 1261**

Folder: Day 5

Form: Plasma Cotinine Samples <Day 5> (6)

Data signed: (hfarmer1) 30 Mar 2015 12:28:10

Generated On: 20 Jul 2016 22:42:34

Not Done	False
----------	-------

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	18 APR 2014
---------------------	-------------

Scheduled Time	T5 <input checked="" type="radio"/>
----------------	-------------------------------------

Time hour:min 24-hour clock	16:34
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 5

Form: Plasma Cotinine Samples <Day 5> (7)

Data signed: (hfarmer1) 30 Mar 2015 12:28:10

Generated On: 20 Jul 2016 22:42:34

Not Done	False
----------	-------

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	18 APR 2014
---------------------	-------------

Scheduled Time	T6 <input checked="" type="radio"/>
----------------	-------------------------------------

Time hour:min 24-hour clock	18:34
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 5

Form: Plasma Cotinine Samples <Day 5> (8)

Data signed: (hfarmer1) 30 Mar 2015 12:28:10

Generated On: 20 Jul 2016 22:42:34

Not Done	False
----------	-------

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	18 APR 2014
---------------------	-------------

Scheduled Time	T7 <input checked="" type="radio"/>
----------------	-------------------------------------

Time hour:min 24-hour clock	20:34
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 5

Form: Plasma Cotinine Samples <Day 5> (9)

Data signed: (hfarmer1) 30 Mar 2015 12:28:10

Generated On: 20 Jul 2016 22:42:34

Not Done	False
----------	-------

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	18 APR 2014
---------------------	-------------

Scheduled Time	T8 <input checked="" type="radio"/>
----------------	-------------------------------------

Time hour:min 24-hour clock	22:34
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 5

Form: CoHb Blood Sample(CC/THS) (1)

Data signed: (hfarmer1) 30 Mar 2015 12:28:10

Generated On: 20 Jul 2016 22:42:34

Not Done	False
----------	-------

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	18 APR 2014
---------------------	-------------

Scheduled Time	Within 15 min prior to smoking <input checked="" type="radio"/>
----------------	---

Time hour:min 24-hour clock	06:28
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 5

Form: CoHb Blood Sample(CC/THS) (2)

Data signed: (hfarmer1) 30 Mar 2015 12:28:10

Generated On: 20 Jul 2016 22:42:34

Not Done	False
----------	-------

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	18 APR 2014
---------------------	-------------

Scheduled Time	12:00 - 13:30 <input checked="" type="radio"/>
----------------	--

Time hour:min 24-hour clock	12:36
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 5

Form: CoHb Blood Sample(CC/THS) (3)

Data signed: (hfarmer1) 30 Mar 2015 12:28:10

Generated On: 20 Jul 2016 22:42:34

Not Done	False
----------	-------

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	18 APR 2014
---------------------	-------------

Scheduled Time	16:00 - 17:30 <input checked="" type="radio"/>
----------------	--

Time hour:min 24-hour clock	16:04
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 5

Form: CoHb Blood Sample(CC/THS) (4)

Data signed: (hfarmer1) 30 Mar 2015 12:28:10

Generated On: 20 Jul 2016 22:42:34

Not Done	False
----------	-------

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	18 APR 2014
---------------------	-------------

Scheduled Time	20:00 - 21:30 <input checked="" type="radio"/>
----------------	--

Time hour:min 24-hour clock	20:34
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 5

Form: CO Breath Test (1)

Data signed: (hfarmer1) 30 Mar 2015 12:28:10

Generated On: 20 Jul 2016 22:42:34

Assessment not done	False
---------------------	-------

If Not Done, please specify the reason: _____

Scheduled Time	Within 15 min prior to smoking <input checked="" type="radio"/>
----------------	---

Actual Time of Assessment hour:min 24-hour clock	06:23
---	-------

Result(ppm)	12
-------------	----

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 5

Form: CO Breath Test (2)

Data signed: (hfarmer1) 30 Mar 2015 12:28:10

Generated On: 20 Jul 2016 22:42:34

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	12:08
---	-------

Result(ppm)	20
-------------	----

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 5

Form: CO Breath Test (3)

Data signed: (hfarmer1) 30 Mar 2015 12:28:10

Generated On: 20 Jul 2016 22:42:34

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	16:08
---	-------

Result(ppm)	12
-------------	----

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 5

Form: CO Breath Test (4)

Data signed: (hfarmer1) 30 Mar 2015 12:28:10

Generated On: 20 Jul 2016 22:42:34

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	20:58
---	-------

Result(ppm)	26
-------------	----

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1261

Folder: Day 5

Form: CYP1A2 activity Sample

Data signed: (hfarmer1) 30 Mar 2015 12:28:08

Generated On: 20 Jul 2016 22:42:34

Time of caffeine tablet intake	10:04
	hour:min 24-hour clock

Sample collection Not Done	False
----------------------------	-------

If Not Done, please specify the reason: _____

Date of sample collection DD/MMM/YYYY	Time of sample collection hour:min 24-hour clock	Parameter
18 APR 2014	16:04	Caffeine
18 APR 2014	16:04	Paraxanthine

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 5

Form: 24 hour urine collections

Data signed: (hfarmer1) 30 Mar 2015 12:28:10

Generated On: 20 Jul 2016 22:42:34

Start Time	06:08
	hour:min 24-hour clock

End Date	19 APR 2014
	DD/MMM/YYYY

End Time	06:06
	hour:min 24-hour clock

Volume	2155
	mL

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 5

Form: Sample Urine Collection

Data signed: (hfarmer1) 30 Mar 2015 12:28:10

Generated On: 20 Jul 2016 22:42:34

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: 1261**

Folder: Day 5

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Data signed: (hfarmer1) 30 Mar 2015 12:28:11

Generated On: 20 Jul 2016 22:42:34

Date of Birth

(b) (6)

Date of assessment
DD/MMM/YYYY

2014 APR 18
DD/MMM/YYYY

Time of assessment

06:02
hour:min 24-hour clock

Assessment Status

Completed ☒

Please indicate for each of the items below, how you have been feeling over the past 24 hours

How have you been feeling over the past 24 hours?

None ☐

1. Angry, irritable, frustrated

How have you been feeling over the past 24 hours?

None ☐

2. Anxious, nervous

How have you been feeling over the past 24 hours?

None ☐

3. Depressed Mood, sad

How have you been feeling over the past 24 hours?

Moderate ☐

4. Desire or craving to smoke

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 5

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Data signed: (hfarmer1) 30 Mar 2015 12:28:11

Generated On: 20 Jul 2016 22:42:34

How have you been feeling over the past 24 hours? None ☐

5. Difficulty concentrating

How have you been feeling over the past 24 hours? Slight ☐

6. Increased appetite, hungry, weight gain

How have you been feeling over the past 24 hours? None ☐

7. Insomnia, sleep problems, awakening at night

How have you been feeling over the past 24 hours? None ☐

8. Restless

How have you been feeling over the past 24 hours? 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? Slight ☐

12. Coughing

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 5

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Data signed: (hfarmer1) 30 Mar 2015 12:28:11

Generated On: 20 Jul 2016 22:42:34

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: 1261**

Folder: Day 5

Form: Cough Assessment

Data signed: (hfarmer1) 30 Mar 2015 12:28:11

Generated On: 20 Jul 2016 22:42:34

Date of Birth

(b) (6)

Date of assessment
DD/MMM/YYYY

2014 APR 18
DD/MMM/YYYY

Time of assessment

06:01
hour:min 24-hour clock

Assessment Status

Completed ☒

Have you experienced a regular need to cough e.g.
coughing several times in the last 24 hrs?

Yes ☒

If YES, please answer the following questions:

First Question: Cough Impact Scale
How much is your cough bothering you?

6

Second Question: Cough Intensity Scale:
How intense is your cough?

Very mild ☒

Third Question: Cough Frequency Scale:
How frequently do you normally have to cough each
day?

Rarely ☒

Fourth Question: Sputum Production
To what extent do you produce sputum when coughing?

No sputum ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 5

Form: Lab_BU_COHB (1)

Data signed: (hfarmer1) 30 Mar 2015 12:28:11

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05115150004280
----------------	----------------

Analyte	CARBOXYHEMOGLOBIN
---------	-------------------

Sample type	BLOOD
-------------	-------

Result	4.40
--------	------

Result Unit	%
-------------	---

Lab Status	OK
------------	----

Sample comment	
----------------	--

Detection method	SPECTROPHOTOMETRIC
------------------	--------------------

Lower limit of quantification	0.500
-------------------------------	-------

Planned time point (Hour)	6
---------------------------	---

Day of Visit	5
--------------	---

Celerion Study Number	AA99128-16
-----------------------	------------

Date of Collection	2014-APR-18
--------------------	-------------

Timepoint-minutes	
-------------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 5

Form: Lab_BU_COHB (1)

Data signed: (hfarmer1) 30 Mar 2015 12:28:11

Generated On: 20 Jul 2016 22:42:34

Start Day (24 hour urine only)

End Day (24 hour Urine Only)

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 5

Form: Lab_BU_COHB (2)

Data signed: (hfarmer1) 30 Mar 2015 12:28:11

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05115150004281
----------------	----------------

Analyte	CARBOXYHEMOGLOBIN
---------	-------------------

Sample type	BLOOD
-------------	-------

Result	6.00
--------	------

Result Unit	%
-------------	---

Lab Status	OK
------------	----

Sample comment	
----------------	--

Detection method	SPECTROPHOTOMETRIC
------------------	--------------------

Lower limit of quantification	0.500
-------------------------------	-------

Planned time point (Hour)	12
---------------------------	----

Day of Visit	5
--------------	---

Celerion Study Number	AA99128-16
-----------------------	------------

Date of Collection	2014-APR-18
--------------------	-------------

Timepoint-minutes	
-------------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 5

Form: Lab_BU_COHB (2)

Data signed: (hfarmer1) 30 Mar 2015 12:28:11

Generated On: 20 Jul 2016 22:42:34

Start Day (24 hour urine only)

End Day (24 hour Urine Only)

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 5

Form: Lab_BU_COHB (3)

Data signed: (hfarmer1) 30 Mar 2015 12:28:11

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05115150004282
----------------	----------------

Analyte	CARBOXYHEMOGLOBIN
---------	-------------------

Sample type	BLOOD
-------------	-------

Result	5.30
--------	------

Result Unit	%
-------------	---

Lab Status	OK
------------	----

Sample comment	
----------------	--

Detection method	SPECTROPHOTOMETRIC
------------------	--------------------

Lower limit of quantification	0.500
-------------------------------	-------

Planned time point (Hour)	16
---------------------------	----

Day of Visit	5
--------------	---

Celerion Study Number	AA99128-16
-----------------------	------------

Date of Collection	2014-APR-18
--------------------	-------------

Timepoint-minutes	
-------------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 5

Form: Lab_BU_COHB (3)

Data signed: (hfarmer1) 30 Mar 2015 12:28:11

Generated On: 20 Jul 2016 22:42:34

Start Day (24 hour urine only) _____

End Day (24 hour Urine Only) _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 5

Form: Lab_BU_COHB (4)

Data signed: (hfarmer1) 30 Mar 2015 12:28:11

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05115150004283
----------------	----------------

Analyte	CARBOXYHEMOGLOBIN
---------	-------------------

Sample type	BLOOD
-------------	-------

Result	6.10
--------	------

Result Unit	%
-------------	---

Lab Status	OK
------------	----

Sample comment	
----------------	--

Detection method	SPECTROPHOTOMETRIC
------------------	--------------------

Lower limit of quantification	0.500
-------------------------------	-------

Planned time point (Hour)	20
---------------------------	----

Day of Visit	5
--------------	---

Celerion Study Number	AA99128-16
-----------------------	------------

Date of Collection	2014-APR-18
--------------------	-------------

Timepoint-minutes	
-------------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 5

Form: Lab_BU_COHB (4)

Data signed: (hfarmer1) 30 Mar 2015 12:28:11

Generated On: 20 Jul 2016 22:42:34

Start Day (24 hour urine only)

End Day (24 hour Urine Only)

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 5

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)

Data signed: (hfarmer1) 30 Mar 2015 12:28:11

Generated On: 20 Jul 2016 22:42:34

Date of Birth

(b) (6)

Date of assessment

2014 APR 18

DD/MMM/YYYY

DD/MMM/YYYY

Time of assessment

20:02

hour:min 24-hour clock

Assessment Status

Completed ☒

1. Was smoking satisfying?

Moderately ☒

2. Did cigarettes taste good?

Little ☒

3. Did you enjoy the sensation in your throat and chest?

Little ☒

4. Did smoking calm you down?

Not at all ☒

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?

Very little ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 5

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)

Data signed: (hfarmer1) 30 Mar 2015 12:28:11

Generated On: 20 Jul 2016 22:42:34

9. Did smoking make you dizzy? Not at all ☐

10. Did smoking make you nauseous? Not at all ☐

11. Did smoking immediately relieve your craving for a
cigarette? Moderately ☐

12. Did you enjoy smoking? Extremely ☐

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 5

Form: Behavioral Risk Factor Surveillance System Questionnaire

Data signed: (hfarmer1) 30 Mar 2015 12:28:08

Generated On: 20 Jul 2016 22:42:34

Type	BEHAVIORAL RISK FACTOR SURVEILLANCE SYSTEM QUESTIONNAIRE
------	--

Was paper questionnaire used?	Yes <input type="radio"/>
-------------------------------	---------------------------

Reason not done	<hr/>
-----------------	-------

Date of assessment	18 APR 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: 1261**

Folder: Day 5

Form: Behavioral Risk Factor Surveillance System Questionnaire

Data signed: (hfarmer1) 30 Mar 2015 12:28:08

Generated On: 20 Jul 2016 22:42:34

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: 1261

Folder: Day 5

Form: Smoking Questionnaire (SQ)

Data signed: (hfarmer1) 30 Mar 2015 12:28:08

Generated On: 20 Jul 2016 22:42:34

Type	SMOKING QUESTIONNAIRE
------	-----------------------

Was paper questionnaire used?	Yes <input checked="" type="radio"/>
-------------------------------	--------------------------------------

Reason not done	<hr/>
-----------------	-------

Date of assessment	18 APR 2014 DD/MMM/YYYY
--------------------	----------------------------

Time of assessment	20:23 hour:min 24-hour clock
--------------------	---------------------------------

1. What is your current cigarette smoking behavior (including hand-rolled cigarettes)?	Daily smoker (at least one cigarette per day, disregarding religious fasting) <input checked="" type="radio"/>
--	--

2. Have you ever smoked 100 cigarettes or more in your life?	Yes <input checked="" type="radio"/>
--	--------------------------------------

3. Did you ever smoke cigarettes regularly, i.e. at least 1 cigarette per day?	Yes <input checked="" type="radio"/>
--	--------------------------------------

4. If you ever smoked cigarettes regularly: At what age did you start to smoke regularly?	11 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: 1261**

Folder: Day 5

Form: Smoking Questionnaire (SQ)

Data signed: (hfarmer1) 30 Mar 2015 12:28:08

Generated On: 20 Jul 2016 22:42:34

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? L&M MENTHOL 100'S

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1261

Folder: Day 5

Form: Smoking Questionnaire (SQ) (1)

Data signed: (hfarmer1) 30 Mar 2015 12:28:08

Generated On: 20 Jul 2016 22:42:34

Type	SMOKING QUESTIONNAIRE
------	-----------------------

Was paper questionnaire used?	Yes <input checked="" type="radio"/>
-------------------------------	--------------------------------------

Reason not done	<hr/>
-----------------	-------

Date of assessment	18 APR 2014 DD/MMM/YYYY
--------------------	----------------------------

Time of assessment	20:23 hour:min 24-hour clock
--------------------	---------------------------------

1. What is your current cigarette smoking behavior (including hand-rolled cigarettes)?	Daily smoker (at least one cigarette per day, disregarding religious fasting) <input checked="" type="radio"/>
--	--

2. Have you ever smoked 100 cigarettes or more in your life?	Yes <input checked="" type="radio"/>
--	--------------------------------------

3. Did you ever smoke cigarettes regularly, i.e. at least 1 cigarette per day?	Yes <input checked="" type="radio"/>
--	--------------------------------------

4. If you ever smoked cigarettes regularly: At what age did you start to smoke regularly?	11 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: 1261**

Folder: Day 5

Form: Smoking Questionnaire (SQ) (1)

Data signed: (hfarmer1) 30 Mar 2015 12:28:08

Generated On: 20 Jul 2016 22:42:34

Months

Days

6. If you ever quit regular cigarette smoking: For how long did you quit altogether?
(Please add together any separate periods of quitting)

Years

00 Years

Months

00 Months

Days

00 Days

7. What brand of cigarettes/hand-rolled tobacco did you predominantly smoke in the last 12 months of smoking?

Time

Currently (last 3 months) ☒

8. On average, how many Manufactured cigarettes
do/did you smoke per day?

Manufactured Cigarettes
per day

20

8. On average, how many Hand-rolled Cigarettes do/did
you smoke per day?

None ☒

Hand-rolled Cigarettes
per day

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 5

Form: Smoking Questionnaire (SQ) (1)

Data signed: (hfarmer1) 30 Mar 2015 12:28:08

Generated On: 20 Jul 2016 22:42:34

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: 1261

Folder: Day 5

Form: Smoking Questionnaire (SQ) (2)

Data signed: (hfarmer1) 30 Mar 2015 12:28:08

Generated On: 20 Jul 2016 22:42:34

Type	SMOKING QUESTIONNAIRE
------	-----------------------

Was paper questionnaire used?	Yes <input type="radio"/>
-------------------------------	---------------------------

Reason not done	<hr/>
-----------------	-------

Date of assessment	18 APR 2014 DD/MMM/YYYY
--------------------	----------------------------

Time of assessment	20:23 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?	11 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: 1261

Folder: Day 5

Form: Smoking Questionnaire (SQ) (2)

Data signed: (hfarmer1) 30 Mar 2015 12:28:08

Generated On: 20 Jul 2016 22:42:34

Months

Days

6. If you ever quit regular cigarette smoking: For how long did you quit altogether?
(Please add together any separate periods of quitting)

Years

00 Years

Months

00 Months

Days

00 Days

7. What brand of cigarettes/hand-rolled tobacco did you predominantly smoke in the last 12 months of smoking?

Time

1 year ago ☒

8. On average, how many Manufactured cigarettes do/did you smoke per day?

Manufactured Cigarettes
per day

20

8. On average, how many Hand-rolled Cigarettes do/did you smoke per day?

None ☒

Hand-rolled Cigarettes
per day

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 5

Form: Smoking Questionnaire (SQ) (2)

Data signed: (hfarmer1) 30 Mar 2015 12:28:08

Generated On: 20 Jul 2016 22:42:34

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: 1261

Folder: Day 5

Form: Smoking Questionnaire (SQ) (3)

Data signed: (hfarmer1) 30 Mar 2015 12:28:08

Generated On: 20 Jul 2016 22:42:34

Type	SMOKING QUESTIONNAIRE
------	-----------------------

Was paper questionnaire used?	Yes <input checked="" type="radio"/>
-------------------------------	--------------------------------------

Reason not done	<hr/>
-----------------	-------

Date of assessment	18 APR 2014 DD/MMM/YYYY
--------------------	----------------------------

Time of assessment	20:23 hour:min 24-hour clock
--------------------	---------------------------------

1. What is your current cigarette smoking behavior (including hand-rolled cigarettes)?	Daily smoker (at least one cigarette per day, disregarding religious fasting) <input checked="" type="radio"/>
--	--

2. Have you ever smoked 100 cigarettes or more in your life?	Yes <input checked="" type="radio"/>
--	--------------------------------------

3. Did you ever smoke cigarettes regularly, i.e. at least 1 cigarette per day?	Yes <input checked="" type="radio"/>
--	--------------------------------------

4. If you ever smoked cigarettes regularly: At what age did you start to smoke regularly?	11 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: 1261

Folder: Day 5

Form: Smoking Questionnaire (SQ) (3)

Data signed: (hfarmer1) 30 Mar 2015 12:28:08

Generated On: 20 Jul 2016 22:42:34

Months

Days

6. If you ever quit regular cigarette smoking: For how long did you quit altogether?
(Please add together any separate periods of quitting)

Years

00 Years

Months

00 Months

Days

00 Days

7. What brand of cigarettes/hand-rolled tobacco did you predominantly smoke in the last 12 months of smoking?

Time

5 years ago ☒

8. On average, how many Manufactured cigarettes do/did you smoke per day?

Manufactured Cigarettes
per day

20

8. On average, how many Hand-rolled Cigarettes do/did you smoke per day?

None ☒

Hand-rolled Cigarettes
per day

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 5

Form: Smoking Questionnaire (SQ) (3)

Data signed: (hfarmer1) 30 Mar 2015 12:28:08

Generated On: 20 Jul 2016 22:42:34

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: 1261

Folder: Day 5

Form: Smoking Questionnaire (SQ) (4)

Data signed: (hfarmer1) 30 Mar 2015 12:28:08

Generated On: 20 Jul 2016 22:42:34

Type	SMOKING QUESTIONNAIRE
------	-----------------------

Was paper questionnaire used?	Yes <input checked="" type="radio"/>
-------------------------------	--------------------------------------

Reason not done	<hr/>
-----------------	-------

Date of assessment	18 APR 2014 DD/MMM/YYYY
--------------------	----------------------------

Time of assessment	20:23 hour:min 24-hour clock
--------------------	---------------------------------

1. What is your current cigarette smoking behavior (including hand-rolled cigarettes)?	Daily smoker (at least one cigarette per day, disregarding religious fasting) <input checked="" type="radio"/>
--	--

2. Have you ever smoked 100 cigarettes or more in your life?	Yes <input checked="" type="radio"/>
--	--------------------------------------

3. Did you ever smoke cigarettes regularly, i.e. at least 1 cigarette per day?	Yes <input checked="" type="radio"/>
--	--------------------------------------

4. If you ever smoked cigarettes regularly: At what age did you start to smoke regularly?	11 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: 1261

Folder: Day 5

Form: Smoking Questionnaire (SQ) (4)

Data signed: (hfarmer1) 30 Mar 2015 12:28:08

Generated On: 20 Jul 2016 22:42:34

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

20

8. On average, how many Hand-rolled Cigarettes do/did you smoke per day?

None ☒

Hand-rolled Cigarettes
per day

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 5

Form: Smoking Questionnaire (SQ) (4)

Data signed: (hfarmer1) 30 Mar 2015 12:28:08

Generated On: 20 Jul 2016 22:42:34

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: 1261

Folder: Day 5

Form: Smoking Questionnaire (SQ) (5)

Data signed: (hfarmer1) 30 Mar 2015 12:28:08

Generated On: 20 Jul 2016 22:42:34

Type	SMOKING QUESTIONNAIRE
------	-----------------------

Was paper questionnaire used?	Yes <input checked="" type="radio"/>
-------------------------------	--------------------------------------

Reason not done	<hr/>
-----------------	-------

Date of assessment	18 APR 2014 DD/MMM/YYYY
--------------------	----------------------------

Time of assessment	20:23 hour:min 24-hour clock
--------------------	---------------------------------

1. What is your current cigarette smoking behavior (including hand-rolled cigarettes)?	Daily smoker (at least one cigarette per day, disregarding religious fasting) <input checked="" type="radio"/>
--	--

2. Have you ever smoked 100 cigarettes or more in your life?	Yes <input checked="" type="radio"/>
--	--------------------------------------

3. Did you ever smoke cigarettes regularly, i.e. at least 1 cigarette per day?	Yes <input checked="" type="radio"/>
--	--------------------------------------

4. If you ever smoked cigarettes regularly: At what age did you start to smoke regularly?	11 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: 1261

Folder: Day 5

Form: Smoking Questionnaire (SQ) (5)

Data signed: (hfarmer1) 30 Mar 2015 12:28:08

Generated On: 20 Jul 2016 22:42:34

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

10

8. On average, how many Hand-rolled Cigarettes do/did you smoke per day?

None ☒

Hand-rolled Cigarettes
per day

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 5

Form: Smoking Questionnaire (SQ) (5)

Data signed: (hfarmer1) 30 Mar 2015 12:28:08

Generated On: 20 Jul 2016 22:42:34

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: 1261

Folder: Day 5

Form: Smoking Questionnaire (SQ) (6)

Data signed: (hfarmer1) 30 Mar 2015 12:28:08

Generated On: 20 Jul 2016 22:42:34

Type	SMOKING QUESTIONNAIRE
------	-----------------------

Was paper questionnaire used?	Yes <input checked="" type="radio"/>
-------------------------------	--------------------------------------

Reason not done	<hr/>
-----------------	-------

Date of assessment	18 APR 2014 DD/MMM/YYYY
--------------------	----------------------------

Time of assessment	20:23 hour:min 24-hour clock
--------------------	---------------------------------

1. What is your current cigarette smoking behavior (including hand-rolled cigarettes)?	Daily smoker (at least one cigarette per day, disregarding religious fasting) <input checked="" type="radio"/>
--	--

2. Have you ever smoked 100 cigarettes or more in your life?	Yes <input checked="" type="radio"/>
--	--------------------------------------

3. Did you ever smoke cigarettes regularly, i.e. at least 1 cigarette per day?	Yes <input checked="" type="radio"/>
--	--------------------------------------

4. If you ever smoked cigarettes regularly: At what age did you start to smoke regularly?	11 Years
---	----------

5. If you are an ex-smoker of cigarettes: For how long have you quit now?	
---	--

Years	<hr/>
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1261

Folder: Day 5

Form: Smoking Questionnaire (SQ) (6)

Data signed: (hfarmer1) 30 Mar 2015 12:28:08

Generated On: 20 Jul 2016 22:42:34

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 10

8. On average, how many Hand-rolled Cigarettes do/did you smoke per day? None ☒

Hand-rolled Cigarettes per day

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 5

Form: Smoking Questionnaire (SQ) (6)

Data signed: (hfarmer1) 30 Mar 2015 12:28:08

Generated On: 20 Jul 2016 22:42:34

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: 1261

Folder: Day 5

Form: Smoking Questionnaire (SQ) (7)

Data signed: (hfarmer1) 30 Mar 2015 12:28:08

Generated On: 20 Jul 2016 22:42:34

Type	SMOKING QUESTIONNAIRE
------	-----------------------

Was paper questionnaire used?	Yes <input checked="" type="radio"/>
-------------------------------	--------------------------------------

Reason not done	<hr/>
-----------------	-------

Date of assessment	18 APR 2014 DD/MMM/YYYY
--------------------	----------------------------

Time of assessment	20:23 hour:min 24-hour clock
--------------------	---------------------------------

1. What is your current cigarette smoking behavior (including hand-rolled cigarettes)?	Daily smoker (at least one cigarette per day, disregarding religious fasting) <input checked="" type="radio"/>
--	--

2. Have you ever smoked 100 cigarettes or more in your life?	Yes <input checked="" type="radio"/>
--	--------------------------------------

3. Did you ever smoke cigarettes regularly, i.e. at least 1 cigarette per day?	Yes <input checked="" type="radio"/>
--	--------------------------------------

4. If you ever smoked cigarettes regularly: At what age did you start to smoke regularly?	11 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: 1261

Folder: Day 5

Form: Smoking Questionnaire (SQ) (7)

Data signed: (hfarmer1) 30 Mar 2015 12:28:08

Generated On: 20 Jul 2016 22:42:34

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

10

8. On average, how many Hand-rolled Cigarettes do/did you smoke per day?

None ☒

Hand-rolled Cigarettes
per day

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 5

Form: Smoking Questionnaire (SQ) (7)

Data signed: (hfarmer1) 30 Mar 2015 12:28:08

Generated On: 20 Jul 2016 22:42:34

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: 1261**

Folder: Day 5

Form: Supplemental Questions

Data signed: (hfarmer1) 30 Mar 2015 12:28:09

Generated On: 20 Jul 2016 22:42:34

Was paper questionnaire used?

Yes ☒

Reason not done

Date of Assessment

18 APR 2014
DD/MMM/YYYY

Time of assessment

20:24

1. How long it takes for the subject to complete the SQ

04 minutes

Comments (open-end)

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 5

Form: Supplemental Questions (1)

Data signed: (hfarmer1) 30 Mar 2015 12:28:09

Generated On: 20 Jul 2016 22:42:34

Was paper questionnaire used? Yes ☐

Reason not done _____

Date of Assessment 18 APR 2014
DD/MMM/YYYY

Time of assessment 20:24

1. How long it takes for the subject to complete the SQ 04 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: 1261**

Folder: Day 5

Form: Supplemental Questions (2)

Data signed: (hfarmer1) 30 Mar 2015 12:28:09

Generated On: 20 Jul 2016 22:42:34

Was paper questionnaire used? Yes ☐

Reason not done _____

Date of Assessment 18 APR 2014
DD/MMM/YYYY

Time of assessment 20:24

1. How long it takes for the subject to complete the SQ 04 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: 1261

Folder: Day 5

Form: Supplemental Questions (3)

Data signed: (hfarmer1) 30 Mar 2015 12:28:09

Generated On: 20 Jul 2016 22:42:34

Was paper questionnaire used? Yes ☐

Reason not done _____

Date of Assessment 18 APR 2014
DD/MMM/YYYY

Time of assessment 20:24

1. How long it takes for the subject to complete the SQ 04 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: 1261

Folder: Day 5

Form: Supplemental Questions (4)

Data signed: (hfarmer1) 30 Mar 2015 12:28:09

Generated On: 20 Jul 2016 22:42:34

Was paper questionnaire used? Yes ☐

Reason not done _____

Date of Assessment 18 APR 2014
DD/MMM/YYYY

Time of assessment 20:24

1. How long it takes for the subject to complete the SQ 04 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: 1261**

Folder: Day 5

Form: Supplemental Questions (5)

Data signed: (hfarmer1) 30 Mar 2015 12:28:09

Generated On: 20 Jul 2016 22:42:34

Was paper questionnaire used? Yes ☐

Reason not done _____

Date of Assessment 18 APR 2014
DD/MMM/YYYY

Time of assessment 20:24

1. How long it takes for the subject to complete the SQ 04 minutes

Question 6. Was the SQ self-explaining? ☐

Answer Yes ☐

Comments (open-end) _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 5

Form: Supplemental Questions (6)

Data signed: (hfarmer1) 30 Mar 2015 12:28:09

Generated On: 20 Jul 2016 22:42:34

Was paper questionnaire used? Yes ☒

Reason not done _____

Date of Assessment 18 APR 2014
DD/MMM/YYYY

Time of assessment 20:24

1. How long it takes for the subject to complete the SQ 04 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: 1261**

Folder: Day 5

Form: Questionnaire on smoking urges (QSU)

Data signed: (hfarmer1) 30 Mar 2015 12:28:11

Generated On: 20 Jul 2016 22:42:34

Type	QSU
------	-----

Date of Birth	(b) (6)
---------------	---------

Date of assessment	2014 APR 18
--------------------	-------------

DD/MMM/YYYY

Time of assessment	20:01
--------------------	-------

hour:min 24-hour clock

Assessment Status	Completed <input checked="" type="radio"/>
-------------------	--

1. I have a desire for a cigarette right now	Do not agree or disagree <input checked="" type="radio"/>
--	---

2. Nothing would be better than smoking a cigarette right now	Do not agree or disagree <input checked="" type="radio"/>
---	---

3. If it were possible I would probably smoke now	Do not agree or disagree <input checked="" type="radio"/>
---	---

4. I could control things better right now if I could smoke	Strongly disagree <input checked="" type="radio"/>
---	--

5. All I want right now is a cigarette	Do not agree or disagree <input checked="" type="radio"/>
--	---

6. I have an urge for a cigarette	Do not agree or disagree <input checked="" type="radio"/>
-----------------------------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 5

Form: Questionnaire on smoking urges (QSU)

Data signed: (hfarmer1) 30 Mar 2015 12:28:11

Generated On: 20 Jul 2016 22:42:34

7. A cigarette would taste good now Do not agree or disagree ☐

8. I would do almost anything for a cigarette now Do not agree or disagree ☐

9. Smoking would make me less depressed Strongly disagree ☐

10. I am going to smoke as soon as possible Do not agree or disagree ☐

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 5

Form: Biomarker-Urine (CEMA, HPMa, HBMA)

Data signed: (hfarmer1) 30 Mar 2015 12:28:13

Generated On: 20 Jul 2016 22:42:34

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 5

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (1)

Data signed: (hfarmer1) 30 Mar 2015 12:28:13

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05112450002930
----------------	----------------

Analyte	HPMA
---------	------

Sample type	URINE
-------------	-------

Result	520
--------	-----

Result Unit	NG/ML
-------------	-------

Lab Status	OK
------------	----

Sample comment	
----------------	--

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	5
--------------	---

Celerion Study Number	AA99128-03
-----------------------	------------

Date of Collection	2014-APR-18
--------------------	-------------

Timepoint-minutes	
-------------------	--

Urine Start Day	5
-----------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 5

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (1)

Data signed: (hfarmer1) 30 Mar 2015 12:28:13

Generated On: 20 Jul 2016 22:42:34

Urine End Day

6

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 5

Form: Biomarker-Urine (CEMA, HPMa, HBMA) (2)

Data signed: (hfarmer1) 30 Mar 2015 12:28:13

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05112450002930
----------------	----------------

Analyte	CEMA
---------	------

Sample type	URINE
-------------	-------

Result	89.2
--------	------

Result Unit	NG/ML
-------------	-------

Lab Status	OK
------------	----

Sample comment	
----------------	--

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	5
--------------	---

Celerion Study Number	AA99128-03
-----------------------	------------

Date of Collection	2014-APR-18
--------------------	-------------

Timepoint-minutes	
-------------------	--

Urine Start Day	5
-----------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 5

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (2)

Data signed: (hfarmer1) 30 Mar 2015 12:28:13

Generated On: 20 Jul 2016 22:42:34

Urine End Day

6

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 5

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (3)

Data signed: (hfarmer1) 30 Mar 2015 12:28:13

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05112450002930
----------------	----------------

Analyte	HBMA
---------	------

Sample type	URINE
-------------	-------

Result	287
--------	-----

Result Unit	NG/ML
-------------	-------

Lab Status	OK
------------	----

Sample comment	
----------------	--

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	5
--------------	---

Celerion Study Number	AA99128-03
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Date of Collection	2014-APR-18
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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: 1261**

Folder: Day 5

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (3)

Data signed: (hfarmer1) 30 Mar 2015 12:28:13

Generated On: 20 Jul 2016 22:42:34

Urine End Day

6

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 5

Form: Biomarker-Urine (NNN, NNAL)

Data signed: (hfarmer1) 30 Mar 2015 12:28:12

Generated On: 20 Jul 2016 22:42:34

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 5

Form: Biomarker-Urine (NNN, NNAL) (1)

Data signed: (hfarmer1) 30 Mar 2015 12:28:12

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05112460003517
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Analyte	NNAL
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Sample type	URINE
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Result	288
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Result Unit	PG/ML
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Lab Status	OK
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Sample comment	
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Detection method	LC-MS/MS
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Planned time point (Hour)	0
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Day of Visit	5
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Celerion Study Number	AA99128-04
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Date of Collection	2014-APR-18
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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: 1261**

Folder: Day 5

Form: Biomarker-Urine (NNN, NNAL) (1)

Data signed: (hfarmer1) 30 Mar 2015 12:28:12

Generated On: 20 Jul 2016 22:42:34

Urine End Day

6

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 5

Form: Biomarker-Urine (NNN, NNAL) (2)

Data signed: (hfarmer1) 30 Mar 2015 12:28:12

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05112460003517
Analyte	NNN
Sample type	URINE
Result	13.8
Result Unit	PG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	5
Celerion Study Number	AA99128-04
Date of Collection	2014-APR-18
Timepoint-minutes	
Urine Start Day	5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 5

Form: Biomarker-Urine (NNN, NNAL) (2)

Data signed: (hfarmer1) 30 Mar 2015 12:28:12

Generated On: 20 Jul 2016 22:42:34

Urine End Day

6

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 5

Form: Biomarker-Urine (HEMA)

Data signed: (hfarmer1) 30 Mar 2015 12:28:12

Generated On: 20 Jul 2016 22:42:34

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 5

Form: Biomarker-Urine (HEMA) (1)

Data signed: (hfarmer1) 30 Mar 2015 12:28:12

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05112470001757
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Analyte	HEMA
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Sample type	URINE
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Result	11.1
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Result Unit	NG/ML
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Lab Status	OK
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Sample comment	
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Detection method	LC-MS/MS
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Planned time point (Hour)	0
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Day of Visit	5
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Celerion Study Number	AA99128-05
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Date of Collection	2014-APR-18
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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: 1261**

Folder: Day 5

Form: Biomarker-Urine (HEMA) (1)

Data signed: (hfarmer1) 30 Mar 2015 12:28:12

Generated On: 20 Jul 2016 22:42:34

Urine End Day

6

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 5

Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)

Data signed: (hfarmer1) 30 Mar 2015 12:28:13

Generated On: 20 Jul 2016 22:42:34

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 5

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(1)**

Data signed: (hfarmer1) 30 Mar 2015 12:28:13

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05112480001163
Analyte	COT
Sample type	URINE
Result	1330
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	5
Celerion Study Number	AA99128-06
Date of Collection	2014-APR-18
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 5

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(1)**

Data signed: (hfarmer1) 30 Mar 2015 12:28:13

Generated On: 20 Jul 2016 22:42:34

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: 1261**

Folder: Day 5

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(2)**

Data signed: (hfarmer1) 30 Mar 2015 12:28:13

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05112480001163
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Analyte	COT-GLUC
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Sample type	URINE
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Result	4380
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Result Unit	NG/ML
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Lab Status	OK
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Sample comment	
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Detection method	LC-MS/MS
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Planned time point (Hour)	0
---------------------------	---

Day of Visit	5
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Celerion Study Number	AA99128-06
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Date of Collection	2014-APR-18
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Timepoint-minutes	
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 5

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(2)**

Data signed: (hfarmer1) 30 Mar 2015 12:28:13

Generated On: 20 Jul 2016 22:42:34

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: 1261**

Folder: Day 5

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(3)**

Data signed: (hfarmer1) 30 Mar 2015 12:28:13

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05112480001163
Analyte	NIC
Sample type	URINE
Result	467
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	5
Celerion Study Number	AA99128-06
Date of Collection	2014-APR-18
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 5

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(3)**

Data signed: (hfarmer1) 30 Mar 2015 12:28:13

Generated On: 20 Jul 2016 22:42:34

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: 1261**

Folder: Day 5

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(4)**

Data signed: (hfarmer1) 30 Mar 2015 12:28:13

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05112480001163
Analyte	NIC-GLUC
Sample type	URINE
Result	888
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	5
Celerion Study Number	AA99128-06
Date of Collection	2014-APR-18
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 5

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(4)**

Data signed: (hfarmer1) 30 Mar 2015 12:28:13

Generated On: 20 Jul 2016 22:42:34

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: 1261**

Folder: Day 5

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(5)**

Data signed: (hfarmer1) 30 Mar 2015 12:28:13

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05112480001163
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Analyte	THCOT
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Sample type	URINE
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Result	2330
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Result Unit	NG/ML
-------------	-------

Lab Status	OK
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Sample comment	
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Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	5
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Celerion Study Number	AA99128-06
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Date of Collection	2014-APR-18
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Timepoint-minutes	
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 5

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(5)**

Data signed: (hfarmer1) 30 Mar 2015 12:28:13

Generated On: 20 Jul 2016 22:42:34

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: 1261**

Folder: Day 5

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(6)**

Data signed: (hfarmer1) 30 Mar 2015 12:28:13

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05112480001163
Analyte	THCOT-GLUC
Sample type	URINE
Result	756
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	5
Celerion Study Number	AA99128-06
Date of Collection	2014-APR-18
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 5

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(6)**

Data signed: (hfarmer1) 30 Mar 2015 12:28:13

Generated On: 20 Jul 2016 22:42:34

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: 1261**

Folder: Day 5

Form: Biomarker-Urine (3-OH BaP)

Data signed: (hfarmer1) 30 Mar 2015 12:28:13

Generated On: 20 Jul 2016 22:42:34

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 5

Form: Biomarker-Urine (3-OH BaP) (1)

Data signed: (hfarmer1) 30 Mar 2015 12:28:13

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05112490001757
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Analyte	3-OH BAP
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Sample type	URINE
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Result	130
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Result Unit	FG/ML
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Lab Status	OK
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Sample comment	
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Detection method	LC-MS/MS
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Planned time point (Hour)	0
---------------------------	---

Day of Visit	5
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Celerion Study Number	AA99128-07
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Date of Collection	2014-APR-18
--------------------	-------------

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: 1261**

Folder: Day 5

Form: Biomarker-Urine (3-OH BaP) (1)

Data signed: (hfarmer1) 30 Mar 2015 12:28:13

Generated On: 20 Jul 2016 22:42:34

Urine End Day

6

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 5

Form: Biomarker-Plasma (Caffeine, Paraxanthine)

Generated On: 20 Jul 2016 22:42:34

Sample type

PLASMA

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 5

Form: Biomarker-Plasma (Caffeine, Paraxanthine) (1)

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05112500000479
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Analyte	CAFFEINE
---------	----------

Sample type	PLASMA
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Result	918
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Result Unit	NG/ML
-------------	-------

Lab Status	OK
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Sample comment	
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Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	6
---------------------------	---

Day of Visit	5
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Celerion Study Number	AA99128-08
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Date of Collection	2014-APR-18
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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: 1261**

Folder: Day 5

Form: Biomarker-Plasma (Caffeine, Paraxanthine) (1)

Generated On: 20 Jul 2016 22:42:34

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 5

Form: Biomarker-Plasma (Caffeine, Paraxanthine) (2)

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05112500000479
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Analyte	PARAXANTHINE
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Sample type	PLASMA
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Result	1540
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Result Unit	NG/ML
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Lab Status	OK
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Sample comment	
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Detection method	LC-MS/MS
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Planned time point (Hour)	6
---------------------------	---

Day of Visit	5
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Celerion Study Number	AA99128-08
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Date of Collection	2014-APR-18
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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: 1261**

Folder: Day 5

Form: Biomarker-Plasma (Caffeine, Paraxanthine) (2)

Generated On: 20 Jul 2016 22:42:34

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 5

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP)

Data signed: (hfarmer1) 30 Mar 2015 12:28:13

Generated On: 20 Jul 2016 22:42:34

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 5

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (1)

Data signed: (hfarmer1) 30 Mar 2015 12:28:13

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05112510001779
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Analyte	1-NA
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Sample type	URINE
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Result	58.4
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Result Unit	PG/ML
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Lab Status	OK
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Sample comment	
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Detection method	LC-MS/MS
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Planned time point (Hour)	0
---------------------------	---

Day of Visit	5
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Celerion Study Number	AA99128-09
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Date of Collection	2014-APR-18
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Timepoint-minutes	
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Urine Start Day	5
-----------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 5

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (1)

Data signed: (hfarmer1) 30 Mar 2015 12:28:13

Generated On: 20 Jul 2016 22:42:34

Urine End Day

6

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 5

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (2)

Data signed: (hfarmer1) 30 Mar 2015 12:28:13

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05112510001779
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Analyte	2-NA
---------	------

Sample type	URINE
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Result	17.5
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Result Unit	PG/ML
-------------	-------

Lab Status	OK
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Sample comment	
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Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	5
--------------	---

Celerion Study Number	AA99128-09
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Date of Collection	2014-APR-18
--------------------	-------------

Timepoint-minutes	
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Urine Start Day	5
-----------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 5

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (2)

Data signed: (hfarmer1) 30 Mar 2015 12:28:13

Generated On: 20 Jul 2016 22:42:34

Urine End Day

6

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 5

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (3)

Data signed: (hfarmer1) 30 Mar 2015 12:28:13

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05112510001779
Analyte	4-ABP
Sample type	URINE
Result	11.5
Result Unit	PG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	5
Celerion Study Number	AA99128-09
Date of Collection	2014-APR-18
Timepoint-minutes	
Urine Start Day	5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 5

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (3)

Data signed: (hfarmer1) 30 Mar 2015 12:28:13

Generated On: 20 Jul 2016 22:42:34

Urine End Day

6

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 5

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (4)

Data signed: (hfarmer1) 30 Mar 2015 12:28:13

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05112510001779
Analyte	O-TOL
Sample type	URINE
Result	98.1
Result Unit	PG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	5
Celerion Study Number	AA99128-09
Date of Collection	2014-APR-18
Timepoint-minutes	
Urine Start Day	5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 5

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (4)

Data signed: (hfarmer1) 30 Mar 2015 12:28:13

Generated On: 20 Jul 2016 22:42:34

Urine End Day

6

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 5

Form: Biomarker-Urine (11-dTXb2)

Data signed: (hfarmer1) 30 Mar 2015 12:28:12

Generated On: 20 Jul 2016 22:42:34

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 5

Form: Biomarker-Urine (11-dTXb2) (1)

Data signed: (hfarmer1) 30 Mar 2015 12:28:12

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05112530000557
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Analyte	11-DTXB2
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Sample type	URINE
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Result	450
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Result Unit	PG/ML
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Lab Status	OK
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Sample comment	
----------------	--

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	AA99128-11
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Date of Collection	2014-APR-18
--------------------	-------------

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: 1261**

Folder: Day 5

Form: Biomarker-Urine (11-dTXb2) (1)

Data signed: (hfarmer1) 30 Mar 2015 12:28:12

Generated On: 20 Jul 2016 22:42:34

Urine End Day

6

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 5

Form: Biomarker-Urine (iPF2a-III)

Data signed: (hfarmer1) 30 Mar 2015 12:28:12

Generated On: 20 Jul 2016 22:42:34

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 5

Form: Biomarker-Urine (iPF2a-III) (1)

Data signed: (hfarmer1) 30 Mar 2015 12:28:12

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05112540000550
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Analyte	IPF2A-III
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Sample type	URINE
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Result	156
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Result Unit	PG/ML
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Lab Status	OK
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Sample comment	
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Detection method	LC-MS/MS
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Planned time point (Hour)	0
---------------------------	---

Day of Visit	5
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Celerion Study Number	AA99128-12
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Date of Collection	2014-APR-18
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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: 1261**

Folder: Day 5

Form: Biomarker-Urine (iPF2a-III) (1)

Data signed: (hfarmer1) 30 Mar 2015 12:28:12

Generated On: 20 Jul 2016 22:42:34

Urine End Day

6

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 5

Form: Biomarker-Urine (Ames)

Data signed: (hfarmer1) 30 Mar 2015 12:28:14

Generated On: 20 Jul 2016 22:42:34

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 5

Form: Biomarker-Urine (Ames) (1)

Data signed: (hfarmer1) 30 Mar 2015 12:28:14

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05113320000239
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Analyte	AMES
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Sample type	URINE
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Result	17.7
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Result Unit	REV/ML
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Lab Status	OK
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Sample comment	
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Detection method	COUNT
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Planned time point (Hour)	0
---------------------------	---

Day of Visit	5
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Celerion Study Number	AA99128-15
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Date of Collection	2014-APR-18
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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: 1261**

Folder: Day 5

Form: Biomarker-Urine (Ames) (1)

Data signed: (hfarmer1) 30 Mar 2015 12:28:14

Generated On: 20 Jul 2016 22:42:34

Urine End Day

6

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 5

Form: Biomarker-Urine (1-OHP)

Data signed: (hfarmer1) 30 Mar 2015 12:28:14

Generated On: 20 Jul 2016 22:42:34

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 5

Form: Biomarker-Urine (1-OHP) (1)

Data signed: (hfarmer1) 30 Mar 2015 12:28:14

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05115190003781
Analyte	1-OHP
Sample type	URINE
Result	134
Result Unit	PG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	5
Celerion Study Number	AA99598-03
Date of Collection	2014-APR-18
Timepoint-minutes	
Urine Start Day	5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 5

Form: Biomarker-Urine (1-OHP) (1)

Data signed: (hfarmer1) 30 Mar 2015 12:28:14

Generated On: 20 Jul 2016 22:42:34

Urine End Day

6

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 5

Form: Biomarker-Urine (SPMA, SBMA)

Data signed: (hfarmer1) 30 Mar 2015 12:28:12

Generated On: 20 Jul 2016 22:42:34

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 5

Form: Biomarker-Urine (SPMA, SBMA) (1)

Data signed: (hfarmer1) 30 Mar 2015 12:28:12

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05115170003772
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Analyte	SBMA
---------	------

Sample type	URINE
-------------	-------

Result	1.86
--------	------

Result Unit	NG/ML
-------------	-------

Lab Status	OK
------------	----

Sample comment	
----------------	--

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	5
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Celerion Study Number	AA99598-01
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Date of Collection	2014-APR-18
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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: 1261**

Folder: Day 5

Form: Biomarker-Urine (SPMA, SBMA) (1)

Data signed: (hfarmer1) 30 Mar 2015 12:28:12

Generated On: 20 Jul 2016 22:42:34

Urine End Day

6

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 5

Form: Biomarker-Urine (SPMA, SBMA) (2)

Data signed: (hfarmer1) 30 Mar 2015 12:28:12

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05115170003772
----------------	----------------

Analyte	SPMA
---------	------

Sample type	URINE
-------------	-------

Result	3.10
--------	------

Result Unit	NG/ML
-------------	-------

Lab Status	OK
------------	----

Sample comment	
----------------	--

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	5
--------------	---

Celerion Study Number	AA99598-01
-----------------------	------------

Date of Collection	2014-APR-18
--------------------	-------------

Timepoint-minutes	
-------------------	--

Urine Start Day	5
-----------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 5

Form: Biomarker-Urine (SPMA, SBMA) (2)

Data signed: (hfarmer1) 30 Mar 2015 12:28:12

Generated On: 20 Jul 2016 22:42:34

Urine End Day

6

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 5

Form: Biomarker-Urine (MHBMA)

Data signed: (hfarmer1) 30 Mar 2015 12:28:12

Generated On: 20 Jul 2016 22:42:34

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 5

Form: Biomarker-Urine (MHBMA) (1)

Data signed: (hfarmer1) 30 Mar 2015 12:28:12

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05115180003781
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Analyte	MHBMA
---------	-------

Sample type	URINE
-------------	-------

Result	1.86
--------	------

Result Unit	NG/ML
-------------	-------

Lab Status	OK
------------	----

Sample comment	
----------------	--

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	5
--------------	---

Celerion Study Number	AA99598-02
-----------------------	------------

Date of Collection	2014-APR-18
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Timepoint-minutes	
-------------------	--

Urine Start Day	5
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 5

Form: Biomarker-Urine (MHBMA) (1)

Data signed: (hfarmer1) 30 Mar 2015 12:28:12

Generated On: 20 Jul 2016 22:42:34

Urine End Day

6

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 5

Form: Biomarker-Urine (Creatinine)

Data signed: (hfarmer1) 30 Mar 2015 12:28:14

Generated On: 20 Jul 2016 22:42:34

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 5

Form: Biomarker-Urine (Creatinine) (1)

Data signed: (hfarmer1) 30 Mar 2015 12:28:14

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05115160001757
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Analyte	CREATININE
---------	------------

Sample type	URINE
-------------	-------

Result	64.1
--------	------

Result Unit	MG/DL
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Lab Status	OK
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Sample comment	
----------------	--

Detection method	SPECTROPHOTOMETRIC
------------------	--------------------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	5
--------------	---

Celerion Study Number	AA99128-14
-----------------------	------------

Date of Collection	2014-APR-18
--------------------	-------------

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: 1261**

Folder: Day 5

Form: Biomarker-Urine (Creatinine) (1)

Data signed: (hfarmer1) 30 Mar 2015 12:28:14

Generated On: 20 Jul 2016 22:42:34

Urine End Day

6

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot)

Data signed: (hfarmer1) 30 Mar 2015 12:28:12

Generated On: 20 Jul 2016 22:42:34

Sample type

PLASMA

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (1)

Data signed: (hfarmer1) 30 Mar 2015 12:28:12

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05112430002001
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Analyte	COT
---------	-----

Sample type	PLASMA
-------------	--------

Result	226
--------	-----

Result Unit	NG/ML
-------------	-------

Lab Status	OK
------------	----

Sample comment	
----------------	--

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	5
--------------	---

Celerion Study Number	AA99128-01
-----------------------	------------

Date of Collection	2014-APR-18
--------------------	-------------

Timepoint-minutes	-15
-------------------	-----

Urine Start Day	
-----------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (1)

Data signed: (hfarmer1) 30 Mar 2015 12:28:12

Generated On: 20 Jul 2016 22:42:34

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (2)

Data signed: (hfarmer1) 30 Mar 2015 12:28:12

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05112430002001
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Analyte	NIC
---------	-----

Sample type	PLASMA
-------------	--------

Result	2.06
--------	------

Result Unit	NG/ML
-------------	-------

Lab Status	OK
------------	----

Sample comment	
----------------	--

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	5
--------------	---

Celerion Study Number	AA99128-01
-----------------------	------------

Date of Collection	2014-APR-18
--------------------	-------------

Timepoint-minutes	-15
-------------------	-----

Urine Start Day	
-----------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (2)

Data signed: (hfarmer1) 30 Mar 2015 12:28:12

Generated On: 20 Jul 2016 22:42:34

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (3)

Data signed: (hfarmer1) 30 Mar 2015 12:28:12

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05112430002002
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Analyte	COT
---------	-----

Sample type	PLASMA
-------------	--------

Result	217
--------	-----

Result Unit	NG/ML
-------------	-------

Lab Status	OK
------------	----

Sample comment	
----------------	--

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	2
---------------------------	---

Day of Visit	5
--------------	---

Celerion Study Number	AA99128-01
-----------------------	------------

Date of Collection	2014-APR-18
--------------------	-------------

Timepoint-minutes	0
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Urine Start Day	
-----------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (3)

Data signed: (hfarmer1) 30 Mar 2015 12:28:12

Generated On: 20 Jul 2016 22:42:34

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (4)

Data signed: (hfarmer1) 30 Mar 2015 12:28:12

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05112430002002
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Analyte	NIC
---------	-----

Sample type	PLASMA
-------------	--------

Result	8.07
--------	------

Result Unit	NG/ML
-------------	-------

Lab Status	OK
------------	----

Sample comment	
----------------	--

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	2
---------------------------	---

Day of Visit	5
--------------	---

Celerion Study Number	AA99128-01
-----------------------	------------

Date of Collection	2014-APR-18
--------------------	-------------

Timepoint-minutes	0
-------------------	---

Urine Start Day	
-----------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (4)

Data signed: (hfarmer1) 30 Mar 2015 12:28:12

Generated On: 20 Jul 2016 22:42:34

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (5)

Data signed: (hfarmer1) 30 Mar 2015 12:28:12

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05112430002003
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Analyte	COT
---------	-----

Sample type	PLASMA
-------------	--------

Result	219
--------	-----

Result Unit	NG/ML
-------------	-------

Lab Status	OK
------------	----

Sample comment	
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Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	4
---------------------------	---

Day of Visit	5
--------------	---

Celerion Study Number	AA99128-01
-----------------------	------------

Date of Collection	2014-APR-18
--------------------	-------------

Timepoint-minutes	0
-------------------	---

Urine Start Day	
-----------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (5)

Data signed: (hfarmer1) 30 Mar 2015 12:28:12

Generated On: 20 Jul 2016 22:42:34

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (6)

Data signed: (hfarmer1) 30 Mar 2015 12:28:12

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05112430002003
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Analyte	NIC
---------	-----

Sample type	PLASMA
-------------	--------

Result	9.94
--------	------

Result Unit	NG/ML
-------------	-------

Lab Status	OK
------------	----

Sample comment	
----------------	--

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	4
---------------------------	---

Day of Visit	5
--------------	---

Celerion Study Number	AA99128-01
-----------------------	------------

Date of Collection	2014-APR-18
--------------------	-------------

Timepoint-minutes	0
-------------------	---

Urine Start Day	
-----------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (6)

Data signed: (hfarmer1) 30 Mar 2015 12:28:12

Generated On: 20 Jul 2016 22:42:34

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (7)

Data signed: (hfarmer1) 30 Mar 2015 12:28:12

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05112430002004
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Analyte	COT
---------	-----

Sample type	PLASMA
-------------	--------

Result	233
--------	-----

Result Unit	NG/ML
-------------	-------

Lab Status	OK
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Sample comment	
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Detection method	LC-MS/MS
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Planned time point (Hour)	6
---------------------------	---

Day of Visit	5
--------------	---

Celerion Study Number	AA99128-01
-----------------------	------------

Date of Collection	2014-APR-18
--------------------	-------------

Timepoint-minutes	0
-------------------	---

Urine Start Day	
-----------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (7)

Data signed: (hfarmer1) 30 Mar 2015 12:28:12

Generated On: 20 Jul 2016 22:42:34

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (8)

Data signed: (hfarmer1) 30 Mar 2015 12:28:12

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05112430002004
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Analyte	NIC
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Sample type	PLASMA
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Result	17.2
--------	------

Result Unit	NG/ML
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Lab Status	OK
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Sample comment	
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Detection method	LC-MS/MS
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Planned time point (Hour)	6
---------------------------	---

Day of Visit	5
--------------	---

Celerion Study Number	AA99128-01
-----------------------	------------

Date of Collection	2014-APR-18
--------------------	-------------

Timepoint-minutes	0
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Urine Start Day	
-----------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (8)

Data signed: (hfarmer1) 30 Mar 2015 12:28:12

Generated On: 20 Jul 2016 22:42:34

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (9)

Data signed: (hfarmer1) 30 Mar 2015 12:28:12

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05112430002005
----------------	----------------

Analyte	COT
---------	-----

Sample type	PLASMA
-------------	--------

Result	232
--------	-----

Result Unit	NG/ML
-------------	-------

Lab Status	OK
------------	----

Sample comment	
----------------	--

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	8
---------------------------	---

Day of Visit	5
--------------	---

Celerion Study Number	AA99128-01
-----------------------	------------

Date of Collection	2014-APR-18
--------------------	-------------

Timepoint-minutes	0
-------------------	---

Urine Start Day	
-----------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (9)

Data signed: (hfarmer1) 30 Mar 2015 12:28:12

Generated On: 20 Jul 2016 22:42:34

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (10)

Data signed: (hfarmer1) 30 Mar 2015 12:28:12

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05112430002005
----------------	----------------

Analyte	NIC
---------	-----

Sample type	PLASMA
-------------	--------

Result	14.0
--------	------

Result Unit	NG/ML
-------------	-------

Lab Status	OK
------------	----

Sample comment	
----------------	--

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	8
---------------------------	---

Day of Visit	5
--------------	---

Celerion Study Number	AA99128-01
-----------------------	------------

Date of Collection	2014-APR-18
--------------------	-------------

Timepoint-minutes	0
-------------------	---

Urine Start Day	
-----------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (10)

Data signed: (hfarmer1) 30 Mar 2015 12:28:12

Generated On: 20 Jul 2016 22:42:34

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (11)

Data signed: (hfarmer1) 30 Mar 2015 12:28:12

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05112430002006
----------------	----------------

Analyte	COT
---------	-----

Sample type	PLASMA
-------------	--------

Result	223
--------	-----

Result Unit	NG/ML
-------------	-------

Lab Status	OK
------------	----

Sample comment	
----------------	--

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	10
---------------------------	----

Day of Visit	5
--------------	---

Celerion Study Number	AA99128-01
-----------------------	------------

Date of Collection	2014-APR-18
--------------------	-------------

Timepoint-minutes	0
-------------------	---

Urine Start Day	
-----------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (11)

Data signed: (hfarmer1) 30 Mar 2015 12:28:12

Generated On: 20 Jul 2016 22:42:34

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (12)

Data signed: (hfarmer1) 30 Mar 2015 12:28:12

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05112430002006
----------------	----------------

Analyte	NIC
---------	-----

Sample type	PLASMA
-------------	--------

Result	6.61
--------	------

Result Unit	NG/ML
-------------	-------

Lab Status	OK
------------	----

Sample comment	
----------------	--

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	10
---------------------------	----

Day of Visit	5
--------------	---

Celerion Study Number	AA99128-01
-----------------------	------------

Date of Collection	2014-APR-18
--------------------	-------------

Timepoint-minutes	0
-------------------	---

Urine Start Day	
-----------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (12)

Data signed: (hfarmer1) 30 Mar 2015 12:28:12

Generated On: 20 Jul 2016 22:42:34

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (13)

Data signed: (hfarmer1) 30 Mar 2015 12:28:12

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05112430002007
----------------	----------------

Analyte	COT
---------	-----

Sample type	PLASMA
-------------	--------

Result	223
--------	-----

Result Unit	NG/ML
-------------	-------

Lab Status	OK
------------	----

Sample comment	
----------------	--

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	12
---------------------------	----

Day of Visit	5
--------------	---

Celerion Study Number	AA99128-01
-----------------------	------------

Date of Collection	2014-APR-18
--------------------	-------------

Timepoint-minutes	0
-------------------	---

Urine Start Day	
-----------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (13)

Data signed: (hfarmer1) 30 Mar 2015 12:28:12

Generated On: 20 Jul 2016 22:42:34

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (14)

Data signed: (hfarmer1) 30 Mar 2015 12:28:12

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05112430002007
----------------	----------------

Analyte	NIC
---------	-----

Sample type	PLASMA
-------------	--------

Result	21.3
--------	------

Result Unit	NG/ML
-------------	-------

Lab Status	OK
------------	----

Sample comment	
----------------	--

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	12
---------------------------	----

Day of Visit	5
--------------	---

Celerion Study Number	AA99128-01
-----------------------	------------

Date of Collection	2014-APR-18
--------------------	-------------

Timepoint-minutes	0
-------------------	---

Urine Start Day	
-----------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (14)

Data signed: (hfarmer1) 30 Mar 2015 12:28:12

Generated On: 20 Jul 2016 22:42:34

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (15)

Data signed: (hfarmer1) 30 Mar 2015 12:28:12

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05112430002008
----------------	----------------

Analyte	COT
---------	-----

Sample type	PLASMA
-------------	--------

Result	224
--------	-----

Result Unit	NG/ML
-------------	-------

Lab Status	OK
------------	----

Sample comment	
----------------	--

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	14
---------------------------	----

Day of Visit	5
--------------	---

Celerion Study Number	AA99128-01
-----------------------	------------

Date of Collection	2014-APR-18
--------------------	-------------

Timepoint-minutes	0
-------------------	---

Urine Start Day	
-----------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (15)

Data signed: (hfarmer1) 30 Mar 2015 12:28:12

Generated On: 20 Jul 2016 22:42:34

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (16)

Data signed: (hfarmer1) 30 Mar 2015 12:28:12

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05112430002008
----------------	----------------

Analyte	NIC
---------	-----

Sample type	PLASMA
-------------	--------

Result	16.7
--------	------

Result Unit	NG/ML
-------------	-------

Lab Status	OK
------------	----

Sample comment	
----------------	--

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	14
---------------------------	----

Day of Visit	5
--------------	---

Celerion Study Number	AA99128-01
-----------------------	------------

Date of Collection	2014-APR-18
--------------------	-------------

Timepoint-minutes	0
-------------------	---

Urine Start Day	
-----------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (16)

Data signed: (hfarmer1) 30 Mar 2015 12:28:12

Generated On: 20 Jul 2016 22:42:34

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (17)

Data signed: (hfarmer1) 30 Mar 2015 12:28:12

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05112430002009
----------------	----------------

Analyte	COT
---------	-----

Sample type	PLASMA
-------------	--------

Result	249
--------	-----

Result Unit	NG/ML
-------------	-------

Lab Status	OK
------------	----

Sample comment	
----------------	--

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	16
---------------------------	----

Day of Visit	5
--------------	---

Celerion Study Number	AA99128-01
-----------------------	------------

Date of Collection	2014-APR-18
--------------------	-------------

Timepoint-minutes	0
-------------------	---

Urine Start Day	
-----------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (17)

Data signed: (hfarmer1) 30 Mar 2015 12:28:12

Generated On: 20 Jul 2016 22:42:34

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (18)

Data signed: (hfarmer1) 30 Mar 2015 12:28:12

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05112430002009
----------------	----------------

Analyte	NIC
---------	-----

Sample type	PLASMA
-------------	--------

Result	31.5
--------	------

Result Unit	NG/ML
-------------	-------

Lab Status	OK
------------	----

Sample comment	
----------------	--

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	16
---------------------------	----

Day of Visit	5
--------------	---

Celerion Study Number	AA99128-01
-----------------------	------------

Date of Collection	2014-APR-18
--------------------	-------------

Timepoint-minutes	0
-------------------	---

Urine Start Day	
-----------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (18)

Data signed: (hfarmer1) 30 Mar 2015 12:28:12

Generated On: 20 Jul 2016 22:42:34

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 6

Form: Date of Visit

Data signed: (hfarmer1) 30 Mar 2015 12:28:14

Generated On: 20 Jul 2016 22:42:34

Date of Visit

19 APR 2014
DD/MMM/YYYY

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 6

Form: Plasma Nicotine Samples <Day 6> (1)

Data signed: (hfarmer1) 30 Mar 2015 12:28:14

Generated On: 20 Jul 2016 22:42:34

Not Done	False
----------	-------

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	19 APR 2014
---------------------	-------------

Scheduled Time	T0 + 20H <input checked="" type="radio"/>
----------------	---

Time hour:min 24-hour clock	02:34
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 6

Form: Plasma Nicotine Samples <Day 6> (2)

Data signed: (hfarmer1) 30 Mar 2015 12:28:14

Generated On: 20 Jul 2016 22:42:34

Not Done	False
----------	-------

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	19 APR 2014
---------------------	-------------

Scheduled Time	T0 + 24H <input checked="" type="radio"/>
----------------	---

Time hour:min 24-hour clock	06:33
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 6

Form: Plasma Cotinine Samples <Day 6> (1)

Data signed: (hfarmer1) 30 Mar 2015 12:28:14

Generated On: 20 Jul 2016 22:42:34

Not Done	False
----------	-------

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	19 APR 2014
---------------------	-------------

Scheduled Time	T0 + 20H <input checked="" type="radio"/>
----------------	---

Time hour:min 24-hour clock	02:34
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 6

Form: Plasma Cotinine Samples <Day 6> (2)

Data signed: (hfarmer1) 30 Mar 2015 12:28:14

Generated On: 20 Jul 2016 22:42:34

Not Done	False
----------	-------

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	19 APR 2014
---------------------	-------------

Scheduled Time	T0 + 24H <input checked="" type="radio"/>
----------------	---

Time hour:min 24-hour clock	06:33
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 6

Form: CoHb Blood Sample <prior to gas transfer and product>

Data signed: (hfarmer1) 30 Mar 2015 12:28:14

Generated On: 20 Jul 2016 22:42:34

Not Done	False
----------	-------

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	19 APR 2014
---------------------	-------------

Timepoint	Prior to gas transfer assessment and prior to product use <input checked="" type="radio"/>
-----------	--

Time hour:min 24-hour clock	06:33
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 6

Form: Oxysterols

Data signed: (hfarmer1) 30 Mar 2015 12:28:14

Generated On: 20 Jul 2016 22:42:34

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	19 APR 2014
---------------------	-------------

Time hour:min 24-hour clock	06:33
--------------------------------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1261

Folder: Day 6

Form: CYP2A6 activity Sample

Data signed: (hfarmer1) 30 Mar 2015 12:28:14

Generated On: 20 Jul 2016 22:42:34

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

19 APR 2014

06:33

trans-3'-hydroxyc
otinine

19 APR 2014

06:33

cotinine

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 6

Form: Risk Marker: sICAM-1

Data signed: (hfarmer1) 30 Mar 2015 12:28:14

Generated On: 20 Jul 2016 22:42:34

Not Done	False
----------	-------

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	19 APR 2014
---------------------	-------------

Time hour:min 24-hour clock	06:33
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 6

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Data signed: (hfarmer1) 30 Mar 2015 12:28:15

Generated On: 20 Jul 2016 22:42:34

Date of Birth

(b) (6)

Date of assessment
DD/MMM/YYYY

2014 APR 19
DD/MMM/YYYY

Time of assessment

06:01
hour:min 24-hour clock

Assessment Status

Completed ☒

Please indicate for each of the items below, how you have been feeling over the past 24 hours

How have you been feeling over the past 24 hours?

None ☐

1. Angry, irritable, frustrated

How have you been feeling over the past 24 hours?

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: 1261**

Folder: Day 6

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Data signed: (hfarmer1) 30 Mar 2015 12:28:15

Generated On: 20 Jul 2016 22:42:34

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: 1261**

Folder: Day 6

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Data signed: (hfarmer1) 30 Mar 2015 12:28:15

Generated On: 20 Jul 2016 22:42:34

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: 1261**

Folder: Day 6

Form: Cough Assessment

Data signed: (hfarmer1) 30 Mar 2015 12:28:14

Generated On: 20 Jul 2016 22:42:34

Date of Birth

(b) (6)

Date of assessment
DD/MMM/YYYY

2014 APR 19
DD/MMM/YYYY

Time of assessment

06:00
hour:min 24-hour clock

Assessment Status

Completed ☒

Have you experienced a regular need to cough e.g.
coughing several times in the last 24 hrs?

No ☒

If YES, please answer the following questions:

First Question: Cough Impact Scale
How much is your cough bothering you?

-9

Second Question: Cough Intensity Scale:
How intense is your cough?

Not Applicable ☒

Third Question: Cough Frequency Scale:
How frequently do you normally have to cough each
day?

Not Applicable ☒

Fourth Question: Sputum Production
To what extent do you produce sputum when coughing?

Not Applicable ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 6

Form: Bio-banking (Transcriptomics)

Data signed: (hfarmer1) 30 Mar 2015 12:28:14

Generated On: 20 Jul 2016 22:42:34

Was a Bio-banking sample for transcriptomics taken?

Yes ☒

Time of Sample Collection

06:33
hour:min 24-hour clock

Was the subject fasting for at least 10 hours at time of
sample collection?

Yes ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 6

Form: Bio-banking (Biomarkers of exposure and risk markers)

Data signed: (hfarmer1) 30 Mar 2015 12:28:14

Generated On: 20 Jul 2016 22:42:34

Was a Bio-banking sample for biomarkers of exposure
and risk markers taken?

Yes ☒

Time of Sample Collection

06:33
hour:min 24-hour clock

Was the subject fasting for at least 10 hours at time of
sample collection?

Yes ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 6

Form: Bio-banking (nasal epithelial collection/buccal collection)

Data signed: (hfarmer1) 30 Mar 2015 12:28:14

Generated On: 20 Jul 2016 22:42:34

Was a Bio-banking sample for nasal epithelial
collection/buccal collection taken?

Yes ☒

Time of Buccal Collection

10:25
hour:min 24-hour clock

Time of Nasal Epithelial Collection

10:23
hour:min 24-hour clock

Was the subject fasting for at least 30 minutes at time of
sample collection?

Yes ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 6

Form: Oxysterol results (1)

Generated On: 20 Jul 2016 22:42:34

Sample Accession number	3317587215
-------------------------	------------

Analyte	22(R)-HYDROXYCHOLESTERO L
---------	------------------------------

Analyte code	22RHCRL
--------------	---------

Result	
--------	--

Result Unit	NG/ML
-------------	-------

Comment	NOT ANALYSED, INCOMPLETE SAMPLE SET
---------	--

Lower limit of quantification	9.46
-------------------------------	------

Date of Collection DD MMM YYYY	
-----------------------------------	--

Collection time hh:mm 24 hour clock	
--	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 6

Form: Oxysterol results (2)

Generated On: 20 Jul 2016 22:42:34

Sample Accession number	3317587215
-------------------------	------------

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: 1261**

Folder: Day 6

Form: Oxysterol results (3)

Generated On: 20 Jul 2016 22:42:34

Sample Accession number	3317587215
-------------------------	------------

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: 1261**

Folder: Day 6

Form: Oxysterol results (4)

Generated On: 20 Jul 2016 22:42:34

Sample Accession number	3317587215
-------------------------	------------

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: 1261**

Folder: Day 6

Form: Oxysterol results (5)

Generated On: 20 Jul 2016 22:42:34

Sample Accession number	3317587215
-------------------------	------------

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: 1261**

Folder: Day 6

Form: Oxysterol results (6)

Generated On: 20 Jul 2016 22:42:34

Sample Accession number	3317587215
-------------------------	------------

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: 1261**

Folder: Day 6

Form: Oxysterol results (7)

Generated On: 20 Jul 2016 22:42:34

Sample Accession number	3317587215
-------------------------	------------

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: 1261**

Folder: Day 6

Form: Oxysterol results (8)

Generated On: 20 Jul 2016 22:42:34

Sample Accession number	3317587215
-------------------------	------------

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: 1261**

Folder: Day 6

Form: Oxysterol results (9)

Generated On: 20 Jul 2016 22:42:34

Sample Accession number	3317587215
-------------------------	------------

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: 1261**

Folder: Day 6

Form: Oxysterol results (10)

Generated On: 20 Jul 2016 22:42:34

Sample Accession number	3317587215
-------------------------	------------

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: 1261**

Folder: Day 6

Form: Oxysterol results (11)

Generated On: 20 Jul 2016 22:42:34

Sample Accession number	3317587215
-------------------------	------------

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: 1261**

Folder: Day 6

Form: Oxysterol results (12)

Generated On: 20 Jul 2016 22:42:34

Sample Accession number	3317587215
-------------------------	------------

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: 1261**

Folder: Day 6

Form: Lab_BU_COHB (1)

Data signed: (hfarmer1) 30 Mar 2015 12:28:15

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05115150004284
----------------	----------------

Analyte	CARBOXYHEMOGLOBIN
---------	-------------------

Sample type	BLOOD
-------------	-------

Result	4.00
--------	------

Result Unit	%
-------------	---

Lab Status	OK
------------	----

Sample comment	
----------------	--

Detection method	SPECTROPHOTOMETRIC
------------------	--------------------

Lower limit of quantification	0.500
-------------------------------	-------

Planned time point (Hour)	6
---------------------------	---

Day of Visit	6
--------------	---

Celerion Study Number	AA99128-16
-----------------------	------------

Date of Collection	2014-APR-19
--------------------	-------------

Timepoint-minutes	
-------------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 6

Form: Lab_BU_COHB (1)

Data signed: (hfarmer1) 30 Mar 2015 12:28:15

Generated On: 20 Jul 2016 22:42:34

Start Day (24 hour urine only) _____

End Day (24 hour Urine Only) _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 6

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)

Data signed: (hfarmer1) 30 Mar 2015 12:28:14

Generated On: 20 Jul 2016 22:42:34

Date of Birth

(b) (6)

Date of assessment

2014 APR 19

DD/MMM/YYYY

DD/MMM/YYYY

Time of assessment

06:03

hour:min 24-hour clock

Assessment Status

Completed ☐

1. Was smoking satisfying?

Not at all ☐

2. Did cigarettes taste good?

Not at all ☐

3. Did you enjoy the sensation in your throat and chest?

Not at all ☐

4. Did smoking calm you down?

Not at all ☐

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: 1261**

Folder: Day 6

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)

Data signed: (hfarmer1) 30 Mar 2015 12:28:14

Generated On: 20 Jul 2016 22:42:34

9. Did smoking make you dizzy? Not at all ☐

10. Did smoking make you nauseous? Not at all ☐

11. Did smoking immediately relieve your craving for a
cigarette? Not at all ☐

12. Did you enjoy smoking? Not at all ☐

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 6

Form: Questionnaire on smoking urges (QSU)

Data signed: (hfarmer1) 30 Mar 2015 12:28:15

Generated On: 20 Jul 2016 22:42:34

Type	QSU
------	-----

Date of Birth	(b) (6)
---------------	---------

Date of assessment	2014 APR 19
--------------------	-------------

DD/MMM/YYYY

Time of assessment	06:03
--------------------	-------

hour:min 24-hour clock

Assessment Status	Completed <input checked="" type="radio"/>
-------------------	--

1. I have a desire for a cigarette right now	Do not agree or disagree <input checked="" type="radio"/>
--	---

2. Nothing would be better than smoking a cigarette right now	Do not agree or disagree <input checked="" type="radio"/>
---	---

3. If it were possible I would probably smoke now	Do not agree or disagree <input checked="" type="radio"/>
---	---

4. I could control things better right now if I could smoke	Do not agree or disagree <input checked="" type="radio"/>
---	---

5. All I want right now is a cigarette	Do not agree or disagree <input checked="" type="radio"/>
--	---

6. I have an urge for a cigarette	Do not agree or disagree <input checked="" type="radio"/>
-----------------------------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 6

Form: Questionnaire on smoking urges (QSU)

Data signed: (hfarmer1) 30 Mar 2015 12:28:15

Generated On: 20 Jul 2016 22:42:34

7. A cigarette would taste good now	Do not agree or disagree <input type="radio"/>
-------------------------------------	--

8. I would do almost anything for a cigarette now	Do not agree or disagree <input type="radio"/>
---	--

9. Smoking would make me less depressed	Do not agree or disagree <input type="radio"/>
---	--

10. I am going to smoke as soon as possible	Do not agree or disagree <input type="radio"/>
---	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 6

Form: Risk Markers(CCLS) (1)

Data signed: (hfarmer1) 30 Mar 2015 12:28:15

Generated On: 20 Jul 2016 22:42:34

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	1261
----------------------	------

Subject Sex	F
-------------	---

Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	DAY6
------------	------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	X175872
--------------	---------

Actual Collection Date	2014 04 19
------------------------	------------

Actual Collection Time	06:33
------------------------	-------

Specimen Condition	
--------------------	--

Battery ID	IM2293
------------	--------

Battery Name	SICAM-1
--------------	---------

Lab Test ID	IMT1768
-------------	---------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 6

Form: Risk Markers(CCLS) (1)

Data signed: (hfarmer1) 30 Mar 2015 12:28:15

Generated On: 20 Jul 2016 22:42:34

Lab Test Name	SICAM-1-RUO
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	228.8
Reported Numeric Result	228.8
Reference Range low	98.8
Reference Range high	320.0
Range Units	NG/ML
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 6

Form: Risk Markers(CCLS) (1)

Data signed: (hfarmer1) 30 Mar 2015 12:28:15

Generated On: 20 Jul 2016 22:42:34

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: 1261**

Folder: Day 6

Form: Biomarker-Plasma (Nic, Cot, tHCot)

Data signed: (hfarmer1) 30 Mar 2015 12:28:15

Generated On: 20 Jul 2016 22:42:34

Sample type

PLASMA

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 6

Form: Biomarker-Plasma (Nic, Cot, tHCot) (1)

Data signed: (hfarmer1) 30 Mar 2015 12:28:15

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05112430002010
----------------	----------------

Analyte	COT
---------	-----

Sample type	PLASMA
-------------	--------

Result	247
--------	-----

Result Unit	NG/ML
-------------	-------

Lab Status	OK
------------	----

Sample comment	
----------------	--

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	20
---------------------------	----

Day of Visit	6
--------------	---

Celerion Study Number	AA99128-01
-----------------------	------------

Date of Collection	2014-APR-19
--------------------	-------------

Timepoint-minutes	0
-------------------	---

Urine Start Day	
-----------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 6

Form: Biomarker-Plasma (Nic, Cot, tHCot) (1)

Data signed: (hfarmer1) 30 Mar 2015 12:28:15

Generated On: 20 Jul 2016 22:42:34

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 6

Form: Biomarker-Plasma (Nic, Cot, tHCot) (2)

Data signed: (hfarmer1) 30 Mar 2015 12:28:15

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05112430002010
----------------	----------------

Analyte	NIC
---------	-----

Sample type	PLASMA
-------------	--------

Result	7.30
--------	------

Result Unit	NG/ML
-------------	-------

Lab Status	OK
------------	----

Sample comment	
----------------	--

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	20
---------------------------	----

Day of Visit	6
--------------	---

Celerion Study Number	AA99128-01
-----------------------	------------

Date of Collection	2014-APR-19
--------------------	-------------

Timepoint-minutes	0
-------------------	---

Urine Start Day	
-----------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 6

Form: Biomarker-Plasma (Nic, Cot, tHCot) (2)

Data signed: (hfarmer1) 30 Mar 2015 12:28:15

Generated On: 20 Jul 2016 22:42:34

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 6

Form: Biomarker-Plasma (Nic, Cot, tHCot) (3)

Data signed: (hfarmer1) 30 Mar 2015 12:28:15

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05112430002011
Analyte	COT
Sample type	PLASMA
Result	217
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	24
Day of Visit	6
Celerion Study Number	AA99128-01
Date of Collection	2014-APR-19
Timepoint-minutes	0
Urine Start Day	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 6

Form: Biomarker-Plasma (Nic, Cot, tHCot) (3)

Data signed: (hfarmer1) 30 Mar 2015 12:28:15

Generated On: 20 Jul 2016 22:42:34

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 6

Form: Biomarker-Plasma (Nic, Cot, tHCot) (4)

Data signed: (hfarmer1) 30 Mar 2015 12:28:15

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05112430002011
----------------	----------------

Analyte	NIC
---------	-----

Sample type	PLASMA
-------------	--------

Result	2.19
--------	------

Result Unit	NG/ML
-------------	-------

Lab Status	OK
------------	----

Sample comment	
----------------	--

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	24
---------------------------	----

Day of Visit	6
--------------	---

Celerion Study Number	AA99128-01
-----------------------	------------

Date of Collection	2014-APR-19
--------------------	-------------

Timepoint-minutes	0
-------------------	---

Urine Start Day	
-----------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 6

Form: Biomarker-Plasma (Nic, Cot, tHCot) (4)

Data signed: (hfarmer1) 30 Mar 2015 12:28:15

Generated On: 20 Jul 2016 22:42:34

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 6

Form: Biomarker-Plasma (Nic, Cot, tHCot) (5)

Data signed: (hfarmer1) 30 Mar 2015 12:28:15

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05112520000479
----------------	----------------

Analyte	COT
---------	-----

Sample type	PLASMA
-------------	--------

Result	210
--------	-----

Result Unit	NG/ML
-------------	-------

Lab Status	OK
------------	----

Sample comment	
----------------	--

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	6
--------------	---

Celerion Study Number	AA99128-10
-----------------------	------------

Date of Collection	2014-APR-19
--------------------	-------------

Timepoint-minutes	0
-------------------	---

Urine Start Day	
-----------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 6

Form: Biomarker-Plasma (Nic, Cot, tHCot) (5)

Data signed: (hfarmer1) 30 Mar 2015 12:28:15

Generated On: 20 Jul 2016 22:42:34

Urine End Day

6

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 6

Form: Biomarker-Plasma (Nic, Cot, tHCot) (6)

Data signed: (hfarmer1) 30 Mar 2015 12:28:15

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05112520000479
----------------	----------------

Analyte	THCOT
---------	-------

Sample type	PLASMA
-------------	--------

Result	56.5
--------	------

Result Unit	NG/ML
-------------	-------

Lab Status	OK
------------	----

Sample comment	
----------------	--

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	6
--------------	---

Celerion Study Number	AA99128-10
-----------------------	------------

Date of Collection	2014-APR-19
--------------------	-------------

Timepoint-minutes	0
-------------------	---

Urine Start Day	
-----------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 6

Form: Biomarker-Plasma (Nic, Cot, tHCot) (6)

Data signed: (hfarmer1) 30 Mar 2015 12:28:15

Generated On: 20 Jul 2016 22:42:34

Urine End Day

6

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Discharge (Confinement)

Form: Date of Discharge

Data signed: (hfarmer1) 30 Mar 2015 12:28:17

Generated On: 20 Jul 2016 22:42:34

Date of Visit

19 APR 2014
DD/MMM/YYYY

Discharge Time

11:25
hour:min 24-hour clock

Is the subject continuing in the ambulatory period?

Yes ☒

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1261

Folder: Discharge (Confinement)

Form: Vital Signs

Data signed: (hfarmer1) 30 Mar 2015 12:28:18

Generated On: 20 Jul 2016 22:42:34

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 09:43
hour:min 24-hour clock

Pulse rate 79
beats per minute

Respiratory rate 20
breaths per minute

Blood Pressure (systolic) 123
mmHg

Blood Pressure (diastolic) 79
mmHg

Vital Signs Position of Subject Supine ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Discharge (Confinement)

Form: Advice on the risk of smoking and debriefing

Data signed: (hfarmer1) 30 Mar 2015 12:28:17

Generated On: 20 Jul 2016 22:42:34

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: 1261**

Folder: Discharge (Confinement)

Form: Physical Examination

Data signed: (hfarmer1) 30 Mar 2015 12:28:16

Generated On: 20 Jul 2016 22:42:34

Was the physical examination performed?

Yes ☒

If No, please specify the reason:

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Discharge (Confinement)

Form: Physical Examination (1)

Data signed: (hfarmer1) 30 Mar 2015 12:28:16

Generated On: 20 Jul 2016 22:42:34

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: 1261**

Folder: Discharge (Confinement)

Form: Physical Examination (2)

Data signed: (hfarmer1) 30 Mar 2015 12:28:16

Generated On: 20 Jul 2016 22:42:34

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: 1261

Folder: Discharge (Confinement)

Form: Physical Examination (3)

Data signed: (hfarmer1) 30 Mar 2015 12:28:16

Generated On: 20 Jul 2016 22:42:34

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: 1261**

Folder: Discharge (Confinement)

Form: Physical Examination (4)

Data signed: (hfarmer1) 30 Mar 2015 12:28:16

Generated On: 20 Jul 2016 22:42:34

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: 1261**

Folder: Discharge (Confinement)

Form: Physical Examination (5)

Data signed: (hfarmer1) 30 Mar 2015 12:28:16

Generated On: 20 Jul 2016 22:42:34

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: 1261**

Folder: Discharge (Confinement)

Form: Physical Examination (6)

Data signed: (hfarmer1) 30 Mar 2015 12:28:16

Generated On: 20 Jul 2016 22:42:34

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: 1261**

Folder: Discharge (Confinement)

Form: Physical Examination (7)

Data signed: (hfarmer1) 30 Mar 2015 12:28:16

Generated On: 20 Jul 2016 22:42:34

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: 1261**

Folder: Discharge (Confinement)

Form: Physical Examination (8)

Data signed: (hfarmer1) 30 Mar 2015 12:28:16

Generated On: 20 Jul 2016 22:42:34

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: 1261**

Folder: Discharge (Confinement)

Form: Physical Examination (9)

Data signed: (hfarmer1) 30 Mar 2015 12:28:16

Generated On: 20 Jul 2016 22:42:34

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: 1261**

Folder: Discharge (Confinement)

Form: Physical Examination (10)

Data signed: (hfarmer1) 30 Mar 2015 12:28:16

Generated On: 20 Jul 2016 22:42:34

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: 1261**

Folder: Discharge (Confinement)

Form: Physical Examination (11)

Data signed: (hfarmer1) 30 Mar 2015 12:28:16

Generated On: 20 Jul 2016 22:42:34

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: 1261**

Folder: Discharge (Confinement)

Form: Physical Examination (12)

Data signed: (hfarmer1) 30 Mar 2015 12:28:16

Generated On: 20 Jul 2016 22:42:34

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: 1261**

Folder: Discharge (Confinement)

Form: Physical Examination (13)

Data signed: (hfarmer1) 30 Mar 2015 12:28:16

Generated On: 20 Jul 2016 22:42:34

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: 1261**

Folder: Discharge (Confinement)

Form: Physical Examination (14)

Data signed: (hfarmer1) 30 Mar 2015 12:28:16

Generated On: 20 Jul 2016 22:42:34

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

System Dentition ☒

Outcome Abnormal ☒

Abnormal, please specify MANY DECAYED TEETH

Clinically significant No ☒

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Discharge (Confinement)

Form: Physical Examination (15)

Data signed: (hfarmer1) 30 Mar 2015 12:28:16

Generated On: 20 Jul 2016 22:42:34

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: 1261**

Folder: Discharge (Confinement)

Form: Physical Examination (16)

Data signed: (hfarmer1) 30 Mar 2015 12:28:16

Generated On: 20 Jul 2016 22:42:34

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: 1261**

Folder: Discharge (Confinement)

Form: Physical Examination (17)

Data signed: (hfarmer1) 30 Mar 2015 12:28:16

Generated On: 20 Jul 2016 22:42:34

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: 1261**

Folder: Discharge (Confinement)

Form: Physical Examination (18)

Data signed: (hfarmer1) 30 Mar 2015 12:28:16

Generated On: 20 Jul 2016 22:42:34

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: 1261**

Folder: Discharge (Confinement)

Form: Physical Examination (19)

Data signed: (hfarmer1) 30 Mar 2015 12:28:16

Generated On: 20 Jul 2016 22:42:34

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: 1261**

Folder: Discharge (Confinement)

Form: Weight

Data signed: (hfarmer1) 30 Mar 2015 12:28:18

Generated On: 20 Jul 2016 22:42:34

Measurement(s) assessed?

Yes ☒

If No, please specify the reason: _____

Date of Assessment

19 APR 2014
DD/MMM/YYYY

Time of assessment

10:33
hour:min 24-hour clock

Weight

71.5
kg

BMI

28.0

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Discharge (Confinement)

Form: ECG (12-Lead Standard)

Data signed: (hfarmer1) 30 Mar 2015 12:28:16

Generated On: 20 Jul 2016 22:42:34

Was the ECG performed? Yes ☒

If No, please specify the reason: _____

Position Supine ☒

Heart Rate 82
beats per minute

QRS Interval 87
msec

QT Interval 351
msec

QTcB Interval 411
msec

PR Interval 156
msec

QTcF Interval 390
msec

Interpretation Normal ☒

If Abnormal, Clinical Significance _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Discharge (Confinement)

Form: ECG (12-Lead Standard)

Data signed: (hfarmer1) 30 Mar 2015 12:28:16

Generated On: 20 Jul 2016 22:42:34

If Not Clinically significant or clinically Significant, Please
specify the finding(s) _____

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1261

Folder: Discharge (Confinement)

Form: Gas Transfer

Data signed: (hfarmer1) 30 Mar 2015 12:28:17

Generated On: 20 Jul 2016 22:42:34

Was the Gas Transfer performed? Yes ☒

If No, please specify the reason: _____

Category _____

Position SITTING

Date of assessment 19 APR 2014
DD/MMM/YYYY

Time of assessment 06:58

DLCO value 17.90
ml/min/mmHg

KCO value 1.15
mmol/min/kPa/L

DLCO/VA value 3.44
mL/min/mmHg/L

Interpretation Abnormal ☒

If Abnormal, Clinical Significance Not clinically significant ☒

If Not Clinically Significant or Clinically Significant, Please DECREASED DLCO
specify the finding(s)

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1261

Folder: Discharge (Confinement)

Form: Lung Volume Measurements

Data signed: (hfarmer1) 30 Mar 2015 12:28:17

Generated On: 20 Jul 2016 22:42:34

Were the Lung Volume Measurements performed? Yes ☒

If No, please specify the reason: _____

Category _____

Position SITTING

Date of assessment 19 APR 2014
DD/MMM/YYYY

Time of assessment 07:00

VC value 3.74
L

TLC value 5.17
L

IC value 3.60
L

FRC value 1.57
L

Interpretation Abnormal ☒

If Abnormal, Clinical Significance Not clinically significant ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Discharge (Confinement)

Form: Lung Volume Measurements

Data signed: (hfarmer1) 30 Mar 2015 12:28:17

Generated On: 20 Jul 2016 22:42:34

If Not Clinically Significant or Clinically Significant, Please DECREASE LUNG VOLUME
specify the finding(s)

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1261

Folder: Discharge (Confinement)

Form: Spirometry with a short-acting bronchodilator

Data signed: (hfarmer1) 30 Mar 2015 12:28:17

Generated On: 20 Jul 2016 22:42:34

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

19 APR 2014

Time of assessment

07:25

Name of bronchodilator

A;BUTEROL SULFATE

Dose

180 MCG

Predicted FVC value

5.20
L

Best measured FVC value

3.64
L

Percent of predicted FVC value

70
%

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1261

Folder: Discharge (Confinement)

Form: Spirometry with a short-acting bronchodilator

Data signed: (hfarmer1) 30 Mar 2015 12:28:17

Generated On: 20 Jul 2016 22:42:34

Best measured FEV1 value	2.83 L
--------------------------	-----------

Predicted FEV1 value	4.26 L
----------------------	-----------

Percent of predicted FEV1 value	66 %
---------------------------------	---------

Calculated ratio between FEV1/FVC	
-----------------------------------	--

MEF 25/75 value	2.52 L/s
-----------------	-------------

Interpretation	Abnormal <input checked="" type="radio"/>
----------------	---

If Abnormal, Clinical Significance	Not clinically significant <input type="radio"/>
------------------------------------	--

If Not Clinically Significant or Clinically Significant, Please DECREASED FVC AND FEV 1 specify the finding(s)

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Discharge (Confinement)

Form: Haematology

Data signed: (hfarmer1) 30 Mar 2015 12:28:16

Generated On: 20 Jul 2016 22:42:34

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: 1261**

Folder: Discharge (Confinement)

Form: Clinical Chemistry

Data signed: (hfarmer1) 30 Mar 2015 12:28:16

Generated On: 20 Jul 2016 22:42:34

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: 1261**

Folder: Discharge (Confinement)

Form: Urine analysis

Data signed: (hfarmer1) 30 Mar 2015 12:28:16

Generated On: 20 Jul 2016 22:42:34

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: 1261**

Folder: Discharge (Confinement)

Form: Urine Pregnancy Test

Data signed: (hfarmer1) 30 Mar 2015 12:28:18

Generated On: 20 Jul 2016 22:42:34

Not Done	False
----------	-------

If Not Done, specify reason	<hr/>
-----------------------------	-------

Date of Test	19 APR 2014 DD/MMM/YYYY
--------------	----------------------------

Time of Test	08:09 hour:min 24-hour clock
--------------	---------------------------------

Specify result	Negative <input checked="" type="radio"/>
----------------	---

If unclear, please confirm with FSH test	<hr/>
--	-------

Specify result of FSH test	<hr/>
----------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Discharge (Confinement)

Form: CO Breath Test

Data signed: (hfarmer1) 30 Mar 2015 12:28:15

Generated On: 20 Jul 2016 22:42:34

Assessment not done	False
---------------------	-------

If Not Done, please specify the reason: _____

Actual Time of Assessment	09:47
	hour:min 24-hour clock

Result	27
	ppm

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (1)

Data signed: (hfarmer1) 30 Mar 2015 12:28:18

Generated On: 20 Jul 2016 22:42:34

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex F

Subject Date of Birth (b) (6)

Visit Name _____

Visit Type Scheduled ☒

Accession ID X175872

Actual Collection Date 2014 04 19

Actual Collection Time 06:33

Specimen Condition _____

Battery ID RC1029

Battery Name TRIGLYCERIDES

Lab Test ID RCT19

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1261

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (1)

Data signed: (hfarmer1) 30 Mar 2015 12:28:18

Generated On: 20 Jul 2016 22:42:34

Lab Test Name	TRIGLYCERIDES (GPO)
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	169
Reported Numeric Result	169
Reference Range low	39
Reference Range high	176
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: 1261**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (1)

Data signed: (hfarmer1) 30 Mar 2015 12:28:18

Generated On: 20 Jul 2016 22:42:34

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (2)

Data signed: (hfarmer1) 30 Mar 2015 12:28:18

Generated On: 20 Jul 2016 22:42:34

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex F

Subject Date of Birth (b) (6) ☒

Visit Name _____

Visit Type Scheduled ☒

Accession ID X175872

Actual Collection Date 2014 04 19

Actual Collection Time 06:33

Specimen Condition _____

Battery ID RC1092

Battery Name FASTING GLUCOSE

Lab Test ID RCT142

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1261

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (2)

Data signed: (hfarmer1) 30 Mar 2015 12:28:18

Generated On: 20 Jul 2016 22:42:34

Lab Test Name	FASTING GLUCOSE
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	86
Reported Numeric Result	86
Reference Range low	70
Reference Range high	100
Range Units	MG/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (2)

Data signed: (hfarmer1) 30 Mar 2015 12:28:18

Generated On: 20 Jul 2016 22:42:34

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (3)

Data signed: (hfarmer1) 30 Mar 2015 12:28:18

Generated On: 20 Jul 2016 22:42:34

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex F

Subject Date of Birth (b) (6)

Visit Name _____

Visit Type Scheduled ☒

Accession ID X175872

Actual Collection Date 2014 04 19

Actual Collection Time 06:33

Specimen Condition _____

Battery ID RC272

Battery Name TOTAL CHOLESTEROL

Lab Test ID RCT20

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1261

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (3)

Data signed: (hfarmer1) 30 Mar 2015 12:28:18

Generated On: 20 Jul 2016 22:42:34

Lab Test Name	CHOLESTEROL (HIGH PERFORMANCE)
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	198
Reported Numeric Result	198
Reference Range low	141
Reference Range high	240
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: 1261**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (3)

Data signed: (hfarmer1) 30 Mar 2015 12:28:18

Generated On: 20 Jul 2016 22:42:34

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: 1261**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (4)

Data signed: (hfarmer1) 30 Mar 2015 12:28:18

Generated On: 20 Jul 2016 22:42:34

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	F
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Subject Date of Birth	(b) (6) 
-----------------------	---

Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	X175872
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Actual Collection Date	2014 04 19
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Actual Collection Time	06:33
------------------------	-------

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: 1261**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (4)

Data signed: (hfarmer1) 30 Mar 2015 12:28:18

Generated On: 20 Jul 2016 22:42:34

Lab Test Name	TOTAL BILIRUBIN
Test ID	
Test Status	Done <input type="checkbox"/>
Reported Text Result	0.4
Reported Numeric Result	0.4
Reference Range low	0.2
Reference Range high	1.2
Range Units	MG/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (4)

Data signed: (hfarmer1) 30 Mar 2015 12:28:18

Generated On: 20 Jul 2016 22:42:34

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (5)

Data signed: (hfarmer1) 30 Mar 2015 12:28:18

Generated On: 20 Jul 2016 22:42:34

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex F

Subject Date of Birth (b) (6)

Visit Name _____

Visit Type Scheduled ☒

Accession ID X175872

Actual Collection Date 2014 04 19

Actual Collection Time 06:33

Specimen Condition _____

Battery ID RC9255

Battery Name CHEMISTRY PANEL

Lab Test ID RCT12

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1261

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (5)

Data signed: (hfarmer1) 30 Mar 2015 12:28:18

Generated On: 20 Jul 2016 22:42:34

Lab Test Name	TOTAL PROTEIN
Test ID	
Test Status	Done <input type="checkbox"/>
Reported Text Result	6.6
Reported Numeric Result	6.6
Reference Range low	6.1
Reference Range high	8.4
Range Units	G/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (5)

Data signed: (hfarmer1) 30 Mar 2015 12:28:18

Generated On: 20 Jul 2016 22:42:34

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (6)

Data signed: (hfarmer1) 30 Mar 2015 12:28:18

Generated On: 20 Jul 2016 22:42:34

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex F

Subject Date of Birth (b) (6)

Visit Name _____

Visit Type Scheduled ☒

Accession ID X175872

Actual Collection Date 2014 04 19

Actual Collection Time 06:33

Specimen Condition _____

Battery ID RC9255

Battery Name CHEMISTRY PANEL

Lab Test ID RCT13

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (6)

Data signed: (hfarmer1) 30 Mar 2015 12:28:18

Generated On: 20 Jul 2016 22:42:34

Lab Test Name	ALBUMIN
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	4.3
Reported Numeric Result	4.3
Reference Range low	3.3
Reference Range high	4.9
Range Units	G/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (6)

Data signed: (hfarmer1) 30 Mar 2015 12:28:18

Generated On: 20 Jul 2016 22:42:34

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (7)

Data signed: (hfarmer1) 30 Mar 2015 12:28:18

Generated On: 20 Jul 2016 22:42:34

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex F

Subject Date of Birth (b) (6)

Visit Name _____

Visit Type Scheduled ☒

Accession ID X175872

Actual Collection Date 2014 04 19

Actual Collection Time 06:33

Specimen Condition _____

Battery ID RC9255

Battery Name CHEMISTRY PANEL

Lab Test ID RCT1407

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1261

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (7)

Data signed: (hfarmer1) 30 Mar 2015 12:28:18

Generated On: 20 Jul 2016 22:42:34

Lab Test Name	ALKALINE PHOSPHATASE
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	52
Reported Numeric Result	52
Reference Range low	31
Reference Range high	106
Range Units	U/L
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (7)

Data signed: (hfarmer1) 30 Mar 2015 12:28:18

Generated On: 20 Jul 2016 22:42:34

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (8)

Data signed: (hfarmer1) 30 Mar 2015 12:28:18

Generated On: 20 Jul 2016 22:42:34

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex F

Subject Date of Birth (b) (6) 

Visit Name _____

Visit Type Scheduled ☒

Accession ID X175872

Actual Collection Date 2014 04 19

Actual Collection Time 06:33

Specimen Condition _____

Battery ID RC9255

Battery Name CHEMISTRY PANEL

Lab Test ID RCT1408

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1261

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (8)

Data signed: (hfarmer1) 30 Mar 2015 12:28:18

Generated On: 20 Jul 2016 22:42:34

Lab Test Name	LDH
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	135
Reported Numeric Result	135
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: 1261**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (8)

Data signed: (hfarmer1) 30 Mar 2015 12:28:18

Generated On: 20 Jul 2016 22:42:34

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (9)

Data signed: (hfarmer1) 30 Mar 2015 12:28:18

Generated On: 20 Jul 2016 22:42:34

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	F
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Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	X175872
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Actual Collection Date	2014 04 19
------------------------	------------

Actual Collection Time	06:33
------------------------	-------

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: 1261

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (9)

Data signed: (hfarmer1) 30 Mar 2015 12:28:18

Generated On: 20 Jul 2016 22:42:34

Lab Test Name	SERUM SODIUM
Test ID	
Test Status	Done <input checked="" type="checkbox"/>
Reported Text Result	142
Reported Numeric Result	142
Reference Range low	132
Reference Range high	147
Range Units	MEQ/L
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (9)

Data signed: (hfarmer1) 30 Mar 2015 12:28:18

Generated On: 20 Jul 2016 22:42:34

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1261

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (10)

Data signed: (hfarmer1) 30 Mar 2015 12:28:18

Generated On: 20 Jul 2016 22:42:34

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex F

Subject Date of Birth (b) (6) 

Visit Name _____

Visit Type Scheduled ☒

Accession ID X175872

Actual Collection Date 2014 04 19

Actual Collection Time 06:33

Specimen Condition _____

Battery ID RC9255

Battery Name CHEMISTRY PANEL

Lab Test ID RCT16

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1261

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (10)

Data signed: (hfarmer1) 30 Mar 2015 12:28:18

Generated On: 20 Jul 2016 22:42:34

Lab Test Name	SERUM POTASSIUM
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	4.4
Reported Numeric Result	4.4
Reference Range low	3.4
Reference Range high	5.4
Range Units	MEQ/L
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (10)

Data signed: (hfarmer1) 30 Mar 2015 12:28:18

Generated On: 20 Jul 2016 22:42:34

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (11)

Data signed: (hfarmer1) 30 Mar 2015 12:28:18

Generated On: 20 Jul 2016 22:42:34

Transmission Type	Cumulative <input type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	F
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Subject Date of Birth	(b) (6) 
-----------------------	---

Visit Name	<hr/>
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Visit Type	Scheduled <input type="radio"/>
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Accession ID	X175872
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Actual Collection Date	2014 04 19
------------------------	------------

Actual Collection Time	06:33
------------------------	-------

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: 1261

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (11)

Data signed: (hfarmer1) 30 Mar 2015 12:28:18

Generated On: 20 Jul 2016 22:42:34

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: 1261**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (11)

Data signed: (hfarmer1) 30 Mar 2015 12:28:18

Generated On: 20 Jul 2016 22:42:34

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (12)

Data signed: (hfarmer1) 30 Mar 2015 12:28:18

Generated On: 20 Jul 2016 22:42:34

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	<hr/>
----------------------	-------

Subject Sex	F
-------------	---

Subject Date of Birth	(b) (6) 
-----------------------	---

Visit Name	<hr/>
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	X175872
--------------	---------

Actual Collection Date	2014 04 19
------------------------	------------

Actual Collection Time	06:33
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	RC9255
------------	--------

Battery Name	CHEMISTRY PANEL
--------------	-----------------

Lab Test ID	RCT3
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (12)

Data signed: (hfarmer1) 30 Mar 2015 12:28:18

Generated On: 20 Jul 2016 22:42:34

Lab Test Name	GGT
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	20
Reported Numeric Result	20
Reference Range low	4
Reference Range high	49
Range Units	U/L
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (12)

Data signed: (hfarmer1) 30 Mar 2015 12:28:18

Generated On: 20 Jul 2016 22:42:34

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (13)

Data signed: (hfarmer1) 30 Mar 2015 12:28:18

Generated On: 20 Jul 2016 22:42:34

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	<hr/>
----------------------	-------

Subject Sex	F
-------------	---

Subject Date of Birth	(b) (6) 
-----------------------	---

Visit Name	<hr/>
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	X175872
--------------	---------

Actual Collection Date	2014 04 19
------------------------	------------

Actual Collection Time	06:33
------------------------	-------

Specimen Condition	<hr/>
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Battery ID	RC9255
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Battery Name	CHEMISTRY PANEL
--------------	-----------------

Lab Test ID	RCT392
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1261

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (13)

Data signed: (hfarmer1) 30 Mar 2015 12:28:18

Generated On: 20 Jul 2016 22:42:34

Lab Test Name	CREATININE (RATE BLANKED)
---------------	---------------------------

Test ID	<hr/>
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Test Status	Done <input checked="" type="radio"/>
-------------	---------------------------------------

Reported Text Result	0.8
----------------------	-----

Reported Numeric Result	0.8
-------------------------	-----

Reference Range low	0.4
---------------------	-----

Reference Range high	1.1
----------------------	-----

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/>
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (13)

Data signed: (hfarmer1) 30 Mar 2015 12:28:18

Generated On: 20 Jul 2016 22:42:34

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (14)

Data signed: (hfarmer1) 30 Mar 2015 12:28:18

Generated On: 20 Jul 2016 22:42:34

Transmission Type Cumulative ☒

Subject ID or Number

Subject Sex F

Subject Date of Birth (b) (6)

Visit Name

Visit Type Scheduled ☒

Accession ID X175872

Actual Collection Date 2014 04 19

Actual Collection Time 06:33

Specimen Condition

Battery ID RC9255

Battery Name CHEMISTRY PANEL

Lab Test ID RCT4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (14)

Data signed: (hfarmer1) 30 Mar 2015 12:28:18

Generated On: 20 Jul 2016 22:42:34

Lab Test Name	ALT (SGPT)
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	20
Reported Numeric Result	20
Reference Range low	6
Reference Range high	34
Range Units	U/L
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (14)

Data signed: (hfarmer1) 30 Mar 2015 12:28:18

Generated On: 20 Jul 2016 22:42:34

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (15)

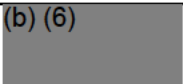
Data signed: (hfarmer1) 30 Mar 2015 12:28:18

Generated On: 20 Jul 2016 22:42:34

Transmission Type Cumulative ☒

Subject ID or Number

Subject Sex F

Subject Date of Birth (b) (6) 

Visit Name

Visit Type Scheduled ☒

Accession ID X175872

Actual Collection Date 2014 04 19

Actual Collection Time 06:33

Specimen Condition

Battery ID RC9255

Battery Name CHEMISTRY PANEL

Lab Test ID RCT5

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1261

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (15)

Data signed: (hfarmer1) 30 Mar 2015 12:28:18

Generated On: 20 Jul 2016 22:42:34

Lab Test Name	AST (SGOT)
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	14
Reported Numeric Result	14
Reference Range low	9
Reference Range high	34
Range Units	U/L
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (15)

Data signed: (hfarmer1) 30 Mar 2015 12:28:18

Generated On: 20 Jul 2016 22:42:34

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (16)

Data signed: (hfarmer1) 30 Mar 2015 12:28:18

Generated On: 20 Jul 2016 22:42:34

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex F

Subject Date of Birth (b) (6) 

Visit Name _____

Visit Type Scheduled ☒

Accession ID X175872

Actual Collection Date 2014 04 19

Actual Collection Time 06:33

Specimen Condition _____

Battery ID RC9255

Battery Name CHEMISTRY PANEL

Lab Test ID RCT6

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1261

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (16)

Data signed: (hfarmer1) 30 Mar 2015 12:28:18

Generated On: 20 Jul 2016 22:42:34

Lab Test Name	UREA NITROGEN
Test ID	
Test Status	Done <input checked="" 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: 1261**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (16)

Data signed: (hfarmer1) 30 Mar 2015 12:28:18

Generated On: 20 Jul 2016 22:42:34

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1261

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (17)

Data signed: (hfarmer1) 30 Mar 2015 12:28:18

Generated On: 20 Jul 2016 22:42:34

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	F
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Subject Date of Birth	(b) (6) 
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	X175872
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Actual Collection Date	2014 04 19
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Actual Collection Time	06:33
------------------------	-------

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: 1261

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (17)

Data signed: (hfarmer1) 30 Mar 2015 12:28:18

Generated On: 20 Jul 2016 22:42:34

Lab Test Name	MONOCYTES
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	0.58
Reported Numeric Result	0.58
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: 1261**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (17)

Data signed: (hfarmer1) 30 Mar 2015 12:28:18

Generated On: 20 Jul 2016 22:42:34

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (18)

Data signed: (hfarmer1) 30 Mar 2015 12:28:18

Generated On: 20 Jul 2016 22:42:34

Transmission Type Cumulative ☐

Subject ID or Number _____

Subject Sex F

Subject Date of Birth (b) (6) 

Visit Name _____

Visit Type Scheduled ☐

Accession ID X175872

Actual Collection Date 2014 04 19

Actual Collection Time 06:33

Specimen Condition _____

Battery ID HM1604

Battery Name HEMATOLOGY
&DIFFERENTIAL PANEL

Lab Test ID HMT100

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1261

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (18)

Data signed: (hfarmer1) 30 Mar 2015 12:28:18

Generated On: 20 Jul 2016 22:42:34

Lab Test Name	MCH
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	31
Reported Numeric Result	31
Reference Range low	26
Reference Range high	34
Range Units	PG
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (18)

Data signed: (hfarmer1) 30 Mar 2015 12:28:18

Generated On: 20 Jul 2016 22:42:34

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (19)

Data signed: (hfarmer1) 30 Mar 2015 12:28:18

Generated On: 20 Jul 2016 22:42:34

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex F

Subject Date of Birth (b) (6)

Visit Name _____

Visit Type Scheduled ☒

Accession ID X175872

Actual Collection Date 2014 04 19

Actual Collection Time 06:33

Specimen Condition _____

Battery ID HM1604

Battery Name HEMATOLOGY
&DIFFERENTIAL PANEL

Lab Test ID HMT102

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (19)

Data signed: (hfarmer1) 30 Mar 2015 12:28:18

Generated On: 20 Jul 2016 22:42:34

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: 1261**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (19)

Data signed: (hfarmer1) 30 Mar 2015 12:28:18

Generated On: 20 Jul 2016 22:42:34

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (20)

Data signed: (hfarmer1) 30 Mar 2015 12:28:18

Generated On: 20 Jul 2016 22:42:34

Transmission Type Cumulative ☐

Subject ID or Number _____

Subject Sex F

Subject Date of Birth (b) (6) 

Visit Name _____

Visit Type Scheduled ☐

Accession ID X175872

Actual Collection Date 2014 04 19

Actual Collection Time 06:33

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: 1261

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (20)

Data signed: (hfarmer1) 30 Mar 2015 12:28:18

Generated On: 20 Jul 2016 22:42:34

Lab Test Name	EOSINOPHILS
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	0.45
Reported Numeric Result	0.45
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: 1261**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (20)

Data signed: (hfarmer1) 30 Mar 2015 12:28:18

Generated On: 20 Jul 2016 22:42:34

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1261

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (21)

Data signed: (hfarmer1) 30 Mar 2015 12:28:18

Generated On: 20 Jul 2016 22:42:34

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	F
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Subject Date of Birth	(b) (6) 
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	X175872
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Actual Collection Date	2014 04 19
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Actual Collection Time	06:33
------------------------	-------

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: 1261**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (21)

Data signed: (hfarmer1) 30 Mar 2015 12:28:18

Generated On: 20 Jul 2016 22:42:34

Lab Test Name	BASOPHILS
Test ID	
Test Status	Done <input type="checkbox"/>
Reported Text Result	0.06
Reported Numeric Result	0.06
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: 1261**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (21)

Data signed: (hfarmer1) 30 Mar 2015 12:28:18

Generated On: 20 Jul 2016 22:42:34

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (22)

Data signed: (hfarmer1) 30 Mar 2015 12:28:18

Generated On: 20 Jul 2016 22:42:34

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	F
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Subject Date of Birth	(b) (6) 
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	X175872
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Actual Collection Date	2014 04 19
------------------------	------------

Actual Collection Time	06:33
------------------------	-------

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: 1261

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (22)

Data signed: (hfarmer1) 30 Mar 2015 12:28:18

Generated On: 20 Jul 2016 22:42:34

Lab Test Name	PLATELETS
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	237
Reported Numeric Result	237
Reference Range low	140
Reference Range high	400
Range Units	X10^3/UL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (22)

Data signed: (hfarmer1) 30 Mar 2015 12:28:18

Generated On: 20 Jul 2016 22:42:34

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (23)

Data signed: (hfarmer1) 30 Mar 2015 12:28:18

Generated On: 20 Jul 2016 22:42:34

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	F
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Subject Date of Birth	(b) (6) 
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	X175872
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Actual Collection Date	2014 04 19
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Actual Collection Time	06:33
------------------------	-------

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: 1261

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (23)

Data signed: (hfarmer1) 30 Mar 2015 12:28:18

Generated On: 20 Jul 2016 22:42:34

Lab Test Name	NEUTROPHILS (%)
Test ID	
Test Status	Done <input checked="" type="checkbox"/>
Reported Text Result	58.2
Reported Numeric Result	58.2
Reference Range low	40.5
Reference Range high	75.0
Range Units	%
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (23)

Data signed: (hfarmer1) 30 Mar 2015 12:28:18

Generated On: 20 Jul 2016 22:42:34

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (24)

Data signed: (hfarmer1) 30 Mar 2015 12:28:18

Generated On: 20 Jul 2016 22:42:34

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	F
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Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	X175872
--------------	---------

Actual Collection Date	2014 04 19
------------------------	------------

Actual Collection Time	06:33
------------------------	-------

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: 1261

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (24)

Data signed: (hfarmer1) 30 Mar 2015 12:28:18

Generated On: 20 Jul 2016 22:42:34

Lab Test Name	LYMPHOCYTES (%)
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	30.2
Reported Numeric Result	30.2
Reference Range low	15.4
Reference Range high	48.5
Range Units	%
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (24)

Data signed: (hfarmer1) 30 Mar 2015 12:28:18

Generated On: 20 Jul 2016 22:42:34

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (25)

Data signed: (hfarmer1) 30 Mar 2015 12:28:18

Generated On: 20 Jul 2016 22:42:34

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	<hr/>
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Subject Sex	F
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Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	X175872
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Actual Collection Date	2014 04 19
------------------------	------------

Actual Collection Time	06:33
------------------------	-------

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: 1261

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (25)

Data signed: (hfarmer1) 30 Mar 2015 12:28:18

Generated On: 20 Jul 2016 22:42:34

Lab Test Name	MONOCYTES (%)
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	6.2
Reported Numeric Result	6.2
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: 1261**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (25)

Data signed: (hfarmer1) 30 Mar 2015 12:28:18

Generated On: 20 Jul 2016 22:42:34

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1261

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (26)

Data signed: (hfarmer1) 30 Mar 2015 12:28:18

Generated On: 20 Jul 2016 22:42:34

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
----------------------	-------

Subject Sex	F
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Subject Date of Birth	(b) (6) 
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	X175872
--------------	---------

Actual Collection Date	2014 04 19
------------------------	------------

Actual Collection Time	06:33
------------------------	-------

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: 1261

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (26)

Data signed: (hfarmer1) 30 Mar 2015 12:28:18

Generated On: 20 Jul 2016 22:42:34

Lab Test Name	EOSINOPHILS (%)
Test ID	
Test Status	Done <input type="checkbox"/>
Reported Text Result	4.8
Reported Numeric Result	4.8
Reference Range low	0.0
Reference Range high	6.8
Range Units	%
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (26)

Data signed: (hfarmer1) 30 Mar 2015 12:28:18

Generated On: 20 Jul 2016 22:42:34

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1261

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (27)

Data signed: (hfarmer1) 30 Mar 2015 12:28:18

Generated On: 20 Jul 2016 22:42:34

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
----------------------	-------

Subject Sex	F
-------------	---

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	X175872
--------------	---------

Actual Collection Date	2014 04 19
------------------------	------------

Actual Collection Time	06:33
------------------------	-------

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: 1261

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (27)

Data signed: (hfarmer1) 30 Mar 2015 12:28:18

Generated On: 20 Jul 2016 22:42:34

Lab Test Name	BASOPHILS (%)
Test ID	
Test Status	Done <input type="checkbox"/>
Reported Text Result	0.6
Reported Numeric Result	0.6
Reference Range low	0.0
Reference Range high	2.0
Range Units	%
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (27)

Data signed: (hfarmer1) 30 Mar 2015 12:28:18

Generated On: 20 Jul 2016 22:42:34

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1261

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (28)

Data signed: (hfarmer1) 30 Mar 2015 12:28:18

Generated On: 20 Jul 2016 22:42:34

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex F

Subject Date of Birth (b) (6) 

Visit Name _____

Visit Type Scheduled ☒

Accession ID X175872

Actual Collection Date 2014 04 19

Actual Collection Time 06:33

Specimen Condition _____

Battery ID HM1604

Battery Name HEMATOLOGY
&DIFFERENTIAL PANEL

Lab Test ID HMT2

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1261

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (28)

Data signed: (hfarmer1) 30 Mar 2015 12:28:18

Generated On: 20 Jul 2016 22:42:34

Lab Test Name	HEMATOCRIT
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	42
Reported Numeric Result	42
Reference Range low	34
Reference Range high	48
Range Units	%
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (28)

Data signed: (hfarmer1) 30 Mar 2015 12:28:18

Generated On: 20 Jul 2016 22:42:34

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (29)

Data signed: (hfarmer1) 30 Mar 2015 12:28:18

Generated On: 20 Jul 2016 22:42:34

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	<hr/>
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Subject Sex	F
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Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	X175872
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Actual Collection Date	2014 04 19
------------------------	------------

Actual Collection Time	06:33
------------------------	-------

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: 1261

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (29)

Data signed: (hfarmer1) 30 Mar 2015 12:28:18

Generated On: 20 Jul 2016 22:42:34

Lab Test Name	RBC
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	4.5
Reported Numeric Result	4.5
Reference Range low	4.1
Reference Range high	5.6
Range Units	X10^6/UL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (29)

Data signed: (hfarmer1) 30 Mar 2015 12:28:18

Generated On: 20 Jul 2016 22:42:34

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (30)

Data signed: (hfarmer1) 30 Mar 2015 12:28:18

Generated On: 20 Jul 2016 22:42:34

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex F

Subject Date of Birth (b) (6) 

Visit Name _____

Visit Type Scheduled ☒

Accession ID X175872

Actual Collection Date 2014 04 19

Actual Collection Time 06:33

Specimen Condition _____

Battery ID HM1604

Battery Name HEMATOLOGY
&DIFFERENTIAL PANEL

Lab Test ID HMT4

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1261

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (30)

Data signed: (hfarmer1) 30 Mar 2015 12:28:18

Generated On: 20 Jul 2016 22:42:34

Lab Test Name	MCV
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	93
Reported Numeric Result	93
Reference Range low	79
Reference Range high	98
Range Units	FL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (30)

Data signed: (hfarmer1) 30 Mar 2015 12:28:18

Generated On: 20 Jul 2016 22:42:34

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1261

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (31)

Data signed: (hfarmer1) 30 Mar 2015 12:28:18

Generated On: 20 Jul 2016 22:42:34

Transmission Type	Cumulative <input type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	F
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Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
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Visit Type	Scheduled <input type="radio"/>
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Accession ID	X175872
--------------	---------

Actual Collection Date	2014 04 19
------------------------	------------

Actual Collection Time	06:33
------------------------	-------

Specimen Condition	<hr/>
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Battery ID	HM1604
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Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
--------------	-----------------------------------

Lab Test ID	HMT40
-------------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1261

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (31)

Data signed: (hfarmer1) 30 Mar 2015 12:28:18

Generated On: 20 Jul 2016 22:42:34

Lab Test Name	HEMOGLOBIN
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	13.9
Reported Numeric Result	13.9
Reference Range low	11.6
Reference Range high	16.4
Range Units	G/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (31)

Data signed: (hfarmer1) 30 Mar 2015 12:28:18

Generated On: 20 Jul 2016 22:42:34

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (32)

Data signed: (hfarmer1) 30 Mar 2015 12:28:18

Generated On: 20 Jul 2016 22:42:34

Transmission Type Cumulative ☐

Subject ID or Number _____

Subject Sex F

Subject Date of Birth (b) (6) 

Visit Name _____

Visit Type Scheduled ☐

Accession ID X175872

Actual Collection Date 2014 04 19

Actual Collection Time 06:33

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: 1261

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (32)

Data signed: (hfarmer1) 30 Mar 2015 12:28:18

Generated On: 20 Jul 2016 22:42:34

Lab Test Name	WBC
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	9.37
Reported Numeric Result	9.37
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: 1261**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (32)

Data signed: (hfarmer1) 30 Mar 2015 12:28:18

Generated On: 20 Jul 2016 22:42:34

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (33)

Data signed: (hfarmer1) 30 Mar 2015 12:28:18

Generated On: 20 Jul 2016 22:42:34

Transmission Type Cumulative ☐

Subject ID or Number _____

Subject Sex F

Subject Date of Birth (b) (6) 

Visit Name _____

Visit Type Scheduled ☐

Accession ID X175872

Actual Collection Date 2014 04 19

Actual Collection Time 06:33

Specimen Condition _____

Battery ID HM1604

Battery Name HEMATOLOGY
&DIFFERENTIAL PANEL

Lab Test ID HMT71

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1261

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (33)

Data signed: (hfarmer1) 30 Mar 2015 12:28:18


Generated On: 20 Jul 2016 22:42:34

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: 1261**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (33)

Data signed: (hfarmer1) 30 Mar 2015 12:28:18

Generated On: 20 Jul 2016 22:42:34

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1261

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (34)

Data signed: (hfarmer1) 30 Mar 2015 12:28:18

Generated On: 20 Jul 2016 22:42:34

Transmission Type Cumulative ☐

Subject ID or Number _____

Subject Sex F

Subject Date of Birth (b) (6)

Visit Name _____

Visit Type Scheduled ☐

Accession ID X175872

Actual Collection Date 2014 04 19

Actual Collection Time 06:33

Specimen Condition _____

Battery ID HM1604

Battery Name HEMATOLOGY
&DIFFERENTIAL PANEL

Lab Test ID HMT8

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1261

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (34)

Data signed: (hfarmer1) 30 Mar 2015 12:28:18

Generated On: 20 Jul 2016 22:42:34

Lab Test Name	NEUTROPHILS
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	5.45
Reported Numeric Result	5.45
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: 1261**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (34)

Data signed: (hfarmer1) 30 Mar 2015 12:28:18

Generated On: 20 Jul 2016 22:42:34

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (35)

Data signed: (hfarmer1) 30 Mar 2015 12:28:18

Generated On: 20 Jul 2016 22:42:34

Transmission Type Cumulative ☐

Subject ID or Number _____

Subject Sex F

Subject Date of Birth (b) (6)

Visit Name _____

Visit Type Scheduled ☐

Accession ID X175872

Actual Collection Date 2014 04 19

Actual Collection Time 06:33

Specimen Condition _____

Battery ID HM1604

Battery Name HEMATOLOGY
&DIFFERENTIAL PANEL

Lab Test ID HMT9

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1261

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (35)

Data signed: (hfarmer1) 30 Mar 2015 12:28:18

Generated On: 20 Jul 2016 22:42:34

Lab Test Name	LYMPHOCYTES
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	2.83
Reported Numeric Result	2.83
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: 1261**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (35)

Data signed: (hfarmer1) 30 Mar 2015 12:28:18

Generated On: 20 Jul 2016 22:42:34

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1261

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (36)

Data signed: (hfarmer1) 30 Mar 2015 12:28:18

Generated On: 20 Jul 2016 22:42:34

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex F

Subject Date of Birth (b) (6) 

Visit Name _____

Visit Type Scheduled ☒

Accession ID X175872

Actual Collection Date 2014 04 19

Actual Collection Time 06:33

Specimen Condition _____

Battery ID UA1538

Battery Name URINE MACRO PANEL

Lab Test ID UAT10

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (36)

Data signed: (hfarmer1) 30 Mar 2015 12:28:18


Generated On: 20 Jul 2016 22:42:34

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: 1261**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (36)

Data signed: (hfarmer1) 30 Mar 2015 12:28:18

Generated On: 20 Jul 2016 22:42:34

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (37)

Data signed: (hfarmer1) 30 Mar 2015 12:28:18

Generated On: 20 Jul 2016 22:42:34

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
----------------------	-------

Subject Sex	F
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Subject Date of Birth	(b) (6) 
-----------------------	---

Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	X175872
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Actual Collection Date	2014 04 19
------------------------	------------

Actual Collection Time	06:33
------------------------	-------

Specimen Condition	<hr/>
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Battery ID	UA1538
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Battery Name	URINE MACRO PANEL
--------------	-------------------

Lab Test ID	UAT2
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1261

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (37)

Data signed: (hfarmer1) 30 Mar 2015 12:28:18

Generated On: 20 Jul 2016 22:42:34

Lab Test Name	UR SPECIFIC GRAVITY
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	1.023
Reported Numeric Result	1.023
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: 1261**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (37)

Data signed: (hfarmer1) 30 Mar 2015 12:28:18

Generated On: 20 Jul 2016 22:42:34

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (38)

Data signed: (hfarmer1) 30 Mar 2015 12:28:18

Generated On: 20 Jul 2016 22:42:34

Transmission Type Cumulative ☒

Subject ID or Number

Subject Sex F

Subject Date of Birth (b) (6) 

Visit Name

Visit Type Scheduled ☒

Accession ID X175872

Actual Collection Date 2014 04 19

Actual Collection Time 06:33

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: 1261

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (38)

Data signed: (hfarmer1) 30 Mar 2015 12:28:18

Generated On: 20 Jul 2016 22:42:34

Lab Test Name	UR PH
Test ID	
Test Status	Done <input type="checkbox"/>
Reported Text Result	6.5
Reported Numeric Result	6.5
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: 1261**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (38)

Data signed: (hfarmer1) 30 Mar 2015 12:28:18

Generated On: 20 Jul 2016 22:42:34

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (39)

Data signed: (hfarmer1) 30 Mar 2015 12:28:18

Generated On: 20 Jul 2016 22:42:34

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex F

Subject Date of Birth (b) (6)

Visit Name _____

Visit Type Scheduled ☒

Accession ID X175872

Actual Collection Date 2014 04 19

Actual Collection Time 06:33

Specimen Condition _____

Battery ID UA1538

Battery Name URINE MACRO PANEL

Lab Test ID UAT43

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (39)

Data signed: (hfarmer1) 30 Mar 2015 12:28:18


Generated On: 20 Jul 2016 22:42:34

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: 1261**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (39)

Data signed: (hfarmer1) 30 Mar 2015 12:28:18

Generated On: 20 Jul 2016 22:42:34

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (40)

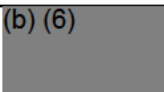
Data signed: (hfarmer1) 30 Mar 2015 12:28:18

Generated On: 20 Jul 2016 22:42:34

Transmission Type Cumulative ☐

Subject ID or Number _____

Subject Sex F

Subject Date of Birth (b) (6) 

Visit Name _____

Visit Type Scheduled ☐

Accession ID X175872

Actual Collection Date 2014 04 19

Actual Collection Time 06:33

Specimen Condition _____

Battery ID UA1538

Battery Name URINE MACRO PANEL

Lab Test ID UAT49

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1261

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (40)

Data signed: (hfarmer1) 30 Mar 2015 12:28:18


Generated On: 20 Jul 2016 22:42:34

Lab Test Name

UR PROTEIN

Test ID

Test Status

Done 

Reported Text Result

TRACE

Reported Numeric Result

Reference Range low

Reference Range high

Range Units

Conventional Text Result

Conventional Numeric Result

Conventional Reference Range Low

Conventional Reference Range High

Conventional Units

SI Text Result

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (40)

Data signed: (hfarmer1) 30 Mar 2015 12:28:18

Generated On: 20 Jul 2016 22:42:34

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

High ☒

Clinically Significant?

No ☒

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (41)

Data signed: (hfarmer1) 30 Mar 2015 12:28:18

Generated On: 20 Jul 2016 22:42:34

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex F

Subject Date of Birth (b) (6)

Visit Name _____

Visit Type Scheduled ☒

Accession ID X175872

Actual Collection Date 2014 04 19

Actual Collection Time 06:33

Specimen Condition _____

Battery ID UA1538

Battery Name URINE MACRO PANEL

Lab Test ID UAT5

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1261

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (41)

Data signed: (hfarmer1) 30 Mar 2015 12:28:18


Generated On: 20 Jul 2016 22:42:34

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: 1261**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (41)

Data signed: (hfarmer1) 30 Mar 2015 12:28:18

Generated On: 20 Jul 2016 22:42:34

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (42)

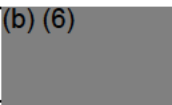
Data signed: (hfarmer1) 30 Mar 2015 12:28:18

Generated On: 20 Jul 2016 22:42:34

Transmission Type Cumulative ☐

Subject ID or Number _____

Subject Sex F

Subject Date of Birth (b) (6) 

Visit Name _____

Visit Type Scheduled ☐

Accession ID X175872

Actual Collection Date 2014 04 19

Actual Collection Time 06:33

Specimen Condition _____

Battery ID UA1538

Battery Name URINE MACRO PANEL

Lab Test ID UAT7

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1261

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (42)

Data signed: (hfarmer1) 30 Mar 2015 12:28:18


Generated On: 20 Jul 2016 22:42:34

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: 1261**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (42)

Data signed: (hfarmer1) 30 Mar 2015 12:28:18

Generated On: 20 Jul 2016 22:42:34

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 30

Form: Date of Visit

Data signed: (hfarmer1) 30 Mar 2015 12:28:36

Generated On: 20 Jul 2016 22:42:34

Visit Not Done	False
----------------	-------

If Not Done, Specify Reason	<hr/>
-----------------------------	-------

Date of Visit	13 MAY 2014 DD/MMM/YYYY
---------------	----------------------------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 30

Form: Vital Signs

Data signed: (hfarmer1) 30 Mar 2015 12:28:36

Generated On: 20 Jul 2016 22:42:34

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

13 MAY 2014
DD/MMM/YYYY

Time of assessment

14:48
hour:min 24-hour clock

Pulse rate

72
beats per minute

Respiratory rate

16
breaths per minute

Blood Pressure (systolic)

115
mmHg

Blood Pressure (diastolic)

79
mmHg

Vital Signs Position of Subject

Supine ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 30

Form: Advice on the risk of smoking and debriefing

Data signed: (hfarmer1) 30 Mar 2015 12:28:36

Generated On: 20 Jul 2016 22:42:34

Date	14 MAY 2014 DD/MMM/YYYY
------	----------------------------

Has the subject received advices on the risks of smoking?	Yes <input type="radio"/>
---	---------------------------

Has a debriefing been performed about THS 2.2?	Yes <input type="radio"/>
--	---------------------------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 30

Form: Physical Examination

Data signed: (hfarmer1) 30 Mar 2015 12:28:33

Generated On: 20 Jul 2016 22:42:34

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of Assessment

13 MAY 2014
DD/MMM/YYYY

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 30

Form: Physical Examination (1)

Data signed: (hfarmer1) 30 Mar 2015 12:28:33

Generated On: 20 Jul 2016 22:42:34

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of Assessment

13 MAY 2014
DD/MMM/YYYY

System

General Appearance ☒

Outcome

Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done

False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 30

Form: Physical Examination (2)

Data signed: (hfarmer1) 30 Mar 2015 12:28:33

Generated On: 20 Jul 2016 22:42:34

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of Assessment

13 MAY 2014
DD/MMM/YYYY

System

HEENT ☒
(head, eyes, ears, nose,
throat)

Outcome

Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done

False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 30

Form: Physical Examination (3)

Data signed: (hfarmer1) 30 Mar 2015 12:28:33

Generated On: 20 Jul 2016 22:42:34

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of Assessment

13 MAY 2014
DD/MMM/YYYY

System

Thyroid Gland ☒

Outcome

Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done

False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 30

Form: Physical Examination (4)

Data signed: (hfarmer1) 30 Mar 2015 12:28:33

Generated On: 20 Jul 2016 22:42:34

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of Assessment

13 MAY 2014
DD/MMM/YYYY

System

Heart ☒

Outcome

Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done

False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 30

Form: Physical Examination (5)

Data signed: (hfarmer1) 30 Mar 2015 12:28:33

Generated On: 20 Jul 2016 22:42:34

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of Assessment

13 MAY 2014
DD/MMM/YYYY

System

Chest ☒

Outcome

Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done

False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 30

Form: Physical Examination (6)

Data signed: (hfarmer1) 30 Mar 2015 12:28:33

Generated On: 20 Jul 2016 22:42:34

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of Assessment 13 MAY 2014
DD/MMM/YYYY

System Lungs ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 30

Form: Physical Examination (7)

Data signed: (hfarmer1) 30 Mar 2015 12:28:33

Generated On: 20 Jul 2016 22:42:34

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of Assessment 13 MAY 2014
DD/MMM/YYYY

System Gastrointestinal ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 30

Form: Physical Examination (8)

Data signed: (hfarmer1) 30 Mar 2015 12:28:33

Generated On: 20 Jul 2016 22:42:34

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of Assessment 13 MAY 2014
DD/MMM/YYYY

System Cardiovascular System ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 30

Form: Physical Examination (9)

Data signed: (hfarmer1) 30 Mar 2015 12:28:33

Generated On: 20 Jul 2016 22:42:34

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of Assessment

13 MAY 2014
DD/MMM/YYYY

System

Neurologic ☒

Outcome

Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done

False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 30

Form: Physical Examination (10)

Data signed: (hfarmer1) 30 Mar 2015 12:28:33

Generated On: 20 Jul 2016 22:42:34

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of Assessment 13 MAY 2014
DD/MMM/YYYY

System Skin ☒

Outcome Abnormal ☒

Abnormal, please specify SMALL BURN LEFT ANTERIOR
CHEST WALL

Clinically significant No ☒

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 30

Form: Physical Examination (11)

Data signed: (hfarmer1) 30 Mar 2015 12:28:33

Generated On: 20 Jul 2016 22:42:34

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of Assessment

13 MAY 2014
DD/MMM/YYYY

System

Back ☒

Outcome

Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done

False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 30

Form: Physical Examination (12)

Data signed: (hfarmer1) 30 Mar 2015 12:28:33

Generated On: 20 Jul 2016 22:42:34

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of Assessment

13 MAY 2014
DD/MMM/YYYY

System

Musculoskeletal ☒

Outcome

Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done

False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 30

Form: Physical Examination (13)

Data signed: (hfarmer1) 30 Mar 2015 12:28:33

Generated On: 20 Jul 2016 22:42:34

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of Assessment 13 MAY 2014
DD/MMM/YYYY

System Abdomen ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 30

Form: Physical Examination (14)

Data signed: (hfarmer1) 30 Mar 2015 12:28:33

Generated On: 20 Jul 2016 22:42:34

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of Assessment 13 MAY 2014
DD/MMM/YYYY

System Dentition ☒

Outcome Abnormal ☒

Abnormal, please specify MANY DECAYED TEETH

Clinically significant No ☒

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 30

Form: Physical Examination (15)

Data signed: (hfarmer1) 30 Mar 2015 12:28:33

Generated On: 20 Jul 2016 22:42:34

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of Assessment

13 MAY 2014
DD/MMM/YYYY

System

Other ☒

Other, Specify _____

Outcome _____

Abnormal, please specify _____

Clinically significant _____

Not Done

True

Not Done; please specify the reason: _____

NOT EXAMINED

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 30

Form: Physical Examination (16)

Data signed: (hfarmer1) 30 Mar 2015 12:28:33

Generated On: 20 Jul 2016 22:42:34

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of Assessment

13 MAY 2014
DD/MMM/YYYY

System

Other ☒

Other, Specify _____

Outcome _____

Abnormal, please specify _____

Clinically significant _____

Not Done

True

Not Done; please specify the reason: _____

NOT EXAMINED

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 30

Form: Physical Examination (17)

Data signed: (hfarmer1) 30 Mar 2015 12:28:33

Generated On: 20 Jul 2016 22:42:34

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of Assessment

13 MAY 2014
DD/MMM/YYYY

System

Other ☒

Other, Specify _____

Outcome _____

Abnormal, please specify _____

Clinically significant _____

Not Done

True

Not Done; please specify the reason: _____

NOT EXAMINED

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 30

Form: Physical Examination (18)

Data signed: (hfarmer1) 30 Mar 2015 12:28:33

Generated On: 20 Jul 2016 22:42:34

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of Assessment

13 MAY 2014
DD/MMM/YYYY

System

Other ☒

Other, Specify _____

Outcome _____

Abnormal, please specify _____

Clinically significant _____

Not Done

True

Not Done; please specify the reason: _____

NOT EXAMINED

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 30

Form: Physical Examination (19)

Data signed: (hfarmer1) 30 Mar 2015 12:28:33

Generated On: 20 Jul 2016 22:42:34

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of Assessment

13 MAY 2014
DD/MMM/YYYY

System

Other ☒

Other, Specify _____

Outcome _____

Abnormal, please specify _____

Clinically significant _____

Not Done

True

Not Done; please specify the reason: _____

NOT EXAMINED

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 30

Form: Weight

Data signed: (hfarmer1) 30 Mar 2015 12:28:36

Generated On: 20 Jul 2016 22:42:34

Measurement(s) assessed?

Yes ☒

If No, please specify the reason: _____

Date of Assessment

13 MAY 2014
DD/MMM/YYYY

Time of assessment

14:50
hour:min 24-hour clock

Weight

72.4
kg

BMI

28.4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 30

Form: ECG (12-Lead Standard)

Data signed: (hfarmer1) 30 Mar 2015 12:28:32

Generated On: 20 Jul 2016 22:42:34

Was the ECG performed?

Yes ☒

If No, please specify the reason: _____

Date of Assessment

13 MAY 2014
DD/MMM/YYYY

Position

Supine ☒

Heart Rate

73
beats per minute

QRS Interval

90
msec

QT Interval

374
msec

QTcB Interval

414
msec

PR Interval

145
msec

QTcF Interval

400
msec

Interpretation

Normal ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 30

Form: ECG (12-Lead Standard)

Data signed: (hfarmer1) 30 Mar 2015 12:28:32

Generated On: 20 Jul 2016 22:42:34

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: 1261**

Folder: Day 30

Form: Haematology

Data signed: (hfarmer1) 30 Mar 2015 12:28:32

Generated On: 20 Jul 2016 22:42:34

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: 1261**

Folder: Day 30

Form: Clinical Chemistry

Data signed: (hfarmer1) 30 Mar 2015 12:28:32

Generated On: 20 Jul 2016 22:42:34

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: 1261**

Folder: Day 30

Form: Urine analysis

Data signed: (hfarmer1) 30 Mar 2015 12:28:32

Generated On: 20 Jul 2016 22:42:34

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: 1261**

Folder: Day 30

Form: Urine Pregnancy Test

Data signed: (hfarmer1) 30 Mar 2015 12:28:36

Generated On: 20 Jul 2016 22:42:34

Not Done	False
----------	-------

If Not Done, specify reason	<hr/>
-----------------------------	-------

Date of Test	13 MAY 2014 DD/MMM/YYYY
--------------	----------------------------

Time of Test	14:53 hour:min 24-hour clock
--------------	---------------------------------

Specify result	Negative <input checked="" type="radio"/>
----------------	---

If unclear, please confirm with FSH test	<hr/>
--	-------

Specify result of FSH test	<hr/>
----------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 30

Form: Plasma Nicotine Sample

Data signed: (hfarmer1) 30 Mar 2015 12:28:33

Generated On: 20 Jul 2016 22:42:34

Not Done	False
----------	-------

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	13 MAY 2014
---------------------	-------------

Time hour:min 24-hour clock	10:04
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 30

Form: Plasma Cotinine Sample

Data signed: (hfarmer1) 30 Mar 2015 12:28:32

Generated On: 20 Jul 2016 22:42:34

Not Done	False
----------	-------

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	13 MAY 2014
---------------------	-------------

Time hour:min 24-hour clock	10:04
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 30

Form: CoHb Blood Sample <D30_D60>

Data signed: (hfarmer1) 30 Mar 2015 12:28:32

Generated On: 20 Jul 2016 22:42:34

Not Done	False
----------	-------

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	13 MAY 2014
---------------------	-------------

Timepoint	10:00 - 11:30 <input checked="" type="radio"/>
-----------	--

Time hour:min 24-hour clock	10:04
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 30

Form: CO Breath Test

Data signed: (hfarmer1) 30 Mar 2015 12:28:32

Generated On: 20 Jul 2016 22:42:34

Assessment not done	False
---------------------	-------

If Not Done, please specify the reason: _____

Actual Date of Assessment	13 MAY 2014 DD/MMM/YYYY
---------------------------	----------------------------

Actual Time of Assessment	10:22 hour:min 24-hour clock
---------------------------	---------------------------------

Result	27 ppm
--------	-----------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 30

Form: Risk markers: hs-CRP, fibrinogen, homocysteine, LDL, HDL, sICAM-1

Data signed: (hfarmer1) 30 Mar 2015 12:28:33

Generated On: 20 Jul 2016 22:42:34

Not Done	False
----------	-------

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	14 MAY 2014
---------------------	-------------

Time hour:min 24-hour clock	06:21
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 30

Form: 24 hour urine collections

Data signed: (hfarmer1) 30 Mar 2015 12:28:36

Generated On: 20 Jul 2016 22:42:34

Start Date	13 MAY 2014 DD/MMM/YYYY
------------	----------------------------

Start Time	09:02 hour:min 24-hour clock
------------	---------------------------------

End Date	14 MAY 2014 DD/MMM/YYYY
----------	----------------------------

End Time	08:32 hour:min 24-hour clock
----------	---------------------------------

Volume	2531 mL
--------	------------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 30

Form: Sample Urine Collection

Data signed: (hfarmer1) 30 Mar 2015 12:28:36

Generated On: 20 Jul 2016 22:42:34

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: 1261**

Folder: Day 30

Form: Lab_BU_CCLS (1)

Data signed: (hfarmer1) 30 Mar 2015 12:28:38

Generated On: 20 Jul 2016 22:42:34

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	<hr/>
----------------------	-------

Subject Sex	F
-------------	---

Subject Date of Birth	(b) (6) 
-----------------------	---

Visit Name	<hr/>
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	X312842
--------------	---------

Actual Collection Date	2014 05 14
------------------------	------------

Actual Collection Time	06:21
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	RC1029
------------	--------

Battery Name	TRIGLYCERIDES
--------------	---------------

Lab Test ID	RCT19
-------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 30

Form: Lab_BU_CCLS (1)

Data signed: (hfarmer1) 30 Mar 2015 12:28:38

Generated On: 20 Jul 2016 22:42:34

Lab Test Name	TRIGLYCERIDES (GPO)
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	332
Reported Numeric Result	332
Reference Range low	39
Reference Range high	176
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: 1261**

Folder: Day 30

Form: Lab_BU_CCLS (1)

Data signed: (hfarmer1) 30 Mar 2015 12:28:38

Generated On: 20 Jul 2016 22:42:34

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

High ☒

Clinically Significant?

No ☒

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 30

Form: Lab_BU_CCLS (2)

Data signed: (hfarmer1) 30 Mar 2015 12:28:38

Generated On: 20 Jul 2016 22:42:34

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	<hr/>
----------------------	-------

Subject Sex	F
-------------	---

Subject Date of Birth	(b) (6) <div></div>
-----------------------	---------------------

Visit Name	<hr/>
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	X312842
--------------	---------

Actual Collection Date	2014 05 14
------------------------	------------

Actual Collection Time	06:21
------------------------	-------

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: 1261**

Folder: Day 30

Form: Lab_BU_CCLS (2)

Data signed: (hfarmer1) 30 Mar 2015 12:28:38

Generated On: 20 Jul 2016 22:42:34

Lab Test Name	FASTING GLUCOSE
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	89
Reported Numeric Result	89
Reference Range low	70
Reference Range high	100
Range Units	MG/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 30

Form: Lab_BU_CCLS (2)

Data signed: (hfarmer1) 30 Mar 2015 12:28:38

Generated On: 20 Jul 2016 22:42:34

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 30

Form: Lab_BU_CCLS (3)

Data signed: (hfarmer1) 30 Mar 2015 12:28:38

Generated On: 20 Jul 2016 22:42:34

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	
----------------------	--

Subject Sex	F
-------------	---

Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	
------------	--

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	X312842
--------------	---------

Actual Collection Date	2014 05 14
------------------------	------------

Actual Collection Time	06:21
------------------------	-------

Specimen Condition	
--------------------	--

Battery ID	RC272
------------	-------

Battery Name	TOTAL CHOLESTEROL
--------------	-------------------

Lab Test ID	RCT20
-------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 30

Form: Lab_BU_CCLS (3)

Data signed: (hfarmer1) 30 Mar 2015 12:28:38

Generated On: 20 Jul 2016 22:42:34

Lab Test Name	CHOLESTEROL (HIGH PERFORMANCE)
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	207
Reported Numeric Result	207
Reference Range low	141
Reference Range high	240
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: 1261**

Folder: Day 30

Form: Lab_BU_CCLS (3)

Data signed: (hfarmer1) 30 Mar 2015 12:28:38

Generated On: 20 Jul 2016 22:42:34

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: 1261**

Folder: Day 30

Form: Lab_BU_CCLS (4)

Data signed: (hfarmer1) 30 Mar 2015 12:28:38

Generated On: 20 Jul 2016 22:42:34

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex F

Subject Date of Birth (b) (6) ☒

Visit Name _____

Visit Type Scheduled ☒

Accession ID X312842

Actual Collection Date 2014 05 14

Actual Collection Time 06:21

Specimen Condition _____

Battery ID RC9255

Battery Name CHEMISTRY PANEL

Lab Test ID RCT1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 30

Form: Lab_BU_CCLS (4)

Data signed: (hfarmer1) 30 Mar 2015 12:28:38

Generated On: 20 Jul 2016 22:42:34

Lab Test Name	TOTAL BILIRUBIN
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	0.2
Reported Numeric Result	0.2
Reference Range low	0.2
Reference Range high	1.2
Range Units	MG/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 30

Form: Lab_BU_CCLS (4)

Data signed: (hfarmer1) 30 Mar 2015 12:28:38

Generated On: 20 Jul 2016 22:42:34

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 30

Form: Lab_BU_CCLS (5)

Data signed: (hfarmer1) 30 Mar 2015 12:28:38

Generated On: 20 Jul 2016 22:42:34

Transmission Type Cumulative ☐

Subject ID or Number _____

Subject Sex F

Subject Date of Birth (b) (6) 

Visit Name _____

Visit Type Scheduled ☐

Accession ID X312842

Actual Collection Date 2014 05 14

Actual Collection Time 06:21

Specimen Condition _____

Battery ID RC9255

Battery Name CHEMISTRY PANEL

Lab Test ID RCT12

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 30

Form: Lab_BU_CCLS (5)

Data signed: (hfarmer1) 30 Mar 2015 12:28:38

Generated On: 20 Jul 2016 22:42:34

Lab Test Name	TOTAL PROTEIN
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	5.7
Reported Numeric Result	5.7
Reference Range low	6.1
Reference Range high	8.4
Range Units	G/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 30

Form: Lab_BU_CCLS (5)

Data signed: (hfarmer1) 30 Mar 2015 12:28:38

Generated On: 20 Jul 2016 22:42:34

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Low ☒

Clinically Significant?

No ☒

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 30

Form: Lab_BU_CCLS (6)

Data signed: (hfarmer1) 30 Mar 2015 12:28:38

Generated On: 20 Jul 2016 22:42:34

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex F

Subject Date of Birth (b) (6) 

Visit Name _____

Visit Type Scheduled ☒

Accession ID X312842

Actual Collection Date 2014 05 14

Actual Collection Time 06:21

Specimen Condition _____

Battery ID RC9255

Battery Name CHEMISTRY PANEL

Lab Test ID RCT13

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 30

Form: Lab_BU_CCLS (6)

Data signed: (hfarmer1) 30 Mar 2015 12:28:38

Generated On: 20 Jul 2016 22:42:34

Lab Test Name	ALBUMIN
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	3.4
Reported Numeric Result	3.4
Reference Range low	3.3
Reference Range high	4.9
Range Units	G/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 30

Form: Lab_BU_CCLS (6)

Data signed: (hfarmer1) 30 Mar 2015 12:28:38

Generated On: 20 Jul 2016 22:42:34

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 30

Form: Lab_BU_CCLS (7)

Data signed: (hfarmer1) 30 Mar 2015 12:28:38

Generated On: 20 Jul 2016 22:42:34

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	F
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Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	X312842
--------------	---------

Actual Collection Date	2014 05 14
------------------------	------------

Actual Collection Time	06:21
------------------------	-------

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: 1261**

Folder: Day 30

Form: Lab_BU_CCLS (7)

Data signed: (hfarmer1) 30 Mar 2015 12:28:38

Generated On: 20 Jul 2016 22:42:34

Lab Test Name	ALKALINE PHOSPHATASE
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	60
Reported Numeric Result	60
Reference Range low	31
Reference Range high	106
Range Units	U/L
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 30

Form: Lab_BU_CCLS (7)

Data signed: (hfarmer1) 30 Mar 2015 12:28:38

Generated On: 20 Jul 2016 22:42:34

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 30

Form: Lab_BU_CCLS (8)

Data signed: (hfarmer1) 30 Mar 2015 12:28:38

Generated On: 20 Jul 2016 22:42:34

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	F
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Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	X312842
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Actual Collection Date	2014 05 14
------------------------	------------

Actual Collection Time	06:21
------------------------	-------

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: 1261**

Folder: Day 30

Form: Lab_BU_CCLS (8)

Data signed: (hfarmer1) 30 Mar 2015 12:28:38

Generated On: 20 Jul 2016 22:42:34

Lab Test Name	LDH
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	150
Reported Numeric Result	150
Reference Range low	53
Reference Range high	234
Range Units	U/L
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 30

Form: Lab_BU_CCLS (8)

Data signed: (hfarmer1) 30 Mar 2015 12:28:38

Generated On: 20 Jul 2016 22:42:34

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 30

Form: Lab_BU_CCLS (9)

Data signed: (hfarmer1) 30 Mar 2015 12:28:38

Generated On: 20 Jul 2016 22:42:34

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	F
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Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	X312842
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Actual Collection Date	2014 05 14
------------------------	------------

Actual Collection Time	06:21
------------------------	-------

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: 1261**

Folder: Day 30

Form: Lab_BU_CCLS (9)

Data signed: (hfarmer1) 30 Mar 2015 12:28:38

Generated On: 20 Jul 2016 22:42:34

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: 1261**

Folder: Day 30

Form: Lab_BU_CCLS (9)

Data signed: (hfarmer1) 30 Mar 2015 12:28:38

Generated On: 20 Jul 2016 22:42:34

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 30

Form: Lab_BU_CCLS (10)

Data signed: (hfarmer1) 30 Mar 2015 12:28:38

Generated On: 20 Jul 2016 22:42:34

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	F
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Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	X312842
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Actual Collection Date	2014 05 14
------------------------	------------

Actual Collection Time	06:21
------------------------	-------

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: 1261

Folder: Day 30

Form: Lab_BU_CCLS (10)

Data signed: (hfarmer1) 30 Mar 2015 12:28:38

Generated On: 20 Jul 2016 22:42:34

Lab Test Name	SERUM POTASSIUM
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	4.3
Reported Numeric Result	4.3
Reference Range low	3.4
Reference Range high	5.4
Range Units	MEQ/L
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 30

Form: Lab_BU_CCLS (10)

Data signed: (hfarmer1) 30 Mar 2015 12:28:38

Generated On: 20 Jul 2016 22:42:34

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 30

Form: Lab_BU_CCLS (11)

Data signed: (hfarmer1) 30 Mar 2015 12:28:38

Generated On: 20 Jul 2016 22:42:34

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	F
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Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	X312842
--------------	---------

Actual Collection Date	2014 05 14
------------------------	------------

Actual Collection Time	06:21
------------------------	-------

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: 1261**

Folder: Day 30

Form: Lab_BU_CCLS (11)

Data signed: (hfarmer1) 30 Mar 2015 12:28:38

Generated On: 20 Jul 2016 22:42:34

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: 1261**

Folder: Day 30

Form: Lab_BU_CCLS (11)

Data signed: (hfarmer1) 30 Mar 2015 12:28:38

Generated On: 20 Jul 2016 22:42:34

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 30

Form: Lab_BU_CCLS (12)

Data signed: (hfarmer1) 30 Mar 2015 12:28:38

Generated On: 20 Jul 2016 22:42:34

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	F
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Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	X312842
--------------	---------

Actual Collection Date	2014 05 14
------------------------	------------

Actual Collection Time	06:21
------------------------	-------

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: 1261**

Folder: Day 30

Form: Lab_BU_CCLS (12)

Data signed: (hfarmer1) 30 Mar 2015 12:28:38

Generated On: 20 Jul 2016 22:42:34

Lab Test Name	GGT
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	17
Reported Numeric Result	17
Reference Range low	4
Reference Range high	49
Range Units	U/L
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 30

Form: Lab_BU_CCLS (12)

Data signed: (hfarmer1) 30 Mar 2015 12:28:38

Generated On: 20 Jul 2016 22:42:34

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 30

Form: Lab_BU_CCLS (13)

Data signed: (hfarmer1) 30 Mar 2015 12:28:38

Generated On: 20 Jul 2016 22:42:34

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	<hr/>
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Subject Sex	F
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Subject Date of Birth	(b) (6)
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	X312842
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Actual Collection Date	2014 05 14
------------------------	------------

Actual Collection Time	06:21
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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: 1261**

Folder: Day 30

Form: Lab_BU_CCLS (13)

Data signed: (hfarmer1) 30 Mar 2015 12:28:38

Generated On: 20 Jul 2016 22:42:34

Lab Test Name	CREATININE (RATE BLANKED)
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Test ID	<hr/>
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Test Status	Done 
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Reported Text Result	0.7
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Reported Numeric Result	0.7
-------------------------	-----

Reference Range low	0.4
---------------------	-----

Reference Range high	1.1
----------------------	-----

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/>
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SI Text Result	<hr/>
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 30

Form: Lab_BU_CCLS (13)

Data signed: (hfarmer1) 30 Mar 2015 12:28:38

Generated On: 20 Jul 2016 22:42:34

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 30

Form: Lab_BU_CCLS (14)

Data signed: (hfarmer1) 30 Mar 2015 12:28:38

Generated On: 20 Jul 2016 22:42:34

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	F
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Subject Date of Birth	(b) (6)
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	X312842
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Actual Collection Date	2014 05 14
------------------------	------------

Actual Collection Time	06:21
------------------------	-------

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: 1261**

Folder: Day 30

Form: Lab_BU_CCLS (14)

Data signed: (hfarmer1) 30 Mar 2015 12:28:38

Generated On: 20 Jul 2016 22:42:34

Lab Test Name	ALT (SGPT)
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	27
Reported Numeric Result	27
Reference Range low	6
Reference Range high	34
Range Units	U/L
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 30

Form: Lab_BU_CCLS (14)

Data signed: (hfarmer1) 30 Mar 2015 12:28:38

Generated On: 20 Jul 2016 22:42:34

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 30

Form: Lab_BU_CCLS (15)

Data signed: (hfarmer1) 30 Mar 2015 12:28:38

Generated On: 20 Jul 2016 22:42:34

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	<hr/>
----------------------	-------

Subject Sex	F
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Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	X312842
--------------	---------

Actual Collection Date	2014 05 14
------------------------	------------

Actual Collection Time	06:21
------------------------	-------

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: 1261**

Folder: Day 30

Form: Lab_BU_CCLS (15)

Data signed: (hfarmer1) 30 Mar 2015 12:28:38

Generated On: 20 Jul 2016 22:42:34

Lab Test Name	AST (SGOT)
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	20
Reported Numeric Result	20
Reference Range low	9
Reference Range high	34
Range Units	U/L
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 30

Form: Lab_BU_CCLS (15)

Data signed: (hfarmer1) 30 Mar 2015 12:28:38

Generated On: 20 Jul 2016 22:42:34

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 30

Form: Lab_BU_CCLS (16)

Data signed: (hfarmer1) 30 Mar 2015 12:28:38

Generated On: 20 Jul 2016 22:42:34

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	<hr/>
----------------------	-------

Subject Sex	F
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Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	X312842
--------------	---------

Actual Collection Date	2014 05 14
------------------------	------------

Actual Collection Time	06:21
------------------------	-------

Specimen Condition	<hr/>
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Battery ID	RC9255
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Battery Name	CHEMISTRY PANEL
--------------	-----------------

Lab Test ID	RCT6
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 30

Form: Lab_BU_CCLS (16)

Data signed: (hfarmer1) 30 Mar 2015 12:28:38

Generated On: 20 Jul 2016 22:42:34

Lab Test Name	UREA NITROGEN
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	13
Reported Numeric Result	13
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: 1261**

Folder: Day 30

Form: Lab_BU_CCLS (16)

Data signed: (hfarmer1) 30 Mar 2015 12:28:38

Generated On: 20 Jul 2016 22:42:34

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 30

Form: Lab_BU_CCLS (17)

Data signed: (hfarmer1) 30 Mar 2015 12:28:38

Generated On: 20 Jul 2016 22:42:34

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	F
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Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	X312842
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Actual Collection Date	2014 05 14
------------------------	------------

Actual Collection Time	06:21
------------------------	-------

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: 1261**

Folder: Day 30

Form: Lab_BU_CCLS (17)

Data signed: (hfarmer1) 30 Mar 2015 12:28:38

Generated On: 20 Jul 2016 22:42:34

Lab Test Name	MONOCYTES
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	0.72
Reported Numeric Result	0.72
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: 1261**

Folder: Day 30

Form: Lab_BU_CCLS (17)

Data signed: (hfarmer1) 30 Mar 2015 12:28:38

Generated On: 20 Jul 2016 22:42:34

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 30

Form: Lab_BU_CCLS (18)

Data signed: (hfarmer1) 30 Mar 2015 12:28:38

Generated On: 20 Jul 2016 22:42:34

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	F
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Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	X312842
--------------	---------

Actual Collection Date	2014 05 14
------------------------	------------

Actual Collection Time	06:21
------------------------	-------

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: 1261

Folder: Day 30

Form: Lab_BU_CCLS (18)

Data signed: (hfarmer1) 30 Mar 2015 12:28:38

Generated On: 20 Jul 2016 22:42:34

Lab Test Name	MCH
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	30
Reported Numeric Result	30
Reference Range low	26
Reference Range high	34
Range Units	PG
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 30

Form: Lab_BU_CCLS (18)

Data signed: (hfarmer1) 30 Mar 2015 12:28:38

Generated On: 20 Jul 2016 22:42:34

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 30

Form: Lab_BU_CCLS (19)

Data signed: (hfarmer1) 30 Mar 2015 12:28:38

Generated On: 20 Jul 2016 22:42:34

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	
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Subject Sex	F
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Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	X312842
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Actual Collection Date	2014 05 14
------------------------	------------

Actual Collection Time	06:21
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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	HMT102
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 30

Form: Lab_BU_CCLS (19)

Data signed: (hfarmer1) 30 Mar 2015 12:28:38

Generated On: 20 Jul 2016 22:42:34

Lab Test Name	MCHC
Test ID	
Test Status	Done <input checked="" 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: 1261**

Folder: Day 30

Form: Lab_BU_CCLS (19)

Data signed: (hfarmer1) 30 Mar 2015 12:28:38

Generated On: 20 Jul 2016 22:42:34

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 30

Form: Lab_BU_CCLS (20)

Data signed: (hfarmer1) 30 Mar 2015 12:28:38

Generated On: 20 Jul 2016 22:42:34

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	F
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Subject Date of Birth	(b) (6)
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	X312842
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Actual Collection Date	2014 05 14
------------------------	------------

Actual Collection Time	06:21
------------------------	-------

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: 1261**

Folder: Day 30

Form: Lab_BU_CCLS (20)

Data signed: (hfarmer1) 30 Mar 2015 12:28:38

Generated On: 20 Jul 2016 22:42:34

Lab Test Name	EOSINOPHILS
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	0.49
Reported Numeric Result	0.49
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: 1261**

Folder: Day 30

Form: Lab_BU_CCLS (20)

Data signed: (hfarmer1) 30 Mar 2015 12:28:38

Generated On: 20 Jul 2016 22:42:34

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 30

Form: Lab_BU_CCLS (21)

Data signed: (hfarmer1) 30 Mar 2015 12:28:38

Generated On: 20 Jul 2016 22:42:34

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	<hr/>
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Subject Sex	F
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Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	X312842
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Actual Collection Date	2014 05 14
------------------------	------------

Actual Collection Time	06:21
------------------------	-------

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: 1261**

Folder: Day 30

Form: Lab_BU_CCLS (21)

Data signed: (hfarmer1) 30 Mar 2015 12:28:38

Generated On: 20 Jul 2016 22:42:34

Lab Test Name	BASOPHILS
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	0.03
Reported Numeric Result	0.03
Reference Range low	0.00
Reference Range high	0.20
Range Units	X10^3/UL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 30

Form: Lab_BU_CCLS (21)

Data signed: (hfarmer1) 30 Mar 2015 12:28:38

Generated On: 20 Jul 2016 22:42:34

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 30

Form: Lab_BU_CCLS (22)

Data signed: (hfarmer1) 30 Mar 2015 12:28:38

Generated On: 20 Jul 2016 22:42:34

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	F
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Subject Date of Birth	(b) (6)
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	X312842
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Actual Collection Date	2014 05 14
------------------------	------------

Actual Collection Time	06:21
------------------------	-------

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: 1261**

Folder: Day 30

Form: Lab_BU_CCLS (22)

Data signed: (hfarmer1) 30 Mar 2015 12:28:38

Generated On: 20 Jul 2016 22:42:34

Lab Test Name	PLATELETS
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	192
Reported Numeric Result	192
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: 1261**

Folder: Day 30

Form: Lab_BU_CCLS (22)

Data signed: (hfarmer1) 30 Mar 2015 12:28:38

Generated On: 20 Jul 2016 22:42:34

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 30

Form: Lab_BU_CCLS (23)

Data signed: (hfarmer1) 30 Mar 2015 12:28:38

Generated On: 20 Jul 2016 22:42:34

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	F
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Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	X312842
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Actual Collection Date	2014 05 14
------------------------	------------

Actual Collection Time	06:21
------------------------	-------

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: 1261**

Folder: Day 30

Form: Lab_BU_CCLS (23)

Data signed: (hfarmer1) 30 Mar 2015 12:28:38

Generated On: 20 Jul 2016 22:42:34

Lab Test Name	NEUTROPHILS (%)
Test ID	
Test Status	Done <input type="checkbox"/>
Reported Text Result	72.6
Reported Numeric Result	72.6
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: 1261**

Folder: Day 30

Form: Lab_BU_CCLS (23)

Data signed: (hfarmer1) 30 Mar 2015 12:28:38

Generated On: 20 Jul 2016 22:42:34

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 30

Form: Lab_BU_CCLS (24)

Data signed: (hfarmer1) 30 Mar 2015 12:28:38

Generated On: 20 Jul 2016 22:42:34

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	F
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Subject Date of Birth	(b) (6)
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	X312842
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Actual Collection Date	2014 05 14
------------------------	------------

Actual Collection Time	06:21
------------------------	-------

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: 1261

Folder: Day 30

Form: Lab_BU_CCLS (24)

Data signed: (hfarmer1) 30 Mar 2015 12:28:38

Generated On: 20 Jul 2016 22:42:34

Lab Test Name	LYMPHOCYTES (%)
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	15.3
Reported Numeric Result	15.3
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: 1261**

Folder: Day 30

Form: Lab_BU_CCLS (24)

Data signed: (hfarmer1) 30 Mar 2015 12:28:38

Generated On: 20 Jul 2016 22:42:34

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Low ☒

Clinically Significant?

No ☒

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 30

Form: Lab_BU_CCLS (25)

Data signed: (hfarmer1) 30 Mar 2015 12:28:38

Generated On: 20 Jul 2016 22:42:34

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	F
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Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	X312842
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Actual Collection Date	2014 05 14
------------------------	------------

Actual Collection Time	06:21
------------------------	-------

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: 1261**

Folder: Day 30

Form: Lab_BU_CCLS (25)

Data signed: (hfarmer1) 30 Mar 2015 12:28:38

Generated On: 20 Jul 2016 22:42:34

Lab Test Name	MONOCYTES (%)
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	7.0
Reported Numeric Result	7.0
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: 1261**

Folder: Day 30

Form: Lab_BU_CCLS (25)

Data signed: (hfarmer1) 30 Mar 2015 12:28:38

Generated On: 20 Jul 2016 22:42:34

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 30

Form: Lab_BU_CCLS (26)

Data signed: (hfarmer1) 30 Mar 2015 12:28:38

Generated On: 20 Jul 2016 22:42:34

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	F
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Subject Date of Birth	(b) (6)
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	X312842
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Actual Collection Date	2014 05 14
------------------------	------------

Actual Collection Time	06:21
------------------------	-------

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: 1261**

Folder: Day 30

Form: Lab_BU_CCLS (26)

Data signed: (hfarmer1) 30 Mar 2015 12:28:38

Generated On: 20 Jul 2016 22:42:34

Lab Test Name	EOSINOPHILS (%)
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	4.8
Reported Numeric Result	4.8
Reference Range low	0.0
Reference Range high	6.8
Range Units	%
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 30

Form: Lab_BU_CCLS (26)

Data signed: (hfarmer1) 30 Mar 2015 12:28:38

Generated On: 20 Jul 2016 22:42:34

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 30

Form: Lab_BU_CCLS (27)

Data signed: (hfarmer1) 30 Mar 2015 12:28:38

Generated On: 20 Jul 2016 22:42:34

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	F
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Subject Date of Birth	(b) (6)
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	X312842
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Actual Collection Date	2014 05 14
------------------------	------------

Actual Collection Time	06:21
------------------------	-------

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: 1261**

Folder: Day 30

Form: Lab_BU_CCLS (27)

Data signed: (hfarmer1) 30 Mar 2015 12:28:38

Generated On: 20 Jul 2016 22:42:34

Lab Test Name	BASOPHILS (%)
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	0.3
Reported Numeric Result	0.3
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: 1261**

Folder: Day 30

Form: Lab_BU_CCLS (27)

Data signed: (hfarmer1) 30 Mar 2015 12:28:38

Generated On: 20 Jul 2016 22:42:34

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 30

Form: Lab_BU_CCLS (28)

Data signed: (hfarmer1) 30 Mar 2015 12:28:38

Generated On: 20 Jul 2016 22:42:34

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
----------------------	-------

Subject Sex	F
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Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	X312842
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Actual Collection Date	2014 05 14
------------------------	------------

Actual Collection Time	06:21
------------------------	-------

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: 1261

Folder: Day 30

Form: Lab_BU_CCLS (28)

Data signed: (hfarmer1) 30 Mar 2015 12:28:38

Generated On: 20 Jul 2016 22:42:34

Lab Test Name	HEMATOCRIT
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	43
Reported Numeric Result	43
Reference Range low	34
Reference Range high	48
Range Units	%
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 30

Form: Lab_BU_CCLS (28)

Data signed: (hfarmer1) 30 Mar 2015 12:28:38

Generated On: 20 Jul 2016 22:42:34

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 30

Form: Lab_BU_CCLS (29)

Data signed: (hfarmer1) 30 Mar 2015 12:28:38

Generated On: 20 Jul 2016 22:42:34

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
----------------------	-------

Subject Sex	F
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Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	X312842
--------------	---------

Actual Collection Date	2014 05 14
------------------------	------------

Actual Collection Time	06:21
------------------------	-------

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: 1261**

Folder: Day 30

Form: Lab_BU_CCLS (29)

Data signed: (hfarmer1) 30 Mar 2015 12:28:38

Generated On: 20 Jul 2016 22:42:34

Lab Test Name	RBC
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	4.6
Reported Numeric Result	4.6
Reference Range low	4.1
Reference Range high	5.6
Range Units	X10^6/UL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 30

Form: Lab_BU_CCLS (29)

Data signed: (hfarmer1) 30 Mar 2015 12:28:38

Generated On: 20 Jul 2016 22:42:34

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 30

Form: Lab_BU_CCLS (30)

Data signed: (hfarmer1) 30 Mar 2015 12:28:38

Generated On: 20 Jul 2016 22:42:34

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	F
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Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	X312842
--------------	---------

Actual Collection Date	2014 05 14
------------------------	------------

Actual Collection Time	06:21
------------------------	-------

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: 1261**

Folder: Day 30

Form: Lab_BU_CCLS (30)

Data signed: (hfarmer1) 30 Mar 2015 12:28:38

Generated On: 20 Jul 2016 22:42:34

Lab Test Name	MCV
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	93
Reported Numeric Result	93
Reference Range low	79
Reference Range high	98
Range Units	FL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 30

Form: Lab_BU_CCLS (30)

Data signed: (hfarmer1) 30 Mar 2015 12:28:38

Generated On: 20 Jul 2016 22:42:34

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 30

Form: Lab_BU_CCLS (31)

Data signed: (hfarmer1) 30 Mar 2015 12:28:38

Generated On: 20 Jul 2016 22:42:34

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
----------------------	-------

Subject Sex	F
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Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	X312842
--------------	---------

Actual Collection Date	2014 05 14
------------------------	------------

Actual Collection Time	06:21
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

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: 1261**

Folder: Day 30

Form: Lab_BU_CCLS (31)

Data signed: (hfarmer1) 30 Mar 2015 12:28:38

Generated On: 20 Jul 2016 22:42:34

Lab Test Name	HEMOGLOBIN
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	14.1
Reported Numeric Result	14.1
Reference Range low	11.6
Reference Range high	16.4
Range Units	G/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 30

Form: Lab_BU_CCLS (31)

Data signed: (hfarmer1) 30 Mar 2015 12:28:38

Generated On: 20 Jul 2016 22:42:34

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 30

Form: Lab_BU_CCLS (32)

Data signed: (hfarmer1) 30 Mar 2015 12:28:38

Generated On: 20 Jul 2016 22:42:34

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	F
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Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	X312842
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Actual Collection Date	2014 05 14
------------------------	------------

Actual Collection Time	06:21
------------------------	-------

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: 1261**

Folder: Day 30

Form: Lab_BU_CCLS (32)

Data signed: (hfarmer1) 30 Mar 2015 12:28:38

Generated On: 20 Jul 2016 22:42:34

Lab Test Name	WBC
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	10.33
Reported Numeric Result	10.33
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: 1261**

Folder: Day 30

Form: Lab_BU_CCLS (32)

Data signed: (hfarmer1) 30 Mar 2015 12:28:38

Generated On: 20 Jul 2016 22:42:34

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 30

Form: Lab_BU_CCLS (33)

Data signed: (hfarmer1) 30 Mar 2015 12:28:38

Generated On: 20 Jul 2016 22:42:34

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	<hr/>
----------------------	-------

Subject Sex	F
-------------	---

Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	X312842
--------------	---------

Actual Collection Date	2014 05 14
------------------------	------------

Actual Collection Time	06:21
------------------------	-------

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: 1261**

Folder: Day 30

Form: Lab_BU_CCLS (33)

Data signed: (hfarmer1) 30 Mar 2015 12:28:38


Generated On: 20 Jul 2016 22:42:34

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: 1261**

Folder: Day 30

Form: Lab_BU_CCLS (33)

Data signed: (hfarmer1) 30 Mar 2015 12:28:38

Generated On: 20 Jul 2016 22:42:34

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 30

Form: Lab_BU_CCLS (34)

Data signed: (hfarmer1) 30 Mar 2015 12:28:38

Generated On: 20 Jul 2016 22:42:34

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	<hr/>
----------------------	-------

Subject Sex	F
-------------	---

Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	X312842
--------------	---------

Actual Collection Date	2014 05 14
------------------------	------------

Actual Collection Time	06:21
------------------------	-------

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: 1261**

Folder: Day 30

Form: Lab_BU_CCLS (34)

Data signed: (hfarmer1) 30 Mar 2015 12:28:38

Generated On: 20 Jul 2016 22:42:34

Lab Test Name	NEUTROPHILS
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	7.50
Reported Numeric Result	7.50
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: 1261**

Folder: Day 30

Form: Lab_BU_CCLS (34)

Data signed: (hfarmer1) 30 Mar 2015 12:28:38

Generated On: 20 Jul 2016 22:42:34

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

High ☒

Clinically Significant?

No ☒

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 30

Form: Lab_BU_CCLS (35)

Data signed: (hfarmer1) 30 Mar 2015 12:28:38

Generated On: 20 Jul 2016 22:42:34

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	<hr/>
----------------------	-------

Subject Sex	F
-------------	---

Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	X312842
--------------	---------

Actual Collection Date	2014 05 14
------------------------	------------

Actual Collection Time	06:21
------------------------	-------

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: 1261**

Folder: Day 30

Form: Lab_BU_CCLS (35)

Data signed: (hfarmer1) 30 Mar 2015 12:28:38

Generated On: 20 Jul 2016 22:42:34

Lab Test Name	LYMPHOCYTES
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	1.59
Reported Numeric Result	1.59
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: 1261**

Folder: Day 30

Form: Lab_BU_CCLS (35)

Data signed: (hfarmer1) 30 Mar 2015 12:28:38

Generated On: 20 Jul 2016 22:42:34

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 30

Form: Lab_BU_CCLS (36)

Data signed: (hfarmer1) 30 Mar 2015 12:28:38

Generated On: 20 Jul 2016 22:42:34

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	<hr/>
----------------------	-------

Subject Sex	F
-------------	---

Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	X312842
--------------	---------

Actual Collection Date	2014 05 14
------------------------	------------

Actual Collection Time	06:21
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	UA1538
------------	--------

Battery Name	URINE MACRO PANEL
--------------	-------------------

Lab Test ID	UAT10
-------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 30

Form: Lab_BU_CCLS (36)

Data signed: (hfarmer1) 30 Mar 2015 12:28:38


Generated On: 20 Jul 2016 22:42:34

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: 1261**

Folder: Day 30

Form: Lab_BU_CCLS (36)

Data signed: (hfarmer1) 30 Mar 2015 12:28:38

Generated On: 20 Jul 2016 22:42:34

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 30

Form: Lab_BU_CCLS (37)

Data signed: (hfarmer1) 30 Mar 2015 12:28:38

Generated On: 20 Jul 2016 22:42:34

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	<hr/>
----------------------	-------

Subject Sex	F
-------------	---

Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	X312842
--------------	---------

Actual Collection Date	2014 05 14
------------------------	------------

Actual Collection Time	06:21
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	UA1538
------------	--------

Battery Name	URINE MACRO PANEL
--------------	-------------------

Lab Test ID	UAT2
-------------	------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1261

Folder: Day 30

Form: Lab_BU_CCLS (37)

Data signed: (hfarmer1) 30 Mar 2015 12:28:38

Generated On: 20 Jul 2016 22:42:34

Lab Test Name	UR SPECIFIC GRAVITY
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	1.015
Reported Numeric Result	1.015
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: 1261**

Folder: Day 30

Form: Lab_BU_CCLS (37)

Data signed: (hfarmer1) 30 Mar 2015 12:28:38

Generated On: 20 Jul 2016 22:42:34

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 30

Form: Lab_BU_CCLS (38)

Data signed: (hfarmer1) 30 Mar 2015 12:28:38

Generated On: 20 Jul 2016 22:42:34

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	<hr/>
----------------------	-------

Subject Sex	F
-------------	---

Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	X312842
--------------	---------

Actual Collection Date	2014 05 14
------------------------	------------

Actual Collection Time	06:21
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	UA1538
------------	--------

Battery Name	URINE MACRO PANEL
--------------	-------------------

Lab Test ID	UAT3
-------------	------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1261

Folder: Day 30

Form: Lab_BU_CCLS (38)

Data signed: (hfarmer1) 30 Mar 2015 12:28:38

Generated On: 20 Jul 2016 22:42:34

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: 1261**

Folder: Day 30

Form: Lab_BU_CCLS (38)

Data signed: (hfarmer1) 30 Mar 2015 12:28:38

Generated On: 20 Jul 2016 22:42:34

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 30

Form: Lab_BU_CCLS (39)

Data signed: (hfarmer1) 30 Mar 2015 12:28:38

Generated On: 20 Jul 2016 22:42:34

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	<hr/>
----------------------	-------

Subject Sex	F
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Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	X312842
--------------	---------

Actual Collection Date	2014 05 14
------------------------	------------

Actual Collection Time	06:21
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	UA1538
------------	--------

Battery Name	URINE MACRO PANEL
--------------	-------------------

Lab Test ID	UAT43
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 30

Form: Lab_BU_CCLS (39)

Data signed: (hfarmer1) 30 Mar 2015 12:28:38


Generated On: 20 Jul 2016 22:42:34

Lab Test Name

UR BLOOD

Test ID

Test Status

Done 

Reported Text Result

+2

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: 1261**

Folder: Day 30

Form: Lab_BU_CCLS (39)

Data signed: (hfarmer1) 30 Mar 2015 12:28:38

Generated On: 20 Jul 2016 22:42:34

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

High ☒

Clinically Significant?

No ☒

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 30

Form: Lab_BU_CCLS (40)

Data signed: (hfarmer1) 30 Mar 2015 12:28:38

Generated On: 20 Jul 2016 22:42:34

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	<hr/>
----------------------	-------

Subject Sex	F
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Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	X312842
--------------	---------

Actual Collection Date	2014 05 14
------------------------	------------

Actual Collection Time	06:21
------------------------	-------

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: 1261**

Folder: Day 30

Form: Lab_BU_CCLS (40)

Data signed: (hfarmer1) 30 Mar 2015 12:28:38


Generated On: 20 Jul 2016 22:42:34

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: 1261**

Folder: Day 30

Form: Lab_BU_CCLS (40)

Data signed: (hfarmer1) 30 Mar 2015 12:28:38

Generated On: 20 Jul 2016 22:42:34

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 30

Form: Lab_BU_CCLS (41)

Data signed: (hfarmer1) 30 Mar 2015 12:28:38

Generated On: 20 Jul 2016 22:42:34

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	<hr/>
----------------------	-------

Subject Sex	F
-------------	---

Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	X312842
--------------	---------

Actual Collection Date	2014 05 14
------------------------	------------

Actual Collection Time	06:21
------------------------	-------

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: 1261**

Folder: Day 30

Form: Lab_BU_CCLS (41)

Data signed: (hfarmer1) 30 Mar 2015 12:28:38


Generated On: 20 Jul 2016 22:42:34

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: 1261**

Folder: Day 30

Form: Lab_BU_CCLS (41)

Data signed: (hfarmer1) 30 Mar 2015 12:28:38

Generated On: 20 Jul 2016 22:42:34

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 30

Form: Lab_BU_CCLS (42)

Data signed: (hfarmer1) 30 Mar 2015 12:28:38

Generated On: 20 Jul 2016 22:42:34

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	<hr/>
----------------------	-------

Subject Sex	F
-------------	---

Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	X312842
--------------	---------

Actual Collection Date	2014 05 14
------------------------	------------

Actual Collection Time	06:21
------------------------	-------

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: 1261**

Folder: Day 30

Form: Lab_BU_CCLS (42)

Data signed: (hfarmer1) 30 Mar 2015 12:28:38


Generated On: 20 Jul 2016 22:42:34

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: 1261**

Folder: Day 30

Form: Lab_BU_CCLS (42)

Data signed: (hfarmer1) 30 Mar 2015 12:28:38

Generated On: 20 Jul 2016 22:42:34

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 30

Form: Lab_BU_COHB (1)

Data signed: (hfarmer1) 30 Mar 2015 12:28:53

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05115150004285
----------------	----------------

Analyte	CARBOXYHEMOGLOBIN
---------	-------------------

Sample type	BLOOD
-------------	-------

Result	8.00
--------	------

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-MAY-13
--------------------	-------------

Timepoint-minutes	
-------------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 30

Form: Lab_BU_COHB (1)

Data signed: (hfarmer1) 30 Mar 2015 12:28:53

Generated On: 20 Jul 2016 22:42:34

Start Day (24 hour urine only) _____

End Day (24 hour Urine Only) _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 30

Form: Cough Assessment (Paper)

Data signed: (hfarmer1) 30 Mar 2015 12:28:34

Generated On: 20 Jul 2016 22:42:34

Was paper questionnaire used? Yes ☐

Reason not done _____

Date of assessment 14 MAY 2014
DD/MMM/YYYY DD/MMM/YYYY

Time of assessment 06:25
hour:min 24-hour clock

Have you experienced a regular need to cough e.g. coughing several times in the last 24 hrs? No ☐

If YES, please answer the following questions:

First Question: Cough Impact Scale
How much is your cough bothering you? _____

Second Question: Cough Intensity Scale:
How intense is your cough? _____

Third Question: Cough Frequency Scale:
How frequently do you normally have to cough each day? _____

Fourth Question: Sputum Production
To what extent do you produce sputum when coughing? _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 30

Form: Cough Assessment (Paper)

Data signed: (hfarmer1) 30 Mar 2015 12:28:34

Generated On: 20 Jul 2016 22:42:34

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: 1261

Folder: Day 30

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS) (Paper)

Data signed: (hfarmer1) 30 Mar 2015 12:28:35

Generated On: 20 Jul 2016 22:42:34

Was paper questionnaire used?

Yes ☒

Reason not done

Date of assessment
DD/MMM/YYYY

14 MAY 2014
DD/MMM/YYYY

Time of assessment

06:26
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: 1261

Folder: Day 30

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS) (Paper) (3)

Data signed: (hfarmer1) 30 Mar 2015 12:28:35

Generated On: 20 Jul 2016 22:42:34

	Result
3. Depressed Mood, sad	None
4. Desire or craving to smoke	Slight
5. Difficulty concentrating	None
6. Increased appetite, hungry, weight gain	Slight
7. Insomnia, sleep problems, awakening at night	None
8. Restless	None
9. Impatient	Slight

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1261

Folder: Day 30

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS) (Paper) (10)

Data signed: (hfarmer1) 30 Mar 2015 12:28:35

Generated On: 20 Jul 2016 22:42:34

	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: 1261**

Folder: Day 30

**Form: Prochaska "Stage of Change" Questionnaire: Intention to Quit
Smoking**

Data signed: (hfarmer1) 30 Mar 2015 12:28:35

Generated On: 20 Jul 2016 22:42:34

Was paper questionnaire used? Yes ☒

Reason not done _____

Type PROCHASKA STAGE OF
CHANGE QUESTIONNAIRE:
INTENTION TO QUIT
SMOKING

Date of assessment 13 MAY 2014
DD/MMM/YYYY

Time of assessment 20:27
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: 1261**

Folder: Day 30

Form: Human Smoking Topography Questionnaire

Data signed: (hfarmer1) 30 Mar 2015 12:28:36

Generated On: 20 Jul 2016 22:42:34

Type	HUMAN SMOKING TOPOGRAPHY QUESTIONNAIRE
------	--

Was paper questionnaire used?	Yes <input type="radio"/>
-------------------------------	---------------------------

Reason not done	<hr/>
-----------------	-------

Date of assessment	13 MAY 2014 DD/MMM/YYYY
--------------------	----------------------------

Time of assessment	20:25 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 disagree <input type="radio"/>
--	---

If you agree or strongly agree, please describe :	<hr/>
---	-------

2. You enjoy smoking with the device as much as without it.	Strongly agree <input type="radio"/>
---	--------------------------------------

If you disagree or strongly disagree, please describe :	<hr/>
---	-------

3. The taste of the conventional cigarettes/products is different with the device.	Strongly disagree <input type="radio"/>
--	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 30

Form: Human Smoking Topography Questionnaire

Data signed: (hfarmer1) 30 Mar 2015 12:28:36

Generated On: 20 Jul 2016 22:42:34

If you agree or strongly agree, please describe : _____

4. The device is easy to use.

Strongly agree ☒

If you disagree or strongly disagree, please describe : _____

5. Your smoking is disturbed by the device.

Strongly disagree ☒

If you agree or strongly agree, please describe : _____

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1261

Folder: Day 30

Form: Questionnaire on smoking urges (QSU) (Paper)

Data signed: (hfarmer1) 30 Mar 2015 12:28:36

Generated On: 20 Jul 2016 22:42:34

Type	QUESTIONNAIRE ON SMOKING URGES
------	-----------------------------------

Was paper questionnaire used?	Yes <input type="radio"/>
-------------------------------	---------------------------

Reason not done	<hr/>
-----------------	-------

Date of assessment	13 MAY 2014
--------------------	-------------

DD/MMM/YYYY

Time of assessment	20:24
--------------------	-------

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	Strongly disagree <input type="radio"/>
---	---

3. If it were possible I would probably smoke now	Strongly 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: 1261**

Folder: Day 30

Form: Questionnaire on smoking urges (QSU) (Paper)

Data signed: (hfarmer1) 30 Mar 2015 12:28:36

Generated On: 20 Jul 2016 22:42:34

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: 1261**

Folder: Day 30

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper)

Data signed: (hfarmer1) 30 Mar 2015 12:28:34

Generated On: 20 Jul 2016 22:42:34

Was paper questionnaire used?

Yes ☒

Reason not done

Date of assessment

13 MAY 2014

DD/MMM/YYYY

DD/MMM/YYYY

Time of assessment

20:27

hour:min 24-hour clock

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 30

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper) (1)

Data signed: (hfarmer1) 30 Mar 2015 12:28:34

Generated On: 20 Jul 2016 22:42:34

Was paper questionnaire used? Yes ☒

Reason not done _____

Date of assessment 13 MAY 2014
DD/MMM/YYYY

Time of assessment 20:27
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 Very little ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 30

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper) (2)

Data signed: (hfarmer1) 30 Mar 2015 12:28:34

Generated On: 20 Jul 2016 22:42:34

Was paper questionnaire used? Yes ☒

Reason not done _____

Date of assessment 13 MAY 2014
DD/MMM/YYYY

Time of assessment 20:27
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 Very little ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 30

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper) (3)

Data signed: (hfarmer1) 30 Mar 2015 12:28:34

Generated On: 20 Jul 2016 22:42:34

Was paper questionnaire used? Yes ☒

Reason not done _____

Date of assessment 13 MAY 2014
DD/MMM/YYYY

Time of assessment 20:27
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 Very little ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 30

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper) (4)

Data signed: (hfarmer1) 30 Mar 2015 12:28:34

Generated On: 20 Jul 2016 22:42:34

Was paper questionnaire used? Yes ☐

Reason not done _____

Date of assessment 13 MAY 2014
DD/MMM/YYYY

Time of assessment 20:27
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 Very little ☐

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 30

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper) (5)

Data signed: (hfarmer1) 30 Mar 2015 12:28:34

Generated On: 20 Jul 2016 22:42:34

Was paper questionnaire used? Yes ☐

Reason not done _____

Date of assessment 13 MAY 2014
DD/MMM/YYYY

Time of assessment 20:27
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 Not at all ☐

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 30

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper) (6)

Data signed: (hfarmer1) 30 Mar 2015 12:28:34

Generated On: 20 Jul 2016 22:42:34

Was paper questionnaire used? Yes ☐

Reason not done _____

Date of assessment 13 MAY 2014
DD/MMM/YYYY

Time of assessment 20:27
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: 1261**

Folder: Day 30

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper) (7)

Data signed: (hfarmer1) 30 Mar 2015 12:28:34

Generated On: 20 Jul 2016 22:42:34

Was paper questionnaire used? Yes ☐

Reason not done _____

Date of assessment 13 MAY 2014
DD/MMM/YYYY

Time of assessment 20:27
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: 1261**

Folder: Day 30

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper) (8)

Data signed: (hfarmer1) 30 Mar 2015 12:28:34

Generated On: 20 Jul 2016 22:42:34

Was paper questionnaire used? Yes ☐

Reason not done _____

Date of assessment 13 MAY 2014
DD/MMM/YYYY

Time of assessment 20:27
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: 1261**

Folder: Day 30

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper) (9)

Data signed: (hfarmer1) 30 Mar 2015 12:28:34

Generated On: 20 Jul 2016 22:42:34

Was paper questionnaire used? Yes ☐

Reason not done _____

Date of assessment 13 MAY 2014
DD/MMM/YYYY

Time of assessment 20:27
hour:min 24-hour clock

If you have smoked since you last completed this questionnaire,
please mark what best represents how smoking made you feel Did smoking make you dizzy? ☐

Response Not at all ☐

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 30

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper) (10)

Data signed: (hfarmer1) 30 Mar 2015 12:28:34

Generated On: 20 Jul 2016 22:42:34

Was paper questionnaire used? Yes ☐

Reason not done _____

Date of assessment 13 MAY 2014
DD/MMM/YYYY

Time of assessment 20:27
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: 1261**

Folder: Day 30

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper) (11)

Data signed: (hfarmer1) 30 Mar 2015 12:28:34

Generated On: 20 Jul 2016 22:42:34

Was paper questionnaire used? Yes ☐

Reason not done _____

Date of assessment 13 MAY 2014
DD/MMM/YYYY

Time of assessment 20:27
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 Not at all ☐

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 30

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper) (12)

Data signed: (hfarmer1) 30 Mar 2015 12:28:34

Generated On: 20 Jul 2016 22:42:34

Was paper questionnaire used? Yes ☐

Reason not done _____

Date of assessment 13 MAY 2014
DD/MMM/YYYY

Time of assessment 20:27
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 Very little ☐

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 30

Form: Risk Markers(CCLS) (1)

Data signed: (hfarmer1) 30 Mar 2015 12:28:36

Generated On: 20 Jul 2016 22:42:34

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	1261
----------------------	------

Subject Sex	F
-------------	---

Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	DAY30
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	X312842
--------------	---------

Actual Collection Date	2014 05 14
------------------------	------------

Actual Collection Time	06:21
------------------------	-------

Specimen Condition	
--------------------	--

Battery ID	RC6871
------------	--------

Battery Name	HDL
--------------	-----

Lab Test ID	RCT1684
-------------	---------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 30

Form: Risk Markers(CCLS) (1)

Data signed: (hfarmer1) 30 Mar 2015 12:28:36


Generated On: 20 Jul 2016 22:42:34

Lab Test Name

DIRECT HDL-C 3RD
GENERATION

Test ID

Test Status

Done 

Reported Text Result

41

Reported Numeric Result

41

Reference Range low

36

Reference Range high

77

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: 1261**

Folder: Day 30

Form: Risk Markers(CCLS) (1)

Data signed: (hfarmer1) 30 Mar 2015 12:28:36

Generated On: 20 Jul 2016 22:42:34

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: 1261**

Folder: Day 30

Form: Risk Markers(CCLS) (2)

Data signed: (hfarmer1) 30 Mar 2015 12:28:36

Generated On: 20 Jul 2016 22:42:34

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	1261
----------------------	------

Subject Sex	F
-------------	---

Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	DAY30
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	X312842
--------------	---------

Actual Collection Date	2014 05 14
------------------------	------------

Actual Collection Time	06:21
------------------------	-------

Specimen Condition	
--------------------	--

Battery ID	SC3249
------------	--------

Battery Name	HS-CRP
--------------	--------

Lab Test ID	SCT1528
-------------	---------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 30

Form: Risk Markers(CCLS) (2)

Data signed: (hfarmer1) 30 Mar 2015 12:28:36


Generated On: 20 Jul 2016 22:42:34

Lab Test Name

C-REACTIVE PROTEIN (N
HS)-QT

Test ID

Test Status

Done 

Reported Text Result

0.110

Reported Numeric Result

0.110

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: 1261**

Folder: Day 30

Form: Risk Markers(CCLS) (2)

Data signed: (hfarmer1) 30 Mar 2015 12:28:36

Generated On: 20 Jul 2016 22:42:34

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: 1261**

Folder: Day 30

Form: Risk Markers(CCLS) (3)

Data signed: (hfarmer1) 30 Mar 2015 12:28:36

Generated On: 20 Jul 2016 22:42:34

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	1261
----------------------	------

Subject Sex	F
-------------	---

Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	DAY30
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	X312842
--------------	---------

Actual Collection Date	2014 05 14
------------------------	------------

Actual Collection Time	06:21
------------------------	-------

Specimen Condition	
--------------------	--

Battery ID	CG267
------------	-------

Battery Name	FIBRINOGEN
--------------	------------

Lab Test ID	CGT285
-------------	--------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1261

Folder: Day 30

Form: Risk Markers(CCLS) (3)

Data signed: (hfarmer1) 30 Mar 2015 12:28:36

Generated On: 20 Jul 2016 22:42:34

Lab Test Name	FIBRINOGEN
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	288
Reported Numeric Result	288
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: 1261**

Folder: Day 30

Form: Risk Markers(CCLS) (3)

Data signed: (hfarmer1) 30 Mar 2015 12:28:36

Generated On: 20 Jul 2016 22:42:34

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: 1261**

Folder: Day 30

Form: Risk Markers(CCLS) (4)

Data signed: (hfarmer1) 30 Mar 2015 12:28:36

Generated On: 20 Jul 2016 22:42:34

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	1261
----------------------	------

Subject Sex	F
-------------	---

Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	DAY30
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	X312842
--------------	---------

Actual Collection Date	2014 05 14
------------------------	------------

Actual Collection Time	06:21
------------------------	-------

Specimen Condition	
--------------------	--

Battery ID	CN236
------------	-------

Battery Name	HOMOCYSTEINE
--------------	--------------

Lab Test ID	CNT145
-------------	--------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1261

Folder: Day 30

Form: Risk Markers(CCLS) (4)

Data signed: (hfarmer1) 30 Mar 2015 12:28:36

Generated On: 20 Jul 2016 22:42:34

Lab Test Name	HOMOCYSTEINE, EDTAPL
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	15.55
Reported Numeric Result	15.55
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: 1261**

Folder: Day 30

Form: Risk Markers(CCLS) (4)

Data signed: (hfarmer1) 30 Mar 2015 12:28:36

Generated On: 20 Jul 2016 22:42:34

SI Numeric Result


SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

High 

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 30

Form: Risk Markers(CCLS) (5)

Data signed: (hfarmer1) 30 Mar 2015 12:28:36

Generated On: 20 Jul 2016 22:42:34

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	1261
----------------------	------

Subject Sex	F
-------------	---

Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	DAY30
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	X312842
--------------	---------

Actual Collection Date	2014 05 14
------------------------	------------

Actual Collection Time	06:21
------------------------	-------

Specimen Condition	
--------------------	--

Battery ID	IM2293
------------	--------

Battery Name	SICAM-1
--------------	---------

Lab Test ID	IMT1768
-------------	---------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 30

Form: Risk Markers(CCLS) (5)

Data signed: (hfarmer1) 30 Mar 2015 12:28:36

Generated On: 20 Jul 2016 22:42:34

Lab Test Name	SICAM-1-RUO
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	230.9
Reported Numeric Result	230.9
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: 1261**

Folder: Day 30

Form: Risk Markers(CCLS) (5)

Data signed: (hfarmer1) 30 Mar 2015 12:28:36

Generated On: 20 Jul 2016 22:42:34

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: 1261**

Folder: Day 30

Form: Risk Markers(CCLS) (6)

Data signed: (hfarmer1) 30 Mar 2015 12:28:36

Generated On: 20 Jul 2016 22:42:34

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	1261
----------------------	------

Subject Sex	F
-------------	---

Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	DAY30
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	X312842
--------------	---------

Actual Collection Date	2014 05 14
------------------------	------------

Actual Collection Time	06:21
------------------------	-------

Specimen Condition	
--------------------	--

Battery ID	RC9267
------------	--------

Battery Name	LDL
--------------	-----

Lab Test ID	RCT2394
-------------	---------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 30

Form: Risk Markers(CCLS) (6)

Data signed: (hfarmer1) 30 Mar 2015 12:28:36

Generated On: 20 Jul 2016 22:42:34

Lab Test Name	DIRECT LDL-C 2ND GEN (-70)
---------------	----------------------------

Test ID	<hr/>
---------	-------

Test Status	Done 
-------------	--

Reported Text Result	122
----------------------	-----

Reported Numeric Result	122
-------------------------	-----

Reference Range low	67
---------------------	----

Reference Range high	150
----------------------	-----

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: 1261**

Folder: Day 30

Form: Risk Markers(CCLS) (6)

Data signed: (hfarmer1) 30 Mar 2015 12:28:36

Generated On: 20 Jul 2016 22:42:34

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: 1261**

Folder: Day 30

Form: Biomarker-Urine (CEMA, HPMA, HBMA)

Data signed: (hfarmer1) 30 Mar 2015 12:28:54

Generated On: 20 Jul 2016 22:42:34

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 30

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (1)

Data signed: (hfarmer1) 30 Mar 2015 12:28:54

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05112450002931
Analyte	HPMA
Sample type	URINE
Result	349
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	30
Celerion Study Number	AA99128-03
Date of Collection	2014-MAY-13
Timepoint-minutes	
Urine Start Day	30

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 30

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (1)

Data signed: (hfarmer1) 30 Mar 2015 12:28:54

Generated On: 20 Jul 2016 22:42:34

Urine End Day	31
---------------	----

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 30

Form: Biomarker-Urine (CEMA, HPMa, HBMA) (2)

Data signed: (hfarmer1) 30 Mar 2015 12:28:54

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05112450002931
----------------	----------------

Analyte	CEMA
---------	------

Sample type	URINE
-------------	-------

Result	45.6
--------	------

Result Unit	NG/ML
-------------	-------

Lab Status	OK
------------	----

Sample comment	
----------------	--

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	30
--------------	----

Celerion Study Number	AA99128-03
-----------------------	------------

Date of Collection	2014-MAY-13
--------------------	-------------

Timepoint-minutes	
-------------------	--

Urine Start Day	30
-----------------	----

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 30

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (2)

Data signed: (hfarmer1) 30 Mar 2015 12:28:54

Generated On: 20 Jul 2016 22:42:34

Urine End Day

31

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 30

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (3)

Data signed: (hfarmer1) 30 Mar 2015 12:28:54

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05112450002931
----------------	----------------

Analyte	HBMA
---------	------

Sample type	URINE
-------------	-------

Result	150
--------	-----

Result Unit	NG/ML
-------------	-------

Lab Status	OK
------------	----

Sample comment	
----------------	--

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	30
--------------	----

Celerion Study Number	AA99128-03
-----------------------	------------

Date of Collection	2014-MAY-13
--------------------	-------------

Timepoint-minutes	
-------------------	--

Urine Start Day	30
-----------------	----

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 30

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (3)

Data signed: (hfarmer1) 30 Mar 2015 12:28:54

Generated On: 20 Jul 2016 22:42:34

Urine End Day

31

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 30

Form: Biomarker-Urine (NNN, NNAL)

Data signed: (hfarmer1) 30 Mar 2015 12:28:53

Generated On: 20 Jul 2016 22:42:34

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 30

Form: Biomarker-Urine (NNN, NNAL) (1)

Data signed: (hfarmer1) 30 Mar 2015 12:28:53

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05112460003518
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Analyte	NNAL
---------	------

Sample type	URINE
-------------	-------

Result	238
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Result Unit	PG/ML
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Lab Status	OK
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Sample comment	
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Detection method	LC-MS/MS
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Planned time point (Hour)	0
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Day of Visit	30
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Celerion Study Number	AA99128-04
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Date of Collection	2014-MAY-13
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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: 1261**

Folder: Day 30

Form: Biomarker-Urine (NNN, NNAL) (1)

Data signed: (hfarmer1) 30 Mar 2015 12:28:53

Generated On: 20 Jul 2016 22:42:34

Urine End Day

31

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 30

Form: Biomarker-Urine (NNN, NNAL) (2)

Data signed: (hfarmer1) 30 Mar 2015 12:28:53

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05112460003518
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Analyte	NNN
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Sample type	URINE
-------------	-------

Result	5.35
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Result Unit	PG/ML
-------------	-------

Lab Status	OK
------------	----

Sample comment	
----------------	--

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	30
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Celerion Study Number	AA99128-04
-----------------------	------------

Date of Collection	2014-MAY-13
--------------------	-------------

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: 1261**

Folder: Day 30

Form: Biomarker-Urine (NNN, NNAL) (2)

Data signed: (hfarmer1) 30 Mar 2015 12:28:53

Generated On: 20 Jul 2016 22:42:34

Urine End Day

31

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 30

Form: Biomarker-Urine (HEMA)

Data signed: (hfarmer1) 30 Mar 2015 12:28:53

Generated On: 20 Jul 2016 22:42:34

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 30

Form: Biomarker-Urine (HEMA) (1)

Data signed: (hfarmer1) 30 Mar 2015 12:28:53

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05112470001758
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Analyte	HEMA
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Sample type	URINE
-------------	-------

Result	3.17
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Result Unit	NG/ML
-------------	-------

Lab Status	OK
------------	----

Sample comment	
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Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	30
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Celerion Study Number	AA99128-05
-----------------------	------------

Date of Collection	2014-MAY-13
--------------------	-------------

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: 1261**

Folder: Day 30

Form: Biomarker-Urine (HEMA) (1)

Data signed: (hfarmer1) 30 Mar 2015 12:28:53

Generated On: 20 Jul 2016 22:42:34

Urine End Day	31
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 30

Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)

Data signed: (hfarmer1) 30 Mar 2015 12:28:54

Generated On: 20 Jul 2016 22:42:34

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 30

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(1)**

Data signed: (hfarmer1) 30 Mar 2015 12:28:54

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05112480001164
Analyte	COT
Sample type	URINE
Result	866
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	30
Celerion Study Number	AA99128-06
Date of Collection	2014-MAY-13
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 30

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(1)**

Data signed: (hfarmer1) 30 Mar 2015 12:28:54

Generated On: 20 Jul 2016 22:42:34

Urine Start Day	30
<hr/>	
Urine End Day	31
<hr/>	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 30

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(2)**

Data signed: (hfarmer1) 30 Mar 2015 12:28:54

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05112480001164
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Analyte	COT-GLUC
---------	----------

Sample type	URINE
-------------	-------

Result	2530
--------	------

Result Unit	NG/ML
-------------	-------

Lab Status	OK
------------	----

Sample comment	
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Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	30
--------------	----

Celerion Study Number	AA99128-06
-----------------------	------------

Date of Collection	2014-MAY-13
--------------------	-------------

Timepoint-minutes	
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 30

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(2)**

Data signed: (hfarmer1) 30 Mar 2015 12:28:54

Generated On: 20 Jul 2016 22:42:34

Urine Start Day	30
<hr/>	
Urine End Day	31
<hr/>	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 30

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(3)**

Data signed: (hfarmer1) 30 Mar 2015 12:28:54

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05112480001164
Analyte	NIC
Sample type	URINE
Result	136
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	30
Celerion Study Number	AA99128-06
Date of Collection	2014-MAY-13
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 30

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(3)**

Data signed: (hfarmer1) 30 Mar 2015 12:28:54

Generated On: 20 Jul 2016 22:42:34

Urine Start Day	30
<hr/>	
Urine End Day	31
<hr/>	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 30

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(4)**

Data signed: (hfarmer1) 30 Mar 2015 12:28:54

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05112480001164
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Analyte	NIC-GLUC
---------	----------

Sample type	URINE
-------------	-------

Result	303
--------	-----

Result Unit	NG/ML
-------------	-------

Lab Status	OK
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Sample comment	
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Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	30
--------------	----

Celerion Study Number	AA99128-06
-----------------------	------------

Date of Collection	2014-MAY-13
--------------------	-------------

Timepoint-minutes	
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 30

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(4)**

Data signed: (hfarmer1) 30 Mar 2015 12:28:54

Generated On: 20 Jul 2016 22:42:34

Urine Start Day	30
<hr/>	
Urine End Day	31
<hr/>	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 30

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(5)**

Data signed: (hfarmer1) 30 Mar 2015 12:28:54

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05112480001164
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Analyte	THCOT
---------	-------

Sample type	URINE
-------------	-------

Result	1640
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Result Unit	NG/ML
-------------	-------

Lab Status	OK
------------	----

Sample comment	
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Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	30
--------------	----

Celerion Study Number	AA99128-06
-----------------------	------------

Date of Collection	2014-MAY-13
--------------------	-------------

Timepoint-minutes	
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 30

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(5)**

Data signed: (hfarmer1) 30 Mar 2015 12:28:54

Generated On: 20 Jul 2016 22:42:34

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: 1261**

Folder: Day 30

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(6)**

Data signed: (hfarmer1) 30 Mar 2015 12:28:54

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05112480001164
----------------	----------------

Analyte	THCOT-GLUC
---------	------------

Sample type	URINE
-------------	-------

Result	556
--------	-----

Result Unit	NG/ML
-------------	-------

Lab Status	OK
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Sample comment	
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Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	30
--------------	----

Celerion Study Number	AA99128-06
-----------------------	------------

Date of Collection	2014-MAY-13
--------------------	-------------

Timepoint-minutes	
-------------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 30

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(6)**

Data signed: (hfarmer1) 30 Mar 2015 12:28:54

Generated On: 20 Jul 2016 22:42:34

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: 1261**

Folder: Day 30

Form: Biomarker-Urine (3-OH BaP)

Data signed: (hfarmer1) 30 Mar 2015 12:28:54

Generated On: 20 Jul 2016 22:42:34

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 30

Form: Biomarker-Urine (3-OH BaP) (1)

Data signed: (hfarmer1) 30 Mar 2015 12:28:54

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05112490001758
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Analyte	3-OH BAP
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Sample type	URINE
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Result	83.6
--------	------

Result Unit	FG/ML
-------------	-------

Lab Status	OK
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Sample comment	
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Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	30
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Celerion Study Number	AA99128-07
-----------------------	------------

Date of Collection	2014-MAY-13
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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: 1261**

Folder: Day 30

Form: Biomarker-Urine (3-OH BaP) (1)

Data signed: (hfarmer1) 30 Mar 2015 12:28:54

Generated On: 20 Jul 2016 22:42:34

Urine End Day

31

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 30

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP)

Data signed: (hfarmer1) 30 Mar 2015 12:28:54

Generated On: 20 Jul 2016 22:42:34

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 30

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (1)

Data signed: (hfarmer1) 30 Mar 2015 12:28:54

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05112510001780
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Analyte	1-NA
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Sample type	URINE
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Result	35.7
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Result Unit	PG/ML
-------------	-------

Lab Status	OK
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Sample comment	
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Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	30
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Celerion Study Number	AA99128-09
-----------------------	------------

Date of Collection	2014-MAY-13
--------------------	-------------

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: 1261**

Folder: Day 30

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (1)

Data signed: (hfarmer1) 30 Mar 2015 12:28:54

Generated On: 20 Jul 2016 22:42:34

Urine End Day

31

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 30

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (2)

Data signed: (hfarmer1) 30 Mar 2015 12:28:54

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05112510001780
Analyte	2-NA
Sample type	URINE
Result	11.8
Result Unit	PG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	30
Celerion Study Number	AA99128-09
Date of Collection	2014-MAY-13
Timepoint-minutes	
Urine Start Day	30

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 30

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (2)

Data signed: (hfarmer1) 30 Mar 2015 12:28:54

Generated On: 20 Jul 2016 22:42:34

Urine End Day

31

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 30

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (3)

Data signed: (hfarmer1) 30 Mar 2015 12:28:54

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05112510001780
Analyte	4-ABP
Sample type	URINE
Result	19.3
Result Unit	PG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	30
Celerion Study Number	AA99128-09
Date of Collection	2014-MAY-13
Timepoint-minutes	
Urine Start Day	30

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 30

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (3)

Data signed: (hfarmer1) 30 Mar 2015 12:28:54

Generated On: 20 Jul 2016 22:42:34

Urine End Day

31

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 30

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (4)

Data signed: (hfarmer1) 30 Mar 2015 12:28:54

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05112510001780
Analyte	O-TOL
Sample type	URINE
Result	62.0
Result Unit	PG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	30
Celerion Study Number	AA99128-09
Date of Collection	2014-MAY-13
Timepoint-minutes	
Urine Start Day	30

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 30

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (4)

Data signed: (hfarmer1) 30 Mar 2015 12:28:54

Generated On: 20 Jul 2016 22:42:34

Urine End Day

31

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 30

Form: Biomarker-Urine (11-dTXb2)

Data signed: (hfarmer1) 30 Mar 2015 12:28:53

Generated On: 20 Jul 2016 22:42:34

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 30

Form: Biomarker-Urine (11-dTXb2) (1)

Data signed: (hfarmer1) 30 Mar 2015 12:28:53

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05112530000558
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Analyte	11-DTXB2
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Sample type	URINE
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Result	60.0
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Result Unit	PG/ML
-------------	-------

Lab Status	OK
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Sample comment	
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Detection method	LC-MS/MS
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Planned time point (Hour)	0
---------------------------	---

Day of Visit	30
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Celerion Study Number	AA99128-11
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Date of Collection	2014-MAY-13
--------------------	-------------

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: 1261**

Folder: Day 30

Form: Biomarker-Urine (11-dTXb2) (1)

Data signed: (hfarmer1) 30 Mar 2015 12:28:53

Generated On: 20 Jul 2016 22:42:34

Urine End Day

31

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 30

Form: Biomarker-Urine (iPF2a-III)

Data signed: (hfarmer1) 30 Mar 2015 12:28:53

Generated On: 20 Jul 2016 22:42:34

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 30

Form: Biomarker-Urine (iPF2a-III) (1)

Data signed: (hfarmer1) 30 Mar 2015 12:28:53

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05112540000551
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Analyte	IPF2A-III
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Sample type	URINE
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Result	141
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Result Unit	PG/ML
-------------	-------

Lab Status	OK
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Sample comment	
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Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	30
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Celerion Study Number	AA99128-12
-----------------------	------------

Date of Collection	2014-MAY-13
--------------------	-------------

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: 1261**

Folder: Day 30

Form: Biomarker-Urine (iPF2a-III) (1)

Data signed: (hfarmer1) 30 Mar 2015 12:28:53

Generated On: 20 Jul 2016 22:42:34

Urine End Day

31

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 30

Form: Biomarker-Urine (1-OHP)

Data signed: (hfarmer1) 30 Mar 2015 12:28:54

Generated On: 20 Jul 2016 22:42:34

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 30

Form: Biomarker-Urine (1-OHP) (1)

Data signed: (hfarmer1) 30 Mar 2015 12:28:54

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05115190003782
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Analyte	1-OHP
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Sample type	URINE
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Result	234
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Result Unit	PG/ML
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Lab Status	OK
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Sample comment	
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Detection method	LC-MS/MS
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Planned time point (Hour)	0
---------------------------	---

Day of Visit	30
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Celerion Study Number	AA99598-03
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Date of Collection	2014-MAY-13
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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: 1261**

Folder: Day 30

Form: Biomarker-Urine (1-OHP) (1)

Data signed: (hfarmer1) 30 Mar 2015 12:28:54

Generated On: 20 Jul 2016 22:42:34

Urine End Day

31

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 30

Form: Biomarker-Urine (SPMA, SBMA)

Data signed: (hfarmer1) 30 Mar 2015 12:28:53

Generated On: 20 Jul 2016 22:42:34

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 30

Form: Biomarker-Urine (SPMA, SBMA) (1)

Data signed: (hfarmer1) 30 Mar 2015 12:28:53

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05115170003773
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Analyte	SBMA
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Sample type	URINE
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Result	1.31
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Result Unit	NG/ML
-------------	-------

Lab Status	OK
------------	----

Sample comment	
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Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	30
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Celerion Study Number	AA99598-01
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Date of Collection	2014-MAY-13
--------------------	-------------

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: 1261**

Folder: Day 30

Form: Biomarker-Urine (SPMA, SBMA) (1)

Data signed: (hfarmer1) 30 Mar 2015 12:28:53

Generated On: 20 Jul 2016 22:42:34

Urine End Day

31

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 30

Form: Biomarker-Urine (SPMA, SBMA) (2)

Data signed: (hfarmer1) 30 Mar 2015 12:28:53

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05115170003773
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Analyte	SPMA
---------	------

Sample type	URINE
-------------	-------

Result	2.17
--------	------

Result Unit	NG/ML
-------------	-------

Lab Status	OK
------------	----

Sample comment	
----------------	--

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	30
--------------	----

Celerion Study Number	AA99598-01
-----------------------	------------

Date of Collection	2014-MAY-13
--------------------	-------------

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: 1261**

Folder: Day 30

Form: Biomarker-Urine (SPMA, SBMA) (2)

Data signed: (hfarmer1) 30 Mar 2015 12:28:53

Generated On: 20 Jul 2016 22:42:34

Urine End Day

31

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 30

Form: Biomarker-Urine (MHBMA)

Data signed: (hfarmer1) 30 Mar 2015 12:28:53

Generated On: 20 Jul 2016 22:42:34

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 30

Form: Biomarker-Urine (MHBMA) (1)

Data signed: (hfarmer1) 30 Mar 2015 12:28:53

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05115180003782
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Analyte	MHBMA
---------	-------

Sample type	URINE
-------------	-------

Result	1.37
--------	------

Result Unit	NG/ML
-------------	-------

Lab Status	OK
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Sample comment	
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Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	30
--------------	----

Celerion Study Number	AA99598-02
-----------------------	------------

Date of Collection	2014-MAY-13
--------------------	-------------

Timepoint-minutes	
-------------------	--

Urine Start Day	30
-----------------	----

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 30

Form: Biomarker-Urine (MHBMA) (1)

Data signed: (hfarmer1) 30 Mar 2015 12:28:53

Generated On: 20 Jul 2016 22:42:34

Urine End Day

31

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 30

Form: Biomarker-Urine (Creatinine)

Data signed: (hfarmer1) 30 Mar 2015 12:28:54

Generated On: 20 Jul 2016 22:42:34

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 30

Form: Biomarker-Urine (Creatinine) (1)

Data signed: (hfarmer1) 30 Mar 2015 12:28:54

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05115160001758
----------------	----------------

Analyte	CREATININE
---------	------------

Sample type	URINE
-------------	-------

Result	52.2
--------	------

Result Unit	MG/DL
-------------	-------

Lab Status	OK
------------	----

Sample comment	
----------------	--

Detection method	SPECTROPHOTOMETRIC
------------------	--------------------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	30
--------------	----

Celerion Study Number	AA99128-14
-----------------------	------------

Date of Collection	2014-MAY-13
--------------------	-------------

Timepoint-minutes	
-------------------	--

Urine Start Day	30
-----------------	----

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 30

Form: Biomarker-Urine (Creatinine) (1)

Data signed: (hfarmer1) 30 Mar 2015 12:28:54

Generated On: 20 Jul 2016 22:42:34

Urine End Day

31

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 30

Form: Biomarker-Plasma (Nic, Cot, tHCot)

Data signed: (hfarmer1) 30 Mar 2015 12:28:53

Generated On: 20 Jul 2016 22:42:34

Sample type

PLASMA

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 30

Form: Biomarker-Plasma (Nic, Cot, tHCot) (1)

Data signed: (hfarmer1) 30 Mar 2015 12:28:53

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05112430002012
----------------	----------------

Analyte	COT
---------	-----

Sample type	PLASMA
-------------	--------

Result	340
--------	-----

Result Unit	NG/ML
-------------	-------

Lab Status	OK
------------	----

Sample comment	
----------------	--

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	30
--------------	----

Celerion Study Number	AA99128-01
-----------------------	------------

Date of Collection	2014-MAY-13
--------------------	-------------

Timepoint-minutes	0
-------------------	---

Urine Start Day	
-----------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 30

Form: Biomarker-Plasma (Nic, Cot, tHCot) (1)

Data signed: (hfarmer1) 30 Mar 2015 12:28:53

Generated On: 20 Jul 2016 22:42:34

Urine End Day

30

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 30

Form: Biomarker-Plasma (Nic, Cot, tHCot) (2)

Data signed: (hfarmer1) 30 Mar 2015 12:28:53

Generated On: 20 Jul 2016 22:42:34

Sample Barcode	05112430002012
----------------	----------------

Analyte	NIC
---------	-----

Sample type	PLASMA
-------------	--------

Result	14.8
--------	------

Result Unit	NG/ML
-------------	-------

Lab Status	OK
------------	----

Sample comment	
----------------	--

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	30
--------------	----

Celerion Study Number	AA99128-01
-----------------------	------------

Date of Collection	2014-MAY-13
--------------------	-------------

Timepoint-minutes	0
-------------------	---

Urine Start Day	
-----------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Day 30

Form: Biomarker-Plasma (Nic, Cot, tHCot) (2)

Data signed: (hfarmer1) 30 Mar 2015 12:28:53

Generated On: 20 Jul 2016 22:42:34

Urine End Day

30

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Product Use

Form: Product administration-mCC

Data signed: (hfarmer1) 30 Mar 2015 12:28:55

Generated On: 20 Jul 2016 22:42:34

At Day 0, Day 1 and Day 4, complete all SODIM related 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: 1261**

Folder: Product Use

Form: Product administration-mCC (1)

Data signed: (hfarmer1) 30 Mar 2015 12:28:55

Generated On: 20 Jul 2016 22:42:34

Date of product use DD/MMM/YYYY	12 APR 2014
------------------------------------	-------------

Visit	Day -1 <input checked="" type="radio"/>
-------	---

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	06:36
----------------------	-------

Time of butt return	06:41
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1261

Folder: Product Use

Form: Product administration-mCC (1)

Data signed: (hfarmer1) 30 Mar 2015 12:28:55

Generated On: 20 Jul 2016 22:42:34

At Day 0, Day 1 and Day 4, complete all SODIM related 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: 1261**

Folder: Product Use

Form: Product administration-mCC (2)

Data signed: (hfarmer1) 30 Mar 2015 12:28:55

Generated On: 20 Jul 2016 22:42:34

Date of product use DD/MMM/YYYY	12 APR 2014
------------------------------------	-------------

Visit	Day -1 <input checked="" type="radio"/>
-------	---

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	08:20
----------------------	-------

Time of butt return	08:28
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1261

Folder: Product Use

Form: Product administration-mCC (2)

Data signed: (hfarmer1) 30 Mar 2015 12:28:55

Generated On: 20 Jul 2016 22:42:34

At Day 0, Day 1 and Day 4, complete all SODIM related 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: 1261**

Folder: Product Use

Form: Product administration-mCC (3)

Data signed: (hfarmer1) 30 Mar 2015 12:28:55

Generated On: 20 Jul 2016 22:42:34

Date of product use DD/MMM/YYYY	12 APR 2014
------------------------------------	-------------

Visit	Day -1 <input checked="" type="radio"/>
-------	---

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	10:08
----------------------	-------

Time of butt return	10:14
---------------------	-------

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: 1261

Folder: Product Use

Form: Product administration-mCC (3)

Data signed: (hfarmer1) 30 Mar 2015 12:28:55

Generated On: 20 Jul 2016 22:42:34

At Day 0, Day 1 and Day 4, complete all SODIM related 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: 1261**

Folder: Product Use

Form: Product administration-mCC (4)

Data signed: (hfarmer1) 30 Mar 2015 12:28:55

Generated On: 20 Jul 2016 22:42:34

Date of product use DD/MMM/YYYY	12 APR 2014
------------------------------------	-------------

Visit	Day -1 <input checked="" type="radio"/>
-------	---

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	11:43
----------------------	-------

Time of butt return	11:50
---------------------	-------

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: 1261

Folder: Product Use

Form: Product administration-mCC (4)

Data signed: (hfarmer1) 30 Mar 2015 12:28:55

Generated On: 20 Jul 2016 22:42:34

At Day 0, Day 1 and Day 4, complete all SODIM related 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: 1261**

Folder: Product Use

Form: Product administration-mCC (5)

Data signed: (hfarmer1) 30 Mar 2015 12:28:55

Generated On: 20 Jul 2016 22:42:34

Date of product use DD/MMM/YYYY	12 APR 2014
------------------------------------	-------------

Visit	Day -1 <input checked="" type="radio"/>
-------	---

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	13:32
----------------------	-------

Time of butt return	13:37
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1261

Folder: Product Use

Form: Product administration-mCC (5)

Data signed: (hfarmer1) 30 Mar 2015 12:28:55

Generated On: 20 Jul 2016 22:42:34

At Day 0, Day 1 and Day 4, complete all SODIM related 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: 1261

Folder: Product Use

Form: Product administration-mCC (6)

Data signed: (hfarmer1) 30 Mar 2015 12:28:55

Generated On: 20 Jul 2016 22:42:34

Date of product use DD/MMM/YYYY	12 APR 2014
------------------------------------	-------------

Visit	Day -1 <input checked="" type="radio"/>
-------	---

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	15:25
----------------------	-------

Time of butt return	15:31
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1261

Folder: Product Use

Form: Product administration-mCC (6)

Data signed: (hfarmer1) 30 Mar 2015 12:28:55

Generated On: 20 Jul 2016 22:42:34

At Day 0, Day 1 and Day 4, complete all SODIM related 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: 1261

Folder: Product Use

Form: Product administration-mCC (7)

Data signed: (hfarmer1) 30 Mar 2015 12:28:55

Generated On: 20 Jul 2016 22:42:34

Date of product use DD/MMM/YYYY	12 APR 2014
------------------------------------	-------------

Visit	Day -1 <input checked="" type="radio"/>
-------	---

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	17:04
----------------------	-------

Time of butt return	17:11
---------------------	-------

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: 1261

Folder: Product Use

Form: Product administration-mCC (7)

Data signed: (hfarmer1) 30 Mar 2015 12:28:55

Generated On: 20 Jul 2016 22:42:34

At Day 0, Day 1 and Day 4, complete all SODIM related 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: 1261**

Folder: Product Use

Form: Product administration-mCC (8)

Data signed: (hfarmer1) 30 Mar 2015 12:28:55

Generated On: 20 Jul 2016 22:42:34

Date of product use DD/MMM/YYYY	12 APR 2014
------------------------------------	-------------

Visit	Day -1 <input checked="" type="radio"/>
-------	---

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	19:37
----------------------	-------

Time of butt return	19:42
---------------------	-------

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: 1261

Folder: Product Use

Form: Product administration-mCC (8)

Data signed: (hfarmer1) 30 Mar 2015 12:28:55

Generated On: 20 Jul 2016 22:42:34

At Day 0, Day 1 and Day 4, complete all SODIM related 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: 1261**

Folder: Product Use

Form: Product administration-mCC (9)

Data signed: (hfarmer1) 30 Mar 2015 12:28:55

Generated On: 20 Jul 2016 22:42:34

Date of product use DD/MMM/YYYY	12 APR 2014
------------------------------------	-------------

Visit	Day -1 <input checked="" type="radio"/>
-------	---

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	21:20
----------------------	-------

Time of butt return	21:28
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1261

Folder: Product Use

Form: Product administration-mCC (9)

Data signed: (hfarmer1) 30 Mar 2015 12:28:55

Generated On: 20 Jul 2016 22:42:34

At Day 0, Day 1 and Day 4, complete all SODIM related 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: 1261**

Folder: Product Use

Form: Product administration-mCC (10)

Data signed: (hfarmer1) 30 Mar 2015 12:28:55

Generated On: 20 Jul 2016 22:42:34

Date of product use DD/MMM/YYYY	13 APR 2014
------------------------------------	-------------

Visit	Day 0 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	07:43
----------------------	-------

Time of butt return	07:49
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	160
---------------------	-----

SODIM sample holder number	0542
----------------------------	------

SODIM file number	08DY0160COHN10542001
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1261

Folder: Product Use

Form: Product administration-mCC (10)

Data signed: (hfarmer1) 30 Mar 2015 12:28:55

Generated On: 20 Jul 2016 22:42:34

At Day 0, Day 1 and Day 4, complete all SODIM related 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: 1261**

Folder: Product Use

Form: Product administration-mCC (11)

Data signed: (hfarmer1) 30 Mar 2015 12:28:55

Generated On: 20 Jul 2016 22:42:34

Date of product use DD/MMM/YYYY	13 APR 2014
------------------------------------	-------------

Visit	Day 0 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	09:44
----------------------	-------

Time of butt return	09:52
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	160
---------------------	-----

SODIM sample holder number	0542
----------------------------	------

SODIM file number	08DY0160COHN10542002
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1261

Folder: Product Use

Form: Product administration-mCC (11)

Data signed: (hfarmer1) 30 Mar 2015 12:28:55

Generated On: 20 Jul 2016 22:42:34

At Day 0, Day 1 and Day 4, complete all SODIM related 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: 1261**

Folder: Product Use

Form: Product administration-mCC (12)

Data signed: (hfarmer1) 30 Mar 2015 12:28:55

Generated On: 20 Jul 2016 22:42:34

Date of product use DD/MMM/YYYY	13 APR 2014
------------------------------------	-------------

Visit	Day 0 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	11:05
----------------------	-------

Time of butt return	11:15
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	160
---------------------	-----

SODIM sample holder number	0542
----------------------------	------

SODIM file number	08DY0160COHN10542003
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1261

Folder: Product Use

Form: Product administration-mCC (12)

Data signed: (hfarmer1) 30 Mar 2015 12:28:55

Generated On: 20 Jul 2016 22:42:34

At Day 0, Day 1 and Day 4, complete all SODIM related 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: 1261**

Folder: Product Use

Form: Product administration-mCC (13)

Data signed: (hfarmer1) 30 Mar 2015 12:28:55

Generated On: 20 Jul 2016 22:42:34

Date of product use DD/MMM/YYYY	13 APR 2014
------------------------------------	-------------

Visit	Day 0 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	14:30
----------------------	-------

Time of butt return	14:38
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	160
---------------------	-----

SODIM sample holder number	0542
----------------------------	------

SODIM file number	08DY0160COHN10542004
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1261

Folder: Product Use

Form: Product administration-mCC (13)

Data signed: (hfarmer1) 30 Mar 2015 12:28:55

Generated On: 20 Jul 2016 22:42:34

At Day 0, Day 1 and Day 4, complete all SODIM related 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: 1261**

Folder: Product Use

Form: Product administration-mCC (14)

Data signed: (hfarmer1) 30 Mar 2015 12:28:55

Generated On: 20 Jul 2016 22:42:34

Date of product use DD/MMM/YYYY	13 APR 2014
------------------------------------	-------------

Visit	Day 0 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	17:03
----------------------	-------

Time of butt return	17:11
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	160
---------------------	-----

SODIM sample holder number	0542
----------------------------	------

SODIM file number	08DY0160COHN10542005
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1261

Folder: Product Use

Form: Product administration-mCC (14)

Data signed: (hfarmer1) 30 Mar 2015 12:28:55

Generated On: 20 Jul 2016 22:42:34

At Day 0, Day 1 and Day 4, complete all SODIM related 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: 1261**

Folder: Product Use

Form: Product administration-mCC (15)

Data signed: (hfarmer1) 30 Mar 2015 12:28:55

Generated On: 20 Jul 2016 22:42:34

Date of product use DD/MMM/YYYY	13 APR 2014
------------------------------------	-------------

Visit	Day 0 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	18:10
----------------------	-------

Time of butt return	18:19
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	160
---------------------	-----

SODIM sample holder number	0542
----------------------------	------

SODIM file number	08DY0160COHN10542006
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1261

Folder: Product Use

Form: Product administration-mCC (15)

Data signed: (hfarmer1) 30 Mar 2015 12:28:55

Generated On: 20 Jul 2016 22:42:34

At Day 0, Day 1 and Day 4, complete all SODIM related 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: 1261**

Folder: Product Use

Form: Product administration-mCC (16)

Data signed: (hfarmer1) 30 Mar 2015 12:28:55

Generated On: 20 Jul 2016 22:42:34

Date of product use DD/MMM/YYYY	13 APR 2014
------------------------------------	-------------

Visit	Day 0 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	20:23
----------------------	-------

Time of butt return	20:31
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	160
---------------------	-----

SODIM sample holder number	0542
----------------------------	------

SODIM file number	08DY0160COHN10542007
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1261

Folder: Product Use

Form: Product administration-mCC (16)

Data signed: (hfarmer1) 30 Mar 2015 12:28:55

Generated On: 20 Jul 2016 22:42:34

At Day 0, Day 1 and Day 4, complete all SODIM related 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: 1261**

Folder: Product Use

Form: Product administration-mCC (17)

Data signed: (hfarmer1) 30 Mar 2015 12:28:55

Generated On: 20 Jul 2016 22:42:34

Date of product use DD/MMM/YYYY	13 APR 2014
------------------------------------	-------------

Visit	Day 0 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	22:02
----------------------	-------

Time of butt return	22:08
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	160
---------------------	-----

SODIM sample holder number	0542
----------------------------	------

SODIM file number	08DY0160COHN10542008
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1261

Folder: Product Use

Form: Product administration-mCC (17)

Data signed: (hfarmer1) 30 Mar 2015 12:28:55

Generated On: 20 Jul 2016 22:42:34

At Day 0, Day 1 and Day 4, complete all SODIM related 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: 1261**

Folder: Product Use

Form: Product administration-mCC (18)

Data signed: (hfarmer1) 30 Mar 2015 12:28:55

Generated On: 20 Jul 2016 22:42:34

Date of product use DD/MMM/YYYY	14 APR 2014
------------------------------------	-------------

Visit	Day 1 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	06:45
----------------------	-------

Time of butt return	06:53
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	160
---------------------	-----

SODIM sample holder number	0542
----------------------------	------

SODIM file number	08DY0160COHN10542009
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1261

Folder: Product Use

Form: Product administration-mCC (18)

Data signed: (hfarmer1) 30 Mar 2015 12:28:55

Generated On: 20 Jul 2016 22:42:34

At Day 0, Day 1 and Day 4, complete all SODIM related 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: 1261**

Folder: Product Use

Form: Product administration-mCC (19)

Data signed: (hfarmer1) 30 Mar 2015 12:28:55

Generated On: 20 Jul 2016 22:42:34

Date of product use DD/MMM/YYYY	14 APR 2014
------------------------------------	-------------

Visit	Day 1 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	09:32
----------------------	-------

Time of butt return	09:40
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	160
---------------------	-----

SODIM sample holder number	0542
----------------------------	------

SODIM file number	08DY0160COHN10542010
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1261

Folder: Product Use

Form: Product administration-mCC (19)

Data signed: (hfarmer1) 30 Mar 2015 12:28:55

Generated On: 20 Jul 2016 22:42:34

At Day 0, Day 1 and Day 4, complete all SODIM related 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: 1261**

Folder: Product Use

Form: Product administration-mCC (20)

Data signed: (hfarmer1) 30 Mar 2015 12:28:55

Generated On: 20 Jul 2016 22:42:34

Date of product use DD/MMM/YYYY	14 APR 2014
------------------------------------	-------------

Visit	Day 1 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	13:15
----------------------	-------

Time of butt return	13:22
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	160
---------------------	-----

SODIM sample holder number	0542
----------------------------	------

SODIM file number	08DY0160COHN10542011
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1261

Folder: Product Use

Form: Product administration-mCC (20)

Data signed: (hfarmer1) 30 Mar 2015 12:28:55

Generated On: 20 Jul 2016 22:42:34

At Day 0, Day 1 and Day 4, complete all SODIM related 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: 1261**

Folder: Product Use

Form: Product administration-mCC (21)

Data signed: (hfarmer1) 30 Mar 2015 12:28:55

Generated On: 20 Jul 2016 22:42:34

Date of product use DD/MMM/YYYY	14 APR 2014
------------------------------------	-------------

Visit	Day 1 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	16:59
----------------------	-------

Time of butt return	17:06
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	160
---------------------	-----

SODIM sample holder number	0542
----------------------------	------

SODIM file number	08DY0160COHN10542012
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1261

Folder: Product Use

Form: Product administration-mCC (21)

Data signed: (hfarmer1) 30 Mar 2015 12:28:55

Generated On: 20 Jul 2016 22:42:34

At Day 0, Day 1 and Day 4, complete all SODIM related 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: 1261**

Folder: Product Use

Form: Product administration-mCC (22)

Data signed: (hfarmer1) 30 Mar 2015 12:28:55

Generated On: 20 Jul 2016 22:42:34

Date of product use DD/MMM/YYYY	14 APR 2014
------------------------------------	-------------

Visit	Day 1 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	18:45
----------------------	-------

Time of butt return	18:52
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	160
---------------------	-----

SODIM sample holder number	0542
----------------------------	------

SODIM file number	08DY0160COHN10542013
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1261

Folder: Product Use

Form: Product administration-mCC (22)

Data signed: (hfarmer1) 30 Mar 2015 12:28:55

Generated On: 20 Jul 2016 22:42:34

At Day 0, Day 1 and Day 4, complete all SODIM related 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: 1261**

Folder: Product Use

Form: Product administration-mCC (23)

Data signed: (hfarmer1) 30 Mar 2015 12:28:55

Generated On: 20 Jul 2016 22:42:34

Date of product use DD/MMM/YYYY	14 APR 2014
------------------------------------	-------------

Visit	Day 1 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	20:51
----------------------	-------

Time of butt return	21:00
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	160
---------------------	-----

SODIM sample holder number	0542
----------------------------	------

SODIM file number	08DY0160COHN10542014
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1261

Folder: Product Use

Form: Product administration-mCC (23)

Data signed: (hfarmer1) 30 Mar 2015 12:28:55

Generated On: 20 Jul 2016 22:42:34

At Day 0, Day 1 and Day 4, complete all SODIM related 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: 1261**

Folder: Product Use

Form: Product administration-mCC (24)

Data signed: (hfarmer1) 30 Mar 2015 12:28:55

Generated On: 20 Jul 2016 22:42:34

Date of product use DD/MMM/YYYY	14 APR 2014
------------------------------------	-------------

Visit	Day 1 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	22:12
----------------------	-------

Time of butt return	22:17
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	160
---------------------	-----

SODIM sample holder number	0542
----------------------------	------

SODIM file number	08DY0160COHN10542015
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1261

Folder: Product Use

Form: Product administration-mCC (24)

Data signed: (hfarmer1) 30 Mar 2015 12:28:55

Generated On: 20 Jul 2016 22:42:34

At Day 0, Day 1 and Day 4, complete all SODIM related 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: 1261**

Folder: Product Use

Form: Product administration-mCC (25)

Data signed: (hfarmer1) 30 Mar 2015 12:28:55

Generated On: 20 Jul 2016 22:42:34

Date of product use DD/MMM/YYYY	15 APR 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	06:32
----------------------	-------

Time of butt return	06:38
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1261

Folder: Product Use

Form: Product administration-mCC (25)

Data signed: (hfarmer1) 30 Mar 2015 12:28:55

Generated On: 20 Jul 2016 22:42:34

At Day 0, Day 1 and Day 4, complete all SODIM related 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: 1261**

Folder: Product Use

Form: Product administration-mCC (26)

Data signed: (hfarmer1) 30 Mar 2015 12:28:55

Generated On: 20 Jul 2016 22:42:34

Date of product use DD/MMM/YYYY	15 APR 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	07:52
----------------------	-------

Time of butt return	07:59
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1261

Folder: Product Use

Form: Product administration-mCC (26)

Data signed: (hfarmer1) 30 Mar 2015 12:28:55

Generated On: 20 Jul 2016 22:42:34

At Day 0, Day 1 and Day 4, complete all SODIM related 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: 1261**

Folder: Product Use

Form: Product administration-mCC (27)

Data signed: (hfarmer1) 30 Mar 2015 12:28:55

Generated On: 20 Jul 2016 22:42:34

Date of product use DD/MMM/YYYY	15 APR 2014
------------------------------------	-------------

Visit	Day 2 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	12:20
----------------------	-------

Time of butt return	12:24
---------------------	-------

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: 1261

Folder: Product Use

Form: Product administration-mCC (27)

Data signed: (hfarmer1) 30 Mar 2015 12:28:55

Generated On: 20 Jul 2016 22:42:34

At Day 0, Day 1 and Day 4, complete all SODIM related 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: 1261**

Folder: Product Use

Form: Product administration-mCC (28)

Data signed: (hfarmer1) 30 Mar 2015 12:28:55

Generated On: 20 Jul 2016 22:42:34

Date of product use DD/MMM/YYYY	15 APR 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	15:12
----------------------	-------

Time of butt return	15:18
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1261

Folder: Product Use

Form: Product administration-mCC (28)

Data signed: (hfarmer1) 30 Mar 2015 12:28:55

Generated On: 20 Jul 2016 22:42:34

At Day 0, Day 1 and Day 4, complete all SODIM related 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: 1261**

Folder: Product Use

Form: Product administration-mCC (29)

Data signed: (hfarmer1) 30 Mar 2015 12:28:55

Generated On: 20 Jul 2016 22:42:34

Date of product use DD/MMM/YYYY	15 APR 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	17:21
----------------------	-------

Time of butt return	17:24
---------------------	-------

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: 1261

Folder: Product Use

Form: Product administration-mCC (29)

Data signed: (hfarmer1) 30 Mar 2015 12:28:55

Generated On: 20 Jul 2016 22:42:34

At Day 0, Day 1 and Day 4, complete all SODIM related 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: 1261**

Folder: Product Use

Form: Product administration-mCC (30)

Data signed: (hfarmer1) 30 Mar 2015 12:28:55

Generated On: 20 Jul 2016 22:42:34

Date of product use DD/MMM/YYYY	15 APR 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	19:40
----------------------	-------

Time of butt return	19:47
---------------------	-------

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: 1261

Folder: Product Use

Form: Product administration-mCC (30)

Data signed: (hfarmer1) 30 Mar 2015 12:28:55

Generated On: 20 Jul 2016 22:42:34

At Day 0, Day 1 and Day 4, complete all SODIM related 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: 1261**

Folder: Product Use

Form: Product administration-mCC (31)

Data signed: (hfarmer1) 30 Mar 2015 12:28:55

Generated On: 20 Jul 2016 22:42:34

Date of product use DD/MMM/YYYY	15 APR 2014
------------------------------------	-------------

Visit	Day 2 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	21:28
----------------------	-------

Time of butt return	21:35
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1261

Folder: Product Use

Form: Product administration-mCC (31)

Data signed: (hfarmer1) 30 Mar 2015 12:28:55

Generated On: 20 Jul 2016 22:42:34

At Day 0, Day 1 and Day 4, complete all SODIM related 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: 1261**

Folder: Product Use

Form: Product administration-mCC (32)

Data signed: (hfarmer1) 30 Mar 2015 12:28:55

Generated On: 20 Jul 2016 22:42:34

Date of product use DD/MMM/YYYY	16 APR 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	06:32
----------------------	-------

Time of butt return	06:38
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1261

Folder: Product Use

Form: Product administration-mCC (32)

Data signed: (hfarmer1) 30 Mar 2015 12:28:55

Generated On: 20 Jul 2016 22:42:34

At Day 0, Day 1 and Day 4, complete all SODIM related 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: 1261**

Folder: Product Use

Form: Product administration-mCC (33)

Data signed: (hfarmer1) 30 Mar 2015 12:28:55

Generated On: 20 Jul 2016 22:42:34

Date of product use DD/MMM/YYYY	16 APR 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	07:47
----------------------	-------

Time of butt return	07:52
---------------------	-------

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: 1261

Folder: Product Use

Form: Product administration-mCC (33)

Data signed: (hfarmer1) 30 Mar 2015 12:28:55

Generated On: 20 Jul 2016 22:42:34

At Day 0, Day 1 and Day 4, complete all SODIM related 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: 1261**

Folder: Product Use

Form: Product administration-mCC (34)

Data signed: (hfarmer1) 30 Mar 2015 12:28:55

Generated On: 20 Jul 2016 22:42:34

Date of product use DD/MMM/YYYY	16 APR 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	09:37
----------------------	-------

Time of butt return	09:41
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1261

Folder: Product Use

Form: Product administration-mCC (34)

Data signed: (hfarmer1) 30 Mar 2015 12:28:55

Generated On: 20 Jul 2016 22:42:34

At Day 0, Day 1 and Day 4, complete all SODIM related 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: 1261**

Folder: Product Use

Form: Product administration-mCC (35)

Data signed: (hfarmer1) 30 Mar 2015 12:28:55

Generated On: 20 Jul 2016 22:42:34

Date of product use DD/MMM/YYYY	16 APR 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	11:18
----------------------	-------

Time of butt return	11:24
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1261

Folder: Product Use

Form: Product administration-mCC (35)

Data signed: (hfarmer1) 30 Mar 2015 12:28:55

Generated On: 20 Jul 2016 22:42:34

At Day 0, Day 1 and Day 4, complete all SODIM related 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: 1261**

Folder: Product Use

Form: Product administration-mCC (36)

Data signed: (hfarmer1) 30 Mar 2015 12:28:55

Generated On: 20 Jul 2016 22:42:34

Date of product use DD/MMM/YYYY	16 APR 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	14:19
----------------------	-------

Time of butt return	14:24
---------------------	-------

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: 1261

Folder: Product Use

Form: Product administration-mCC (36)

Data signed: (hfarmer1) 30 Mar 2015 12:28:55

Generated On: 20 Jul 2016 22:42:34

At Day 0, Day 1 and Day 4, complete all SODIM related 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: 1261**

Folder: Product Use

Form: Product administration-mCC (37)

Data signed: (hfarmer1) 30 Mar 2015 12:28:55

Generated On: 20 Jul 2016 22:42:34

Date of product use DD/MMM/YYYY	16 APR 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	17:04
---------------------	-------

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: 1261

Folder: Product Use

Form: Product administration-mCC (37)

Data signed: (hfarmer1) 30 Mar 2015 12:28:55

Generated On: 20 Jul 2016 22:42:34

At Day 0, Day 1 and Day 4, complete all SODIM related 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: 1261**

Folder: Product Use

Form: Product administration-mCC (38)

Data signed: (hfarmer1) 30 Mar 2015 12:28:55

Generated On: 20 Jul 2016 22:42:34

Date of product use DD/MMM/YYYY	16 APR 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	17:45
----------------------	-------

Time of butt return	17:49
---------------------	-------

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: 1261

Folder: Product Use

Form: Product administration-mCC (38)

Data signed: (hfarmer1) 30 Mar 2015 12:28:55

Generated On: 20 Jul 2016 22:42:34

At Day 0, Day 1 and Day 4, complete all SODIM related 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: 1261**

Folder: Product Use

Form: Product administration-mCC (39)

Data signed: (hfarmer1) 30 Mar 2015 12:28:55

Generated On: 20 Jul 2016 22:42:34

Date of product use DD/MMM/YYYY	16 APR 2014
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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	19:13
----------------------	-------

Time of butt return	19:18
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1261

Folder: Product Use

Form: Product administration-mCC (39)

Data signed: (hfarmer1) 30 Mar 2015 12:28:55

Generated On: 20 Jul 2016 22:42:34

At Day 0, Day 1 and Day 4, complete all SODIM related 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: 1261**

Folder: Product Use

Form: Product administration-mCC (40)

Data signed: (hfarmer1) 30 Mar 2015 12:28:55

Generated On: 20 Jul 2016 22:42:34

Date of product use DD/MMM/YYYY	16 APR 2014
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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	21:43
----------------------	-------

Time of butt return	21:49
---------------------	-------

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: 1261

Folder: Product Use

Form: Product administration-mCC (40)

Data signed: (hfarmer1) 30 Mar 2015 12:28:55

Generated On: 20 Jul 2016 22:42:34

At Day 0, Day 1 and Day 4, complete all SODIM related 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: 1261**

Folder: Product Use

Form: Product administration-mCC (41)

Data signed: (hfarmer1) 30 Mar 2015 12:28:55

Generated On: 20 Jul 2016 22:42:34

Date of product use DD/MMM/YYYY	17 APR 2014
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Visit	Day 4 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	06:30
----------------------	-------

Time of butt return	06:36
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	160
---------------------	-----

SODIM sample holder number	0542
----------------------------	------

SODIM file number	08DY0160COHN10542016
-------------------	----------------------

Comment	_____
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1261

Folder: Product Use

Form: Product administration-mCC (41)

Data signed: (hfarmer1) 30 Mar 2015 12:28:55

Generated On: 20 Jul 2016 22:42:34

At Day 0, Day 1 and Day 4, complete all SODIM related 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: 1261**

Folder: Product Use

Form: Product administration-mCC (42)

Data signed: (hfarmer1) 30 Mar 2015 12:28:55

Generated On: 20 Jul 2016 22:42:34

Date of product use DD/MMM/YYYY	17 APR 2014
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Visit	Day 4 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	08:29
----------------------	-------

Time of butt return	08:36
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	160
---------------------	-----

SODIM sample holder number	0542
----------------------------	------

SODIM file number	08DY0160COHN10542017
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1261

Folder: Product Use

Form: Product administration-mCC (42)

Data signed: (hfarmer1) 30 Mar 2015 12:28:55

Generated On: 20 Jul 2016 22:42:34

At Day 0, Day 1 and Day 4, complete all SODIM related 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: 1261**

Folder: Product Use

Form: Product administration-mCC (43)

Data signed: (hfarmer1) 30 Mar 2015 12:28:55

Generated On: 20 Jul 2016 22:42:34

Date of product use DD/MMM/YYYY	17 APR 2014
------------------------------------	-------------

Visit	Day 4 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	12:15
----------------------	-------

Time of butt return	12:23
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	160
---------------------	-----

SODIM sample holder number	0542
----------------------------	------

SODIM file number	08DY0160COHN10542018
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1261

Folder: Product Use

Form: Product administration-mCC (43)

Data signed: (hfarmer1) 30 Mar 2015 12:28:55

Generated On: 20 Jul 2016 22:42:34

At Day 0, Day 1 and Day 4, complete all SODIM related 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: 1261**

Folder: Product Use

Form: Product administration-mCC (44)

Data signed: (hfarmer1) 30 Mar 2015 12:28:55

Generated On: 20 Jul 2016 22:42:34

Date of product use DD/MMM/YYYY	17 APR 2014
------------------------------------	-------------

Visit	Day 4 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	14:24
----------------------	-------

Time of butt return	14:30
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	160
---------------------	-----

SODIM sample holder number	0542
----------------------------	------

SODIM file number	08DY0160COHN10542019
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1261

Folder: Product Use

Form: Product administration-mCC (44)

Data signed: (hfarmer1) 30 Mar 2015 12:28:55

Generated On: 20 Jul 2016 22:42:34

At Day 0, Day 1 and Day 4, complete all SODIM related 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: 1261**

Folder: Product Use

Form: Product administration-mCC (45)

Data signed: (hfarmer1) 30 Mar 2015 12:28:55

Generated On: 20 Jul 2016 22:42:34

Date of product use DD/MMM/YYYY	17 APR 2014
------------------------------------	-------------

Visit	Day 4 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	16:08
----------------------	-------

Time of butt return	16:16
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	160
---------------------	-----

SODIM sample holder number	0542
----------------------------	------

SODIM file number	08DY0160COHN10542020
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1261

Folder: Product Use

Form: Product administration-mCC (45)

Data signed: (hfarmer1) 30 Mar 2015 12:28:55

Generated On: 20 Jul 2016 22:42:34

At Day 0, Day 1 and Day 4, complete all SODIM related 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: 1261**

Folder: Product Use

Form: Product administration-mCC (46)

Data signed: (hfarmer1) 30 Mar 2015 12:28:55

Generated On: 20 Jul 2016 22:42:34

Date of product use DD/MMM/YYYY	17 APR 2014
------------------------------------	-------------

Visit	Day 4 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	18:18
----------------------	-------

Time of butt return	18:26
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	160
---------------------	-----

SODIM sample holder number	0542
----------------------------	------

SODIM file number	08DY0160COHN10542021
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1261

Folder: Product Use

Form: Product administration-mCC (46)

Data signed: (hfarmer1) 30 Mar 2015 12:28:55

Generated On: 20 Jul 2016 22:42:34

At Day 0, Day 1 and Day 4, complete all SODIM related 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: 1261**

Folder: Product Use

Form: Product administration-mCC (47)

Data signed: (hfarmer1) 30 Mar 2015 12:28:55

Generated On: 20 Jul 2016 22:42:34

Date of product use DD/MMM/YYYY	17 APR 2014
------------------------------------	-------------

Visit	Day 4 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	20:36
----------------------	-------

Time of butt return	20:41
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	160
---------------------	-----

SODIM sample holder number	0542
----------------------------	------

SODIM file number	08DY0160COHN10542022
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1261

Folder: Product Use

Form: Product administration-mCC (47)

Data signed: (hfarmer1) 30 Mar 2015 12:28:55

Generated On: 20 Jul 2016 22:42:34

At Day 0, Day 1 and Day 4, complete all SODIM related 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: 1261**

Folder: Product Use

Form: Product administration-mCC (48)

Data signed: (hfarmer1) 30 Mar 2015 12:28:55

Generated On: 20 Jul 2016 22:42:34

Date of product use DD/MMM/YYYY	17 APR 2014
------------------------------------	-------------

Visit	Day 4 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	21:45
----------------------	-------

Time of butt return	21:48
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	160
---------------------	-----

SODIM sample holder number	0542
----------------------------	------

SODIM file number	08DY0160COHN10542023
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1261

Folder: Product Use

Form: Product administration-mCC (48)

Data signed: (hfarmer1) 30 Mar 2015 12:28:55

Generated On: 20 Jul 2016 22:42:34

At Day 0, Day 1 and Day 4, complete all SODIM related 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: 1261**

Folder: Product Use

Form: Product administration-mCC (49)

Data signed: (hfarmer1) 30 Mar 2015 12:28:55

Generated On: 20 Jul 2016 22:42:34

Date of product use DD/MMM/YYYY	18 APR 2014
------------------------------------	-------------

Visit	Day 5 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	06:34
----------------------	-------

Time of butt return	06:38
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1261

Folder: Product Use

Form: Product administration-mCC (49)

Data signed: (hfarmer1) 30 Mar 2015 12:28:55

Generated On: 20 Jul 2016 22:42:34

At Day 0, Day 1 and Day 4, complete all SODIM related 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: 1261**

Folder: Product Use

Form: Product administration-mCC (50)

Data signed: (hfarmer1) 30 Mar 2015 12:28:55

Generated On: 20 Jul 2016 22:42:34

Date of product use DD/MMM/YYYY	18 APR 2014
------------------------------------	-------------

Visit	Day 5 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	08:43
----------------------	-------

Time of butt return	08:48
---------------------	-------

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: 1261

Folder: Product Use

Form: Product administration-mCC (50)

Data signed: (hfarmer1) 30 Mar 2015 12:28:55

Generated On: 20 Jul 2016 22:42:34

At Day 0, Day 1 and Day 4, complete all SODIM related 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: 1261**

Folder: Product Use

Form: Product administration-mCC (51)

Data signed: (hfarmer1) 30 Mar 2015 12:28:55

Generated On: 20 Jul 2016 22:42:34

Date of product use DD/MMM/YYYY	18 APR 2014
------------------------------------	-------------

Visit	Day 5 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	11:50
----------------------	-------

Time of butt return	11:54
---------------------	-------

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: 1261

Folder: Product Use

Form: Product administration-mCC (51)

Data signed: (hfarmer1) 30 Mar 2015 12:28:55

Generated On: 20 Jul 2016 22:42:34

At Day 0, Day 1 and Day 4, complete all SODIM related 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: 1261**

Folder: Product Use

Form: Product administration-mCC (52)

Data signed: (hfarmer1) 30 Mar 2015 12:28:55

Generated On: 20 Jul 2016 22:42:34

Date of product use DD/MMM/YYYY	18 APR 2014
------------------------------------	-------------

Visit	Day 5 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	13:27
----------------------	-------

Time of butt return	13:31
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1261

Folder: Product Use

Form: Product administration-mCC (52)

Data signed: (hfarmer1) 30 Mar 2015 12:28:55

Generated On: 20 Jul 2016 22:42:34

At Day 0, Day 1 and Day 4, complete all SODIM related 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: 1261**

Folder: Product Use

Form: Product administration-mCC (53)

Data signed: (hfarmer1) 30 Mar 2015 12:28:55

Generated On: 20 Jul 2016 22:42:34

Date of product use DD/MMM/YYYY	18 APR 2014
------------------------------------	-------------

Visit	Day 5 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	16:49
----------------------	-------

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: 1261

Folder: Product Use

Form: Product administration-mCC (53)

Data signed: (hfarmer1) 30 Mar 2015 12:28:55

Generated On: 20 Jul 2016 22:42:34

At Day 0, Day 1 and Day 4, complete all SODIM related 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: 1261**

Folder: Product Use

Form: Product administration-mCC (54)

Data signed: (hfarmer1) 30 Mar 2015 12:28:55

Generated On: 20 Jul 2016 22:42:34

Date of product use DD/MMM/YYYY	18 APR 2014
------------------------------------	-------------

Visit	Day 5 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	17:41
----------------------	-------

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: 1261

Folder: Product Use

Form: Product administration-mCC (54)

Data signed: (hfarmer1) 30 Mar 2015 12:28:55

Generated On: 20 Jul 2016 22:42:34

At Day 0, Day 1 and Day 4, complete all SODIM related 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: 1261**

Folder: Product Use

Form: Product administration-mCC (55)

Data signed: (hfarmer1) 30 Mar 2015 12:28:55

Generated On: 20 Jul 2016 22:42:34

Date of product use DD/MMM/YYYY	18 APR 2014
------------------------------------	-------------

Visit	Day 5 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	18:53
----------------------	-------

Time of butt return	18:58
---------------------	-------

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: 1261

Folder: Product Use

Form: Product administration-mCC (55)

Data signed: (hfarmer1) 30 Mar 2015 12:28:55

Generated On: 20 Jul 2016 22:42:34

At Day 0, Day 1 and Day 4, complete all SODIM related 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: 1261

Folder: Product Use

Form: Product administration-mCC (56)

Data signed: (hfarmer1) 30 Mar 2015 12:28:55

Generated On: 20 Jul 2016 22:42:34

Date of product use DD/MMM/YYYY	18 APR 2014
------------------------------------	-------------

Visit	Day 5 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	20:38
----------------------	-------

Time of butt return	20:45
---------------------	-------

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: 1261

Folder: Product Use

Form: Product administration-mCC (56)

Data signed: (hfarmer1) 30 Mar 2015 12:28:55

Generated On: 20 Jul 2016 22:42:34

At Day 0, Day 1 and Day 4, complete all SODIM related 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: 1261**

Folder: Product Use

Form: Product administration-mCC (57)

Data signed: (hfarmer1) 30 Mar 2015 12:28:55

Generated On: 20 Jul 2016 22:42:34

Date of product use DD/MMM/YYYY	18 APR 2014
------------------------------------	-------------

Visit	Day 5 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	22:03
----------------------	-------

Time of butt return	22:06
---------------------	-------

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: 1261

Folder: Product Use

Form: Product administration-mCC (57)

Data signed: (hfarmer1) 30 Mar 2015 12:28:55

Generated On: 20 Jul 2016 22:42:34

At Day 0, Day 1 and Day 4, complete all SODIM related 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: 1261**

Folder: Product Use

Form: Product administration-mCC (58)

Data signed: (hfarmer1) 30 Mar 2015 12:28:55

Generated On: 20 Jul 2016 22:42:34

Date of product use DD/MMM/YYYY	19 APR 2014
------------------------------------	-------------

Visit	Day 6 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	07:36
----------------------	-------

Time of butt return	07:41
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1261

Folder: Product Use

Form: Product administration-mCC (58)

Data signed: (hfarmer1) 30 Mar 2015 12:28:55

Generated On: 20 Jul 2016 22:42:34

At Day 0, Day 1 and Day 4, complete all SODIM related 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: 1261**

Folder: Product Use

Form: Product administration-mCC (59)

Data signed: (hfarmer1) 30 Mar 2015 12:28:55

Generated On: 20 Jul 2016 22:42:34

Date of product use DD/MMM/YYYY	19 APR 2014
------------------------------------	-------------

Visit	Day 6 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	08:39
----------------------	-------

Time of butt return	08:43
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1261

Folder: Product Use

Form: Product administration-mCC (59)

Data signed: (hfarmer1) 30 Mar 2015 12:28:55

Generated On: 20 Jul 2016 22:42:34

At Day 0, Day 1 and Day 4, complete all SODIM related 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: 1261

Folder: Product Use

Form: Product administration-mCC (60)

Data signed: (hfarmer1) 30 Mar 2015 12:28:55

Generated On: 20 Jul 2016 22:42:34

Date of product use DD/MMM/YYYY	19 APR 2014
------------------------------------	-------------

Visit	Day 6 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	09:13
----------------------	-------

Time of butt return	09:16
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1261

Folder: Product Use

Form: Product administration-mCC (60)

Data signed: (hfarmer1) 30 Mar 2015 12:28:55

Generated On: 20 Jul 2016 22:42:34

At Day 0, Day 1 and Day 4, complete all SODIM related 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: 1261

Folder: Product Use

Form: Product administration-mCC (61)

Data signed: (hfarmer1) 30 Mar 2015 12:28:55

Generated On: 20 Jul 2016 22:42:34

Date of product use DD/MMM/YYYY	19 APR 2014
------------------------------------	-------------

Visit	Day 6 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	09:48
----------------------	-------

Time of butt return	09:52
---------------------	-------

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: 1261

Folder: Product Use

Form: Product administration-mCC (61)

Data signed: (hfarmer1) 30 Mar 2015 12:28:55

Generated On: 20 Jul 2016 22:42:34

At Day 0, Day 1 and Day 4, complete all SODIM related 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: 1261**

Folder: Product Use

Form: Product administration-mCC (62)

Data signed: (hfarmer1) 30 Mar 2015 12:28:55

Generated On: 20 Jul 2016 22:42:34

Date of product use DD/MMM/YYYY	19 APR 2014
------------------------------------	-------------

Visit	Day 6 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	11:16
----------------------	-------

Time of butt return	11:19
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1261

Folder: Product Use

Form: Product administration-mCC (62)

Data signed: (hfarmer1) 30 Mar 2015 12:28:55

Generated On: 20 Jul 2016 22:42:34

At Day 0, Day 1 and Day 4, complete all SODIM related 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: 1261**

Folder: Product Use

Form: Product administration-mCC (63)

Data signed: (hfarmer1) 30 Mar 2015 12:28:55

Generated On: 20 Jul 2016 22:42:34

Date of product use DD/MMM/YYYY	13 MAY 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	84
---------------------	----

SODIM sample holder number	0209
----------------------------	------

SODIM file number	08DY0084COHN30209001
-------------------	----------------------

Comment	<hr/>
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1261

Folder: Product Use

Form: Product administration-mCC (63)

Data signed: (hfarmer1) 30 Mar 2015 12:28:55

Generated On: 20 Jul 2016 22:42:34

At Day 0, Day 1 and Day 4, complete all SODIM related 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: 1261**

Folder: Product Use

Form: Product administration-mCC (64)

Data signed: (hfarmer1) 30 Mar 2015 12:28:55

Generated On: 20 Jul 2016 22:42:34

Date of product use DD/MMM/YYYY	13 MAY 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	84
---------------------	----

SODIM sample holder number	0209
----------------------------	------

SODIM file number	08DY0084COHN30209002
-------------------	----------------------

Comment	<hr/>
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1261

Folder: Product Use

Form: Product administration-mCC (64)

Data signed: (hfarmer1) 30 Mar 2015 12:28:55

Generated On: 20 Jul 2016 22:42:34

At Day 0, Day 1 and Day 4, complete all SODIM related 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: 1261**

Folder: Product Use

Form: Product administration-THS menthol

Data signed: (hfarmer1) 30 Mar 2015 12:29:02

Generated On: 20 Jul 2016 22:42:34

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: 1261**

Folder: Product Use

Form: Product administration-THS menthol (1)

Data signed: (hfarmer1) 30 Mar 2015 12:29:02

Generated On: 20 Jul 2016 22:42:34

Date of product use DD/MMM/YYYY	11 APR 2014
------------------------------------	-------------

Visit	Day -2 <input type="radio"/>
-------	------------------------------

Type of Product Use	THS 2.2 Menthol <input type="radio"/>
---------------------	---------------------------------------

If type of Product Use different from the randomization please explain	PRODUCT TEST
---	--------------

Time of distribution	16:11
----------------------	-------

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/>
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Batch Number	B08545
--------------	--------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1261

Folder: Product Use

Form: Product administration-THS menthol (1)

Data signed: (hfarmer1) 30 Mar 2015 12:29:02

Generated On: 20 Jul 2016 22:42:34

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: 1261**

Folder: Product Use

Form: HST 4 hours (1)

Data signed: (hfarmer1) 30 Mar 2015 12:29:03

Generated On: 20 Jul 2016 22:42:34

Visit	Day 30 <input type="radio"/>
-------	------------------------------

Not Done	False
----------	-------

If Not Done, please specify _____

Date	13 MAY 2014
DD/MMM/YYYY	

SODIM device distribution time	08:34
hour:min 24-hour clock	

SODIM device collection time	12:34
hour:min 24-hour clock	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Product Use

Form: HST 4 hours (2)

Data signed: (hfarmer1) 30 Mar 2015 12:29:03

Generated On: 20 Jul 2016 22:42:34

Visit	Day 60 <input checked="" type="radio"/>
-------	---

Not Done	True
----------	------

If Not Done, please specify

SUBJECT IS AN EARLY
TERMINATION

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: 1261**

Folder: Product Use

Form: HST 4 hours (3)

Data signed: (hfarmer1) 30 Mar 2015 12:29:03

Generated On: 20 Jul 2016 22:42:34

Visit	Day 90 <input checked="" type="radio"/>
-------	---

Not Done	True
----------	------

If Not Done, please specify

SUBJECT IS AN EARLY
TERMINATION

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: 1261**

Folder: Product Use

Form: Topography files status for mCC (1)

Generated On: 20 Jul 2016 22:42:34

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: 1261**

Folder: Product Use

Form: Topography files status for mCC (2)

Generated On: 20 Jul 2016 22:42:34

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: 1261**

Folder: Product Use

Form: Topography files status for mCC (3)

Generated On: 20 Jul 2016 22:42:34

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: 1261**

Folder: Product Use

Form: Topography files status for mCC (4)

Generated On: 20 Jul 2016 22:42:34

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: 1261**

Folder: Product Use

Form: Topography files status for mCC (5)

Generated On: 20 Jul 2016 22:42:34

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: 1261**

Folder: Product Use

Form: Topography files status for mCC (6)

Generated On: 20 Jul 2016 22:42:34

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: 1261**

Folder: Product Use

Form: Topography files status for mCC (7)

Generated On: 20 Jul 2016 22:42:34

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: 1261**

Folder: Product Use

Form: Topography files status for mCC (8)

Generated On: 20 Jul 2016 22:42:34

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: 1261**

Folder: Product Use

Form: Topography files status for mCC (9)

Generated On: 20 Jul 2016 22:42:34

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: 1261**

Folder: Product Use

Form: Topography files status for mCC (10)

Generated On: 20 Jul 2016 22:42:34

SODIM file number	08DY0160COHN10542001
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File Status	Accepted <input checked="" type="radio"/>
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Rejection / Error reason	
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Date of analysis DD/MMM/YYYY	08 SEP 2014
---------------------------------	-------------

Operator	Thierry Bachmann <input checked="" type="radio"/>
----------	---

Comment	
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Modified File Number	
----------------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Product Use

Form: Topography files status for mCC (11)

Generated On: 20 Jul 2016 22:42:34

SODIM file number	08DY0160COHN10542002
-------------------	----------------------

File Status	Accepted <input checked="" type="radio"/>
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Rejection / Error reason	
--------------------------	--

Date of analysis DD/MMM/YYYY	08 SEP 2014
---------------------------------	-------------

Operator	Thierry Bachmann <input checked="" type="radio"/>
----------	---

Comment	
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Modified File Number	
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Product Use

Form: Topography files status for mCC (12)

Generated On: 20 Jul 2016 22:42:34

SODIM file number	08DY0160COHN10542003
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File Status	Accepted 
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Rejection / Error reason	
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Date of analysis DD/MMM/YYYY	08 SEP 2014
---------------------------------	-------------

Operator	Thierry Bachmann 
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Comment	
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Modified File Number	
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Product Use

Form: Topography files status for mCC (13)

Generated On: 20 Jul 2016 22:42:34

SODIM file number	08DY0160COHN10542004
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File Status	Accepted <input checked="" type="radio"/>
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Rejection / Error reason	
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Date of analysis DD/MMM/YYYY	08 SEP 2014
---------------------------------	-------------

Operator	Thierry Bachmann <input checked="" type="radio"/>
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Comment	
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Modified File Number	
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Product Use

Form: Topography files status for mCC (14)

Generated On: 20 Jul 2016 22:42:34

SODIM file number	08DY0160COHN10542005
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File Status	Accepted <input checked="" type="radio"/>
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Rejection / Error reason	
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Date of analysis DD/MMM/YYYY	08 SEP 2014
---------------------------------	-------------

Operator	Thierry Bachmann <input checked="" type="radio"/>
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Comment	
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Modified File Number	
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Product Use

Form: Topography files status for mCC (15)

Generated On: 20 Jul 2016 22:42:34

SODIM file number	08DY0160COHN10542006
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File Status	Accepted 
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Rejection / Error reason	<hr/>
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Date of analysis DD/MMM/YYYY	08 SEP 2014
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Operator	Thierry Bachmann 
----------	--

Comment	<hr/>
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Modified File Number	<hr/>
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Product Use

Form: Topography files status for mCC (16)

Generated On: 20 Jul 2016 22:42:34

SODIM file number	08DY0160COHN10542007
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File Status	Accepted 
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Rejection / Error reason	<hr/>
--------------------------	-------

Date of analysis DD/MMM/YYYY	08 SEP 2014
---------------------------------	-------------

Operator	Thierry Bachmann 
----------	--

Comment	<hr/>
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Modified File Number	<hr/>
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Product Use

Form: Topography files status for mCC (17)


Generated On: 20 Jul 2016 22:42:34

SODIM file number	08DY0160COHN10542008
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File Status	Accepted 
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Rejection / Error reason	<hr/>
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Date of analysis DD/MMM/YYYY	08 SEP 2014
---------------------------------	-------------

Operator	Thierry Bachmann 
----------	--

Comment	<hr/>
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Modified File Number	<hr/>
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Product Use

Form: Topography files status for mCC (18)

Generated On: 20 Jul 2016 22:42:34

SODIM file number	08DY0160COHN10542009
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File Status	Accepted 
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Rejection / Error reason	<hr/>
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Date of analysis DD/MMM/YYYY	08 SEP 2014
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Operator	Thierry Bachmann 
----------	--

Comment	<hr/>
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Modified File Number	<hr/>
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Product Use

Form: Topography files status for mCC (19)

Generated On: 20 Jul 2016 22:42:34

SODIM file number	08DY0160COHN10542010
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File Status	Accepted <input checked="" type="radio"/>
-------------	---

Rejection / Error reason	
--------------------------	--

Date of analysis DD/MMM/YYYY	08 SEP 2014
---------------------------------	-------------

Operator	Thierry Bachmann <input checked="" type="radio"/>
----------	---

Comment	
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Modified File Number	
----------------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Product Use

Form: Topography files status for mCC (20)

Generated On: 20 Jul 2016 22:42:34

SODIM file number	08DY0160COHN10542011
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File Status	Accepted <input checked="" type="radio"/>
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Rejection / Error reason	<hr/>
--------------------------	-------

Date of analysis DD/MMM/YYYY	08 SEP 2014
---------------------------------	-------------

Operator	Thierry Bachmann <input checked="" type="radio"/>
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Comment	<hr/>
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Modified File Number	<hr/>
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Product Use

Form: Topography files status for mCC (21)

Generated On: 20 Jul 2016 22:42:34

SODIM file number	08DY0160COHN10542012
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File Status	Accepted <input checked="" type="radio"/>
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Rejection / Error reason	<hr/>
--------------------------	-------

Date of analysis DD/MMM/YYYY	08 SEP 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: 1261**

Folder: Product Use

Form: Topography files status for mCC (22)

Generated On: 20 Jul 2016 22:42:34

SODIM file number	08DY0160COHN10542013
-------------------	----------------------

File Status	Accepted <input checked="" type="radio"/>
-------------	---

Rejection / Error reason	
--------------------------	--

Date of analysis DD/MMM/YYYY	08 SEP 2014
---------------------------------	-------------

Operator	Thierry Bachmann <input checked="" type="radio"/>
----------	---

Comment	
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Modified File Number	
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Product Use

Form: Topography files status for mCC (23)

Generated On: 20 Jul 2016 22:42:34

SODIM file number	08DY0160COHN10542014
-------------------	----------------------

File Status	Accepted <input checked="" type="radio"/>
-------------	---

Rejection / Error reason	
--------------------------	--

Date of analysis DD/MMM/YYYY	08 SEP 2014
---------------------------------	-------------

Operator	Thierry Bachmann <input checked="" type="radio"/>
----------	---

Comment	
---------	--

Modified File Number	
----------------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Product Use

Form: Topography files status for mCC (24)

Generated On: 20 Jul 2016 22:42:34

SODIM file number	08DY0160COHN10542015
-------------------	----------------------

File Status	Accepted <input checked="" type="radio"/>
-------------	---

Rejection / Error reason	
--------------------------	--

Date of analysis DD/MMM/YYYY	08 SEP 2014
---------------------------------	-------------

Operator	Thierry Bachmann <input checked="" type="radio"/>
----------	---

Comment	
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Modified File Number	
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Product Use

Form: Topography files status for mCC (25)

Generated On: 20 Jul 2016 22:42:34

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: 1261**

Folder: Product Use

Form: Topography files status for mCC (26)

Generated On: 20 Jul 2016 22:42:34

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: 1261**

Folder: Product Use

Form: Topography files status for mCC (27)

Generated On: 20 Jul 2016 22:42:34

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: 1261**

Folder: Product Use

Form: Topography files status for mCC (28)

Generated On: 20 Jul 2016 22:42:34

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: 1261**

Folder: Product Use

Form: Topography files status for mCC (29)

Generated On: 20 Jul 2016 22:42:34

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: 1261**

Folder: Product Use

Form: Topography files status for mCC (30)

Generated On: 20 Jul 2016 22:42:34

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: 1261**

Folder: Product Use

Form: Topography files status for mCC (31)

Generated On: 20 Jul 2016 22:42:34

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: 1261**

Folder: Product Use

Form: Topography files status for mCC (32)

Generated On: 20 Jul 2016 22:42:34

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: 1261**

Folder: Product Use

Form: Topography files status for mCC (33)

Generated On: 20 Jul 2016 22:42:34

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: 1261**

Folder: Product Use

Form: Topography files status for mCC (34)

Generated On: 20 Jul 2016 22:42:34

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: 1261**

Folder: Product Use

Form: Topography files status for mCC (35)

Generated On: 20 Jul 2016 22:42:34

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: 1261**

Folder: Product Use

Form: Topography files status for mCC (36)

Generated On: 20 Jul 2016 22:42:34

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: 1261**

Folder: Product Use

Form: Topography files status for mCC (37)

Generated On: 20 Jul 2016 22:42:34

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: 1261**

Folder: Product Use

Form: Topography files status for mCC (38)

Generated On: 20 Jul 2016 22:42:34

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: 1261**

Folder: Product Use

Form: Topography files status for mCC (39)

Generated On: 20 Jul 2016 22:42:34

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: 1261**

Folder: Product Use

Form: Topography files status for mCC (40)

Generated On: 20 Jul 2016 22:42:34

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: 1261**

Folder: Product Use

Form: Topography files status for mCC (41)

Generated On: 20 Jul 2016 22:42:34

SODIM file number	08DY0160COHN10542016
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File Status	Accepted <input checked="" type="radio"/>
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Rejection / Error reason	<hr/>
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Date of analysis DD/MMM/YYYY	08 SEP 2014
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Operator	Thierry Bachmann <input checked="" type="radio"/>
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Comment	<hr/>
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Modified File Number	<hr/>
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Product Use

Form: Topography files status for mCC (42)

Generated On: 20 Jul 2016 22:42:34

SODIM file number	08DY0160COHN10542017
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File Status	Accepted <input checked="" type="radio"/>
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Rejection / Error reason	
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Date of analysis DD/MMM/YYYY	08 SEP 2014
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Operator	Thierry Bachmann <input checked="" type="radio"/>
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Comment	
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Modified File Number	
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Product Use

Form: Topography files status for mCC (43)

Generated On: 20 Jul 2016 22:42:34

SODIM file number	08DY0160COHN10542018
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File Status	Accepted <input checked="" type="radio"/>
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Rejection / Error reason	
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Date of analysis DD/MMM/YYYY	08 SEP 2014
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Operator	Thierry Bachmann <input checked="" type="radio"/>
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Comment	
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Modified File Number	
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Product Use

Form: Topography files status for mCC (44)

Generated On: 20 Jul 2016 22:42:34

SODIM file number	08DY0160COHN10542019
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File Status	Accepted <input checked="" type="radio"/>
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Rejection / Error reason	<hr/>
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Date of analysis DD/MMM/YYYY	08 SEP 2014
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Operator	Thierry Bachmann <input checked="" type="radio"/>
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Comment	<hr/>
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Modified File Number	<hr/>
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Product Use

Form: Topography files status for mCC (45)

Generated On: 20 Jul 2016 22:42:34

SODIM file number	08DY0160COHN10542020
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File Status	Accepted <input checked="" type="radio"/>
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Rejection / Error reason	
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Date of analysis DD/MMM/YYYY	08 SEP 2014
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Operator	Thierry Bachmann <input checked="" type="radio"/>
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Comment	
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Modified File Number	
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Product Use

Form: Topography files status for mCC (46)

Generated On: 20 Jul 2016 22:42:34

SODIM file number	08DY0160COHN10542021
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File Status	Accepted <input checked="" type="radio"/>
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Rejection / Error reason	
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Date of analysis DD/MMM/YYYY	08 SEP 2014
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Operator	Thierry Bachmann <input checked="" type="radio"/>
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Comment	
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Modified File Number	
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Product Use

Form: Topography files status for mCC (47)

Generated On: 20 Jul 2016 22:42:34

SODIM file number	08DY0160COHN10542022
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File Status	Accepted <input checked="" type="radio"/>
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Rejection / Error reason	<hr/>
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Date of analysis DD/MMM/YYYY	08 SEP 2014
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Operator	Thierry Bachmann <input checked="" type="radio"/>
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Comment	<hr/>
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Modified File Number	<hr/>
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Product Use

Form: Topography files status for mCC (48)


Generated On: 20 Jul 2016 22:42:34

SODIM file number	08DY0160COHN10542023
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File Status	Error 
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Rejection / Error reason	INVERSED PIPE
--------------------------	---------------

Date of analysis DD/MMM/YYYY	08 SEP 2014
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Operator	Thierry Bachmann 
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Comment	<hr/>
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Modified File Number	<hr/>
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Product Use

Form: Topography files status for mCC (49)

Generated On: 20 Jul 2016 22:42:34

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: 1261**

Folder: Product Use

Form: Topography files status for mCC (50)

Generated On: 20 Jul 2016 22:42:34

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: 1261**

Folder: Product Use

Form: Topography files status for mCC (51)

Generated On: 20 Jul 2016 22:42:34

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: 1261**

Folder: Product Use

Form: Topography files status for mCC (52)

Generated On: 20 Jul 2016 22:42:34

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: 1261**

Folder: Product Use

Form: Topography files status for mCC (53)

Generated On: 20 Jul 2016 22:42:34

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: 1261**

Folder: Product Use

Form: Topography files status for mCC (54)

Generated On: 20 Jul 2016 22:42:34

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: 1261**

Folder: Product Use

Form: Topography files status for mCC (55)

Generated On: 20 Jul 2016 22:42:34

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: 1261**

Folder: Product Use

Form: Topography files status for mCC (56)

Generated On: 20 Jul 2016 22:42:34

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: 1261**

Folder: Product Use

Form: Topography files status for mCC (57)

Generated On: 20 Jul 2016 22:42:34

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: 1261**

Folder: Product Use

Form: Topography files status for mCC (58)

Generated On: 20 Jul 2016 22:42:34

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: 1261**

Folder: Product Use

Form: Topography files status for mCC (59)

Generated On: 20 Jul 2016 22:42:34

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: 1261**

Folder: Product Use

Form: Topography files status for mCC (60)

Generated On: 20 Jul 2016 22:42:34

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: 1261**

Folder: Product Use

Form: Topography files status for mCC (61)

Generated On: 20 Jul 2016 22:42:34

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: 1261**

Folder: Product Use

Form: Topography files status for mCC (62)

Generated On: 20 Jul 2016 22:42:34

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: 1261**

Folder: Product Use

Form: Topography files status for mCC (63)

Generated On: 20 Jul 2016 22:42:34

SODIM file number	08DY0084COHN30209001
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File Status	Accepted 
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Rejection / Error reason	<hr/>
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Date of analysis DD/MMM/YYYY	08 SEP 2014
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Operator	Thierry Bachmann 
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Comment	<hr/>
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Modified File Number	<hr/>
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Product Use

Form: Topography files status for mCC (64)

Generated On: 20 Jul 2016 22:42:34

SODIM file number	08DY0084COHN30209002
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File Status	Accepted 
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Rejection / Error reason	<hr/>
--------------------------	-------

Date of analysis DD/MMM/YYYY	08 SEP 2014
---------------------------------	-------------

Operator	Thierry Bachmann 
----------	--

Comment	<hr/>
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Modified File Number	<hr/>
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Product Use

Form: Product use diary(Paper)

Data signed: (hfarmer1) 30 Mar 2015 12:29:02

Generated On: 20 Jul 2016 22:42:34

Was paper questionnaire used?

No ☒

Reason not done

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Product Use

Form: Product use diary(Paper) (1)

Data signed: (hfarmer1) 30 Mar 2015 12:29:02

Generated On: 20 Jul 2016 22:42:34

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: 1261**

Folder: Product Use

Form: Product use diary(Paper) (1)

Data signed: (hfarmer1) 30 Mar 2015 12:29:02

Generated On: 20 Jul 2016 22:42:34

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: 1261**

Folder: Adverse Events

Form: Adverse Events Y/N

Data signed: (hfarmer1) 30 Mar 2015 12:29:03

Generated On: 20 Jul 2016 22:42:34

Was there any Adverse Event for this subject?

Yes ☒

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1261

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (hfarmer1) 30 Mar 2015 12:29:03

Generated On: 20 Jul 2016 22:42:34

AE Identifier	1
---------------	---

Adverse Event	HEADACHE
---------------	----------

Start Date	12 APR 2014
------------	-------------

DD/MMM/YYYY

End Date	14 APR 2014
----------	-------------

DD/MMM/YYYY

Ongoing at final contact	No <input type="radio"/>
--------------------------	--------------------------

Severity	Mild Adverse Event <input type="radio"/>
----------	--

Serious AE	No <input type="radio"/>
------------	--------------------------

Seriousness Criteria

Treatment given	No <input type="radio"/>
-----------------	--------------------------

AE related to Study Procedure	Not Related <input type="radio"/>
-------------------------------	-----------------------------------

Relationship to mCC/THS	Not Related <input type="radio"/>
-------------------------	-----------------------------------

AE expectedness

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (hfarmer1) 30 Mar 2015 12:29:03

Generated On: 20 Jul 2016 22:42:34

Action taken with study product

None ☒

Other action taken

Outcome

Recovered or Resolved ☒

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1261

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (hfarmer1) 30 Mar 2015 12:29:03

Generated On: 20 Jul 2016 22:42:34

AE Identifier	2
---------------	---

Adverse Event	BLISTER OPEN ON LEFT CHEST WALL ANTERIOR
---------------	---

Start Date	12 MAY 2014
------------	-------------

DD/MMM/YYYY

End Date

DD/MMM/YYYY

Ongoing at final contact	Yes <input type="radio"/>
--------------------------	---------------------------

Severity	Mild Adverse Event <input type="radio"/>
----------	--

Serious AE	No <input type="radio"/>
------------	--------------------------

Seriousness Criteria

Treatment given	No <input type="radio"/>
-----------------	--------------------------

AE related to Study Procedure	Not Related <input type="radio"/>
-------------------------------	-----------------------------------

Relationship to mCC/THS	Not Related <input type="radio"/>
-------------------------	-----------------------------------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (hfarmer1) 30 Mar 2015 12:29:03

Generated On: 20 Jul 2016 22:42:34

AE expectedness

Action taken with study product

None ☐

Other action taken

Outcome

Unknown ☐

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1261

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (hfarmer1) 30 Mar 2015 12:29:03

Generated On: 20 Jul 2016 22:42:34

AE Identifier	3
---------------	---

Adverse Event	ELEVATED TRIGLYCERIDES
---------------	------------------------

Start Date	14 MAY 2014
------------	-------------

DD/MMM/YYYY

End Date

DD/MMM/YYYY

Ongoing at final contact	Yes <input type="radio"/>
--------------------------	---------------------------

Severity	Mild Adverse Event <input type="radio"/>
----------	--

Serious AE	No <input type="radio"/>
------------	--------------------------

Seriousness Criteria

Treatment given	No <input type="radio"/>
-----------------	--------------------------

AE related to Study Procedure	Not Related <input type="radio"/>
-------------------------------	-----------------------------------

Relationship to mCC/THS	Not Related <input type="radio"/>
-------------------------	-----------------------------------

AE expectedness

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (hfarmer1) 30 Mar 2015 12:29:03

Generated On: 20 Jul 2016 22:42:34

Action taken with study product

None ☒

Other action taken

Outcome

Unknown ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Folder: Previous and Concomitant Medication

Form: Previous and Concomitant Medication Y/N

Data signed: (hfarmer1) 30 Mar 2015 12:29:04

Generated On: 20 Jul 2016 22:42:34

Has the subject taken previous or concomitant
medication?

No ☒

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1261

Form: Product use diary (1)

Data signed: (hfarmer1) 30 Mar 2015 12:26:57

Generated On: 20 Jul 2016 22:42:34

Date of Birth	(b) (6)
Date of completion DD/MMM/YYYY	2014 APR 19
Time of completion hh:mm	19:20
Date the questionnaire was completed for DD/MMM/YYYY	2014 APR 19
Assessment Status	Completed <input checked="" type="radio"/>
What tobacco/nicotine product did you use today?	CC <input checked="" type="radio"/>
How many THS 2.2 tobacco sticks did you use today?	-9
How many CC/ roll-your-own did you smoke today?	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: 1261

Form: Product use diary (1)

Data signed: (hfarmer1) 30 Mar 2015 12:26:57

Generated On: 20 Jul 2016 22:42:34

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: 1261

Form: Product use diary (2)

Data signed: (hfarmer1) 30 Mar 2015 12:26:57

Generated On: 20 Jul 2016 22:42:34

Date of Birth	(b) (6)
Date of completion DD/MMM/YYYY	2014 APR 20
Time of completion hh:mm	19:15
Date the questionnaire was completed for DD/MMM/YYYY	2014 APR 20
Assessment Status	Completed <input checked="" type="radio"/>
What tobacco/nicotine product did you use today?	CC <input checked="" type="radio"/>
How many THS 2.2 tobacco sticks did you use today?	-9
How many CC/ roll-your-own did you smoke today?	15
What NRT product did you used today?	Not Applicable <input checked="" type="radio"/>
How many times did you use an inhaler today?	-9
How many times did you use a nasal spray today?	-9
How many gums did you use today?	-9
How many lozenges did you use today?	-9

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1261

Form: Product use diary (2)

Data signed: (hfarmer1) 30 Mar 2015 12:26:57

Generated On: 20 Jul 2016 22:42:34

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: 1261

Form: Product use diary (3)

Data signed: (hfarmer1) 30 Mar 2015 12:26:57

Generated On: 20 Jul 2016 22:42:34

Date of Birth	(b) (6)
Date of completion DD/MMM/YYYY	2014 APR 21
Time of completion hh:mm	18:04
Date the questionnaire was completed for DD/MMM/YYYY	2014 APR 21
Assessment Status	Completed <input checked="" type="radio"/>
What tobacco/nicotine product did you use today?	CC <input checked="" type="radio"/>
How many THS 2.2 tobacco sticks did you use today?	-9
How many CC/ roll-your-own did you smoke today?	15
What NRT product did you used today?	Not Applicable <input checked="" type="radio"/>
How many times did you use an inhaler today?	-9
How many times did you use a nasal spray today?	-9
How many gums did you use today?	-9
How many lozenges did you use today?	-9

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1261

Form: Product use diary (3)

Data signed: (hfarmer1) 30 Mar 2015 12:26:57

Generated On: 20 Jul 2016 22:42:34

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: 1261

Form: Product use diary (4)

Data signed: (hfarmer1) 30 Mar 2015 12:26:57

Generated On: 20 Jul 2016 22:42:34

Date of Birth

(b) (6)

Date of completion
DD/MMM/YYYY

2014 APR 22

Time of completion
hh:mm

19:15

Date the questionnaire was completed for
DD/MMM/YYYY

2014 APR 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?

23

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: 1261

Form: Product use diary (4)

Data signed: (hfarmer1) 30 Mar 2015 12:26:57

Generated On: 20 Jul 2016 22:42:34

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: 1261

Form: Product use diary (5)

Data signed: (hfarmer1) 30 Mar 2015 12:26:57

Generated On: 20 Jul 2016 22:42:34

Date of Birth	(b) (6)
Date of completion DD/MMM/YYYY	2014 APR 23
Time of completion hh:mm	20:03
Date the questionnaire was completed for DD/MMM/YYYY	2014 APR 23
Assessment Status	Completed <input checked="" type="radio"/>
What tobacco/nicotine product did you use today?	CC <input checked="" type="radio"/>
How many THS 2.2 tobacco sticks did you use today?	-9
How many CC/ roll-your-own did you smoke today?	20
What NRT product did you used today?	Not Applicable <input checked="" type="radio"/>
How many times did you use an inhaler today?	-9
How many times did you use a nasal spray today?	-9
How many gums did you use today?	-9
How many lozenges did you use today?	-9

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1261

Form: Product use diary (5)

Data signed: (hfarmer1) 30 Mar 2015 12:26:57

Generated On: 20 Jul 2016 22:42:34

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: 1261

Form: Product use diary (6)

Data signed: (hfarmer1) 30 Mar 2015 12:26:57

Generated On: 20 Jul 2016 22:42:34

Date of Birth

(b) (6)

Date of completion
DD/MMM/YYYY

2014 APR 24

Time of completion
hh:mm

19:38

Date the questionnaire was completed for
DD/MMM/YYYY

2014 APR 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?

23

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: 1261

Form: Product use diary (6)

Data signed: (hfarmer1) 30 Mar 2015 12:26:57

Generated On: 20 Jul 2016 22:42:34

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: 1261

Form: Product use diary (7)

Data signed: (hfarmer1) 30 Mar 2015 12:26:57

Generated On: 20 Jul 2016 22:42:34

Date of Birth	(b) (6)
Date of completion DD/MMM/YYYY	2014 APR 25
Time of completion hh:mm	19:03
Date the questionnaire was completed for DD/MMM/YYYY	2014 APR 25
Assessment Status	Completed <input checked="" type="radio"/>
What tobacco/nicotine product did you use today?	CC <input checked="" type="radio"/>
How many THS 2.2 tobacco sticks did you use today?	-9
How many CC/ roll-your-own did you smoke today?	24
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: 1261

Form: Product use diary (7)

Data signed: (hfarmer1) 30 Mar 2015 12:26:57

Generated On: 20 Jul 2016 22:42:34

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: 1261

Form: Product use diary (8)

Data signed: (hfarmer1) 30 Mar 2015 12:26:57

Generated On: 20 Jul 2016 22:42:34

Date of Birth	(b) (6)
Date of completion DD/MMM/YYYY	2014 APR 27
Time of completion hh:mm	11:56
Date the questionnaire was completed for DD/MMM/YYYY	2014 APR 26
Assessment Status	Completed <input checked="" type="radio"/>
What tobacco/nicotine product did you use today?	CC <input checked="" type="radio"/>
How many THS 2.2 tobacco sticks did you use today?	-9
How many CC/ roll-your-own did you smoke today?	22
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: 1261

Form: Product use diary (8)

Data signed: (hfarmer1) 30 Mar 2015 12:26:57

Generated On: 20 Jul 2016 22:42:34

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: 1261

Form: Product use diary (9)

Data signed: (hfarmer1) 30 Mar 2015 12:26:57

Generated On: 20 Jul 2016 22:42:34

Date of Birth	(b) (6)
Date of completion DD/MMM/YYYY	2014 APR 27
Time of completion hh:mm	18:14
Date the questionnaire was completed for DD/MMM/YYYY	2014 APR 27
Assessment Status	Completed <input checked="" type="radio"/>
What tobacco/nicotine product did you use today?	CC <input checked="" type="radio"/>
How many THS 2.2 tobacco sticks did you use today?	-9
How many CC/ roll-your-own did you smoke today?	15
What NRT product did you used today?	Not Applicable <input checked="" type="radio"/>
How many times did you use an inhaler today?	-9
How many times did you use a nasal spray today?	-9
How many gums did you use today?	-9
How many lozenges did you use today?	-9

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1261

Form: Product use diary (9)

Data signed: (hfarmer1) 30 Mar 2015 12:26:57

Generated On: 20 Jul 2016 22:42:34

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: 1261

Form: Product use diary (10)

Data signed: (hfarmer1) 30 Mar 2015 12:26:57

Generated On: 20 Jul 2016 22:42:34

Date of Birth	(b) (6)
Date of completion DD/MMM/YYYY	2014 APR 28
Time of completion hh:mm	19:50
Date the questionnaire was completed for DD/MMM/YYYY	2014 APR 28
Assessment Status	Completed <input checked="" type="radio"/>
What tobacco/nicotine product did you use today?	CC <input checked="" type="radio"/>
How many THS 2.2 tobacco sticks did you use today?	-9
How many CC/ roll-your-own did you smoke today?	22
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: 1261

Form: Product use diary (10)

Data signed: (hfarmer1) 30 Mar 2015 12:26:57

Generated On: 20 Jul 2016 22:42:34

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: 1261

Form: Product use diary (11)

Data signed: (hfarmer1) 30 Mar 2015 12:26:57

Generated On: 20 Jul 2016 22:42:34

Date of Birth

(b) (6)

Date of completion
DD/MMM/YYYY

2014 APR 29

Time of completion
hh:mm

21:01

Date the questionnaire was completed for
DD/MMM/YYYY

2014 APR 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?

23

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: 1261

Form: Product use diary (11)

Data signed: (hfarmer1) 30 Mar 2015 12:26:57

Generated On: 20 Jul 2016 22:42:34

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: 1261

Form: Product use diary (12)

Data signed: (hfarmer1) 30 Mar 2015 12:26:57

Generated On: 20 Jul 2016 22:42:34

Date of Birth

(b) (6)

Date of completion
DD/MMM/YYYY

2014 APR 30

Time of completion
hh:mm

18:51

Date the questionnaire was completed for
DD/MMM/YYYY

2014 APR 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?

22

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: 1261

Form: Product use diary (12)

Data signed: (hfarmer1) 30 Mar 2015 12:26:57

Generated On: 20 Jul 2016 22:42:34

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: 1261

Form: Product use diary (13)

Data signed: (hfarmer1) 30 Mar 2015 12:26:57

Generated On: 20 Jul 2016 22:42:34

Date of Birth

(b) (6)

Date of completion
DD/MMM/YYYY

2014 MAY 01

Time of completion
hh:mm

19:09

Date the questionnaire was completed for
DD/MMM/YYYY

2014 MAY 01

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?

22

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: 1261

Form: Product use diary (13)

Data signed: (hfarmer1) 30 Mar 2015 12:26:57

Generated On: 20 Jul 2016 22:42:34

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: 1261

Form: Product use diary (14)

Data signed: (hfarmer1) 30 Mar 2015 12:26:57

Generated On: 20 Jul 2016 22:42:34

Date of Birth

(b) (6)

Date of completion
DD/MMM/YYYY

2014 MAY 02

Time of completion
hh:mm

20:00

Date the questionnaire was completed for
DD/MMM/YYYY

2014 MAY 02

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?

36

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: 1261

Form: Product use diary (14)

Data signed: (hfarmer1) 30 Mar 2015 12:26:57

Generated On: 20 Jul 2016 22:42:34

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: 1261

Form: Product use diary (15)

Data signed: (hfarmer1) 30 Mar 2015 12:26:57

Generated On: 20 Jul 2016 22:42:34

Date of Birth

(b) (6)

Date of completion
DD/MMM/YYYY

2014 MAY 03

Time of completion
hh:mm

19:21

Date the questionnaire was completed for
DD/MMM/YYYY

2014 MAY 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?

22

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: 1261

Form: Product use diary (15)

Data signed: (hfarmer1) 30 Mar 2015 12:26:57

Generated On: 20 Jul 2016 22:42:34

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: 1261

Form: Product use diary (16)

Data signed: (hfarmer1) 30 Mar 2015 12:26:57

Generated On: 20 Jul 2016 22:42:34

Date of Birth	(b) (6)
Date of completion DD/MMM/YYYY	2014 MAY 04
Time of completion hh:mm	20:00
Date the questionnaire was completed for DD/MMM/YYYY	2014 MAY 04
Assessment Status	Completed <input checked="" type="radio"/>
What tobacco/nicotine product did you use today?	CC <input checked="" type="radio"/>
How many THS 2.2 tobacco sticks did you use today?	-9
How many CC/ roll-your-own did you smoke today?	23
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: 1261

Form: Product use diary (16)

Data signed: (hfarmer1) 30 Mar 2015 12:26:57

Generated On: 20 Jul 2016 22:42:34

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: 1261

Form: Product use diary (17)

Data signed: (hfarmer1) 30 Mar 2015 12:26:57

Generated On: 20 Jul 2016 22:42:34

Date of Birth

(b) (6)

Date of completion
DD/MMM/YYYY

2014 MAY 05

Time of completion
hh:mm

20:00

Date the questionnaire was completed for
DD/MMM/YYYY

2014 MAY 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?

16

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: 1261

Form: Product use diary (17)

Data signed: (hfarmer1) 30 Mar 2015 12:26:57

Generated On: 20 Jul 2016 22:42:34

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: 1261

Form: Product use diary (18)

Data signed: (hfarmer1) 30 Mar 2015 12:26:57

Generated On: 20 Jul 2016 22:42:34

Date of Birth	(b) (6)
Date of completion DD/MMM/YYYY	2014 MAY 06
Time of completion hh:mm	20:12
Date the questionnaire was completed for DD/MMM/YYYY	2014 MAY 06
Assessment Status	Completed <input checked="" type="radio"/>
What tobacco/nicotine product did you use today?	CC <input checked="" type="radio"/>
How many THS 2.2 tobacco sticks did you use today?	-9
How many CC/ roll-your-own did you smoke today?	25
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: 1261

Form: Product use diary (18)

Data signed: (hfarmer1) 30 Mar 2015 12:26:57

Generated On: 20 Jul 2016 22:42:34

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: 1261**

Form: Product use diary (19)

Data signed: (hfarmer1) 30 Mar 2015 12:26:57

Generated On: 20 Jul 2016 22:42:34

Date of Birth	(b) (6)
Date of completion DD/MMM/YYYY	2014 MAY 07
Time of completion hh:mm	20:01
Date the questionnaire was completed for DD/MMM/YYYY	2014 MAY 07
Assessment Status	Completed <input checked="" type="radio"/>
What tobacco/nicotine product did you use today?	CC <input checked="" type="radio"/>
How many THS 2.2 tobacco sticks did you use today?	-9
How many CC/ roll-your-own did you smoke today?	23
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: 1261

Form: Product use diary (19)

Data signed: (hfarmer1) 30 Mar 2015 12:26:57

Generated On: 20 Jul 2016 22:42:34

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: 1261

Form: Product use diary (21)

Data signed: (hfarmer1) 30 Mar 2015 12:26:57

Generated On: 20 Jul 2016 22:42:34

Date of Birth

(b) (6)

Date of completion
DD/MMM/YYYY

2014 MAY 08

Time of completion
hh:mm

20:01

Date the questionnaire was completed for
DD/MMM/YYYY

2014 MAY 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?

16

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: 1261

Form: Product use diary (21)

Data signed: (hfarmer1) 30 Mar 2015 12:26:57

Generated On: 20 Jul 2016 22:42:34

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: 1261

Form: Product use diary (22)

Data signed: (hfarmer1) 30 Mar 2015 12:26:57

Generated On: 20 Jul 2016 22:42:34

Date of Birth	(b) (6)
Date of completion DD/MMM/YYYY	2014 MAY 09
Time of completion hh:mm	19:07
Date the questionnaire was completed for DD/MMM/YYYY	2014 MAY 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?	21
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: 1261

Form: Product use diary (22)

Data signed: (hfarmer1) 30 Mar 2015 12:26:57

Generated On: 20 Jul 2016 22:42:34

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: 1261

Form: Product use diary (23)

Data signed: (hfarmer1) 30 Mar 2015 12:26:57

Generated On: 20 Jul 2016 22:42:34

Date of Birth	(b) (6)
Date of completion DD/MMM/YYYY	2014 MAY 10
Time of completion hh:mm	19:53
Date the questionnaire was completed for DD/MMM/YYYY	2014 MAY 10
Assessment Status	Completed <input checked="" type="radio"/>
What tobacco/nicotine product did you use today?	CC <input checked="" type="radio"/>
How many THS 2.2 tobacco sticks did you use today?	-9
How many CC/ roll-your-own did you smoke today?	19
What NRT product did you used today?	Not Applicable <input checked="" type="radio"/>
How many times did you use an inhaler today?	-9
How many times did you use a nasal spray today?	-9
How many gums did you use today?	-9
How many lozenges did you use today?	-9

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1261

Form: Product use diary (23)

Data signed: (hfarmer1) 30 Mar 2015 12:26:57

Generated On: 20 Jul 2016 22:42:34

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: 1261

Form: Product use diary (24)

Data signed: (hfarmer1) 30 Mar 2015 12:26:57

Generated On: 20 Jul 2016 22:42:34

Date of Birth	(b) (6)
Date of completion DD/MMM/YYYY	2014 MAY 11
Time of completion hh:mm	19:35
Date the questionnaire was completed for DD/MMM/YYYY	2014 MAY 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?	28
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: 1261

Form: Product use diary (24)

Data signed: (hfarmer1) 30 Mar 2015 12:26:57

Generated On: 20 Jul 2016 22:42:34

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: 1261

Form: Product use diary (25)

Data signed: (hfarmer1) 30 Mar 2015 12:26:57

Generated On: 20 Jul 2016 22:42:34

Date of Birth	(b) (6)
Date of completion DD/MMM/YYYY	2014 MAY 12
Time of completion hh:mm	20:00
Date the questionnaire was completed for DD/MMM/YYYY	2014 MAY 12
Assessment Status	Completed <input checked="" type="radio"/>
What tobacco/nicotine product did you use today?	CC <input checked="" type="radio"/>
How many THS 2.2 tobacco sticks did you use today?	-9
How many CC/ roll-your-own did you smoke today?	19
What NRT product did you used today?	Not Applicable <input checked="" type="radio"/>
How many times did you use an inhaler today?	-9
How many times did you use a nasal spray today?	-9
How many gums did you use today?	-9
How many lozenges did you use today?	-9

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1261

Form: Product use diary (25)

Data signed: (hfarmer1) 30 Mar 2015 12:26:57

Generated On: 20 Jul 2016 22:42:34

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: 1261

Form: Product use diary (26)

Data signed: (hfarmer1) 30 Mar 2015 12:26:57

Generated On: 20 Jul 2016 22:42:34

Date of Birth

(b) (6)

Date of completion
DD/MMM/YYYY

2014 MAY 13

Time of completion
hh:mm

20:00

Date the questionnaire was completed for
DD/MMM/YYYY

2014 MAY 13

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: 1261

Form: Product use diary (26)

Data signed: (hfarmer1) 30 Mar 2015 12:26:57

Generated On: 20 Jul 2016 22:42:34

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: 1261

Form: Product use diary (27)

Data signed: (hfarmer1) 30 Mar 2015 12:26:57

Generated On: 20 Jul 2016 22:42:34

Date of Birth	(b) (6)
Date of completion DD/MMM/YYYY	2014 MAY 14
Time of completion hh:mm	20:02
Date the questionnaire was completed for DD/MMM/YYYY	2014 MAY 14
Assessment Status	Completed <input checked="" type="radio"/>
What tobacco/nicotine product did you use today?	CC <input checked="" type="radio"/>
How many THS 2.2 tobacco sticks did you use today?	-9
How many CC/ roll-your-own did you smoke today?	16
What NRT product did you used today?	Not Applicable <input checked="" type="radio"/>
How many times did you use an inhaler today?	-9
How many times did you use a nasal spray today?	-9
How many gums did you use today?	-9
How many lozenges did you use today?	-9

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1261

Form: Product use diary (27)

Data signed: (hfarmer1) 30 Mar 2015 12:26:57

Generated On: 20 Jul 2016 22:42:34

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: 1261**

Form: Product use diary (28)

Data signed: (hfarmer1) 30 Mar 2015 12:26:57

Generated On: 20 Jul 2016 22:42:34

Date of Birth	(b) (6)
Date of completion DD/MMM/YYYY	2014 MAY 15
Time of completion hh:mm	19:06
Date the questionnaire was completed for DD/MMM/YYYY	2014 MAY 15
Assessment Status	Completed <input checked="" type="radio"/>
What tobacco/nicotine product did you use today?	CC <input checked="" type="radio"/>
How many THS 2.2 tobacco sticks did you use today?	-9
How many CC/ roll-your-own did you smoke today?	16
What NRT product did you used today?	Not Applicable <input checked="" type="radio"/>
How many times did you use an inhaler today?	-9
How many times did you use a nasal spray today?	-9
How many gums did you use today?	-9
How many lozenges did you use today?	-9

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1261

Form: Product use diary (28)

Data signed: (hfarmer1) 30 Mar 2015 12:26:57

Generated On: 20 Jul 2016 22:42:34

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: 1261

Form: Product use diary (29)

Data signed: (hfarmer1) 30 Mar 2015 12:26:57

Generated On: 20 Jul 2016 22:42:34

Date of Birth	(b) (6)
Date of completion DD/MMM/YYYY	2014 MAY 16
Time of completion hh:mm	20:10
Date the questionnaire was completed for DD/MMM/YYYY	2014 MAY 16
Assessment Status	Completed <input checked="" type="radio"/>
What tobacco/nicotine product did you use today?	CC <input checked="" type="radio"/>
How many THS 2.2 tobacco sticks did you use today?	-9
How many CC/ roll-your-own did you smoke today?	20
What NRT product did you used today?	Not Applicable <input checked="" type="radio"/>
How many times did you use an inhaler today?	-9
How many times did you use a nasal spray today?	-9
How many gums did you use today?	-9
How many lozenges did you use today?	-9

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1261

Form: Product use diary (29)

Data signed: (hfarmer1) 30 Mar 2015 12:26:57

Generated On: 20 Jul 2016 22:42:34

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: 1261

Form: Product use diary (30)

Data signed: (hfarmer1) 30 Mar 2015 12:26:57

Generated On: 20 Jul 2016 22:42:34

Date of Birth	(b) (6)
Date of completion DD/MMM/YYYY	2014 MAY 17
Time of completion hh:mm	20:01
Date the questionnaire was completed for DD/MMM/YYYY	2014 MAY 17
Assessment Status	Completed <input checked="" type="radio"/>
What tobacco/nicotine product did you use today?	CC <input checked="" type="radio"/>
How many THS 2.2 tobacco sticks did you use today?	-9
How many CC/ roll-your-own did you smoke today?	20
What NRT product did you used today?	Not Applicable <input checked="" type="radio"/>
How many times did you use an inhaler today?	-9
How many times did you use a nasal spray today?	-9
How many gums did you use today?	-9
How many lozenges did you use today?	-9

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1261

Form: Product use diary (30)

Data signed: (hfarmer1) 30 Mar 2015 12:26:57

Generated On: 20 Jul 2016 22:42:34

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: 1261

Form: Product use diary (31)

Data signed: (hfarmer1) 30 Mar 2015 12:26:57

Generated On: 20 Jul 2016 22:42:34

Date of Birth	(b) (6)
Date of completion DD/MMM/YYYY	2014 MAY 18
Time of completion hh:mm	21:01
Date the questionnaire was completed for DD/MMM/YYYY	2014 MAY 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?	16
What NRT product did you used today?	Not Applicable <input checked="" type="radio"/>
How many times did you use an inhaler today?	-9
How many times did you use a nasal spray today?	-9
How many gums did you use today?	-9
How many lozenges did you use today?	-9

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1261

Form: Product use diary (31)

Data signed: (hfarmer1) 30 Mar 2015 12:26:57

Generated On: 20 Jul 2016 22:42:34

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: 1261

Form: Product use diary (32)

Data signed: (hfarmer1) 30 Mar 2015 12:26:57

Generated On: 20 Jul 2016 22:42:34

Date of Birth	(b) (6)
Date of completion DD/MMM/YYYY	2014 MAY 19
Time of completion hh:mm	22:01
Date the questionnaire was completed for DD/MMM/YYYY	2014 MAY 19
Assessment Status	Completed <input checked="" type="radio"/>
What tobacco/nicotine product did you use today?	CC <input checked="" type="radio"/>
How many THS 2.2 tobacco sticks did you use today?	-9
How many CC/ roll-your-own did you smoke today?	17
What NRT product did you used today?	Not Applicable <input checked="" type="radio"/>
How many times did you use an inhaler today?	-9
How many times did you use a nasal spray today?	-9
How many gums did you use today?	-9
How many lozenges did you use today?	-9

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1261

Form: Product use diary (32)

Data signed: (hfarmer1) 30 Mar 2015 12:26:57

Generated On: 20 Jul 2016 22:42:34

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: 1261

Form: Product use diary (33)

Data signed: (hfarmer1) 30 Mar 2015 12:26:57

Generated On: 20 Jul 2016 22:42:34

Date of Birth	(b) (6)
Date of completion DD/MMM/YYYY	2014 MAY 20
Time of completion hh:mm	20:01
Date the questionnaire was completed for DD/MMM/YYYY	2014 MAY 20
Assessment Status	Completed <input checked="" type="radio"/>
What tobacco/nicotine product did you use today?	CC <input checked="" type="radio"/>
How many THS 2.2 tobacco sticks did you use today?	-9
How many CC/ roll-your-own did you smoke today?	17
What NRT product did you used today?	Not Applicable <input checked="" type="radio"/>
How many times did you use an inhaler today?	-9
How many times did you use a nasal spray today?	-9
How many gums did you use today?	-9
How many lozenges did you use today?	-9

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1261

Form: Product use diary (33)

Data signed: (hfarmer1) 30 Mar 2015 12:26:57

Generated On: 20 Jul 2016 22:42:34

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: 1261

Form: Product use diary (34)

Data signed: (hfarmer1) 30 Mar 2015 12:26:57

Generated On: 20 Jul 2016 22:42:34

Date of Birth	(b) (6)
Date of completion DD/MMM/YYYY	2014 MAY 21
Time of completion hh:mm	20:01
Date the questionnaire was completed for DD/MMM/YYYY	2014 MAY 21
Assessment Status	Completed <input checked="" type="radio"/>
What tobacco/nicotine product did you use today?	CC <input checked="" type="radio"/>
How many THS 2.2 tobacco sticks did you use today?	-9
How many CC/ roll-your-own did you smoke today?	19
What NRT product did you used today?	Not Applicable <input checked="" type="radio"/>
How many times did you use an inhaler today?	-9
How many times did you use a nasal spray today?	-9
How many gums did you use today?	-9
How many lozenges did you use today?	-9

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1261

Form: Product use diary (34)

Data signed: (hfarmer1) 30 Mar 2015 12:26:57

Generated On: 20 Jul 2016 22:42:34

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: 1261

Form: Product use diary (35)

Data signed: (hfarmer1) 30 Mar 2015 12:26:57

Generated On: 20 Jul 2016 22:42:34

Date of Birth	(b) (6)
Date of completion DD/MMM/YYYY	2014 MAY 23
Time of completion hh:mm	20:12
Date the questionnaire was completed for DD/MMM/YYYY	2014 MAY 23
Assessment Status	Completed <input checked="" type="radio"/>
What tobacco/nicotine product did you use today?	CC <input checked="" type="radio"/>
How many THS 2.2 tobacco sticks did you use today?	-9
How many CC/ roll-your-own did you smoke today?	20
What NRT product did you used today?	Not Applicable <input checked="" type="radio"/>
How many times did you use an inhaler today?	-9
How many times did you use a nasal spray today?	-9
How many gums did you use today?	-9
How many lozenges did you use today?	-9

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1261

Form: Product use diary (35)

Data signed: (hfarmer1) 30 Mar 2015 12:26:57

Generated On: 20 Jul 2016 22:42:34

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: 1261

Form: Product use diary (36)

Data signed: (hfarmer1) 30 Mar 2015 12:26:57

Generated On: 20 Jul 2016 22:42:34

Date of Birth	(b) (6)
Date of completion DD/MMM/YYYY	2014 MAY 25
Time of completion hh:mm	11:42
Date the questionnaire was completed for DD/MMM/YYYY	2014 MAY 24
Assessment Status	Completed <input checked="" type="radio"/>
What tobacco/nicotine product did you use today?	CC <input checked="" type="radio"/>
How many THS 2.2 tobacco sticks did you use today?	-9
How many CC/ roll-your-own did you smoke today?	42
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: 1261

Form: Product use diary (36)

Data signed: (hfarmer1) 30 Mar 2015 12:26:57

Generated On: 20 Jul 2016 22:42:34

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: 1261

Form: Product use diary (37)

Data signed: (hfarmer1) 30 Mar 2015 12:26:57

Generated On: 20 Jul 2016 22:42:34

Date of Birth	(b) (6)
Date of completion DD/MMM/YYYY	2014 MAY 25
Time of completion hh:mm	20:01
Date the questionnaire was completed for DD/MMM/YYYY	2014 MAY 25
Assessment Status	Completed <input checked="" type="radio"/>
What tobacco/nicotine product did you use today?	CC <input checked="" type="radio"/>
How many THS 2.2 tobacco sticks did you use today?	-9
How many CC/ roll-your-own did you smoke today?	33
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: 1261

Form: Product use diary (37)

Data signed: (hfarmer1) 30 Mar 2015 12:26:57

Generated On: 20 Jul 2016 22:42:34

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: 1261

Form: Product use diary (38)

Data signed: (hfarmer1) 30 Mar 2015 12:26:57

Generated On: 20 Jul 2016 22:42:34

Date of Birth	(b) (6)
Date of completion DD/MMM/YYYY	2014 MAY 26
Time of completion hh:mm	20:01
Date the questionnaire was completed for DD/MMM/YYYY	2014 MAY 26
Assessment Status	Completed <input checked="" type="radio"/>
What tobacco/nicotine product did you use today?	CC <input checked="" type="radio"/>
How many THS 2.2 tobacco sticks did you use today?	-9
How many CC/ roll-your-own did you smoke today?	31
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: 1261

Form: Product use diary (38)

Data signed: (hfarmer1) 30 Mar 2015 12:26:57

Generated On: 20 Jul 2016 22:42:34

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: 1261

Form: Product use diary (39)

Data signed: (hfarmer1) 30 Mar 2015 12:26:57

Generated On: 20 Jul 2016 22:42:34

Date of Birth

(b) (6)

Date of completion
DD/MMM/YYYY

2014 MAY 28

Time of completion
hh:mm

08:41

Date the questionnaire was completed for
DD/MMM/YYYY

2014 MAY 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?

23

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: 1261

Form: Product use diary (39)

Data signed: (hfarmer1) 30 Mar 2015 12:26:57

Generated On: 20 Jul 2016 22:42:34

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: 1261

Form: Product use diary (40)

Data signed: (hfarmer1) 30 Mar 2015 12:26:57

Generated On: 20 Jul 2016 22:42:34

Date of Birth	(b) (6)
Date of completion DD/MMM/YYYY	2014 MAY 28
Time of completion hh:mm	21:02
Date the questionnaire was completed for DD/MMM/YYYY	2014 MAY 28
Assessment Status	Completed <input checked="" type="radio"/>
What tobacco/nicotine product did you use today?	CC <input checked="" type="radio"/>
How many THS 2.2 tobacco sticks did you use today?	-9
How many CC/ roll-your-own did you smoke today?	25
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: 1261

Form: Product use diary (40)

Data signed: (hfarmer1) 30 Mar 2015 12:26:57

Generated On: 20 Jul 2016 22:42:34

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: 1261

Form: Product use diary (41)

Data signed: (hfarmer1) 30 Mar 2015 12:26:57

Generated On: 20 Jul 2016 22:42:34

Date of Birth

(b) (6)

Date of completion
DD/MMM/YYYY

2014 MAY 29

Time of completion
hh:mm

22:08

Date the questionnaire was completed for
DD/MMM/YYYY

2014 MAY 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?

26

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: 1261

Form: Product use diary (41)

Data signed: (hfarmer1) 30 Mar 2015 12:26:57

Generated On: 20 Jul 2016 22:42:34

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: 1261

Form: Product use diary (42)

Data signed: (hfarmer1) 30 Mar 2015 12:26:57

Generated On: 20 Jul 2016 22:42:34

Date of Birth	(b) (6)
Date of completion DD/MMM/YYYY	2014 MAY 30
Time of completion hh:mm	21:32
Date the questionnaire was completed for DD/MMM/YYYY	2014 MAY 30
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?	30
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: 1261

Form: Product use diary (42)

Data signed: (hfarmer1) 30 Mar 2015 12:26:57

Generated On: 20 Jul 2016 22:42:34

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: 1261

Form: Product use diary (43)

Data signed: (hfarmer1) 30 Mar 2015 12:26:57

Generated On: 20 Jul 2016 22:42:34

Date of Birth	(b) (6)
Date of completion DD/MMM/YYYY	2014 MAY 31
Time of completion hh:mm	21:01
Date the questionnaire was completed for DD/MMM/YYYY	2014 MAY 31
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?	23
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: 1261

Form: Product use diary (43)

Data signed: (hfarmer1) 30 Mar 2015 12:26:57

Generated On: 20 Jul 2016 22:42:34

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: 1261**

Form: Product use diary (44)

Data signed: (hfarmer1) 30 Mar 2015 12:26:57

Generated On: 20 Jul 2016 22:42:34

Date of Birth	(b) (6)
Date of completion DD/MMM/YYYY	2014 JUN 01
Time of completion hh:mm	20:01
Date the questionnaire was completed for DD/MMM/YYYY	2014 JUN 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?	22
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: 1261

Form: Product use diary (44)

Data signed: (hfarmer1) 30 Mar 2015 12:26:57

Generated On: 20 Jul 2016 22:42:34

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: 1261**

Form: End of study

Data signed: (hfarmer1) 30 Mar 2015 12:26:56

Generated On: 20 Jul 2016 22:42:34

End of study date

02 JUL 2014
DD/MMM/YYYY

Has the subject completed the study ?

No ☒

If No, please specify the reason:

Withdrawal by Subject ☒

Details:

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Form: Consent Withdrawal

Data signed: (hfarmer1) 30 Mar 2015 12:26:57

Generated On: 20 Jul 2016 22:42:34

Did the subject withdraw it's consent to the biobanking
for BoExp and risk markers?

No ☒

Date of withdrawal of consent for biobanking for BoEXP
and risk markers

Did the subject withdraw it's consent to the
transcriptomics analysis?

No ☒

Date of withdrawal of consent for transcriptomics
analysis

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1261**

Form: Withdrawal

Data signed: (hfarmer1) 30 Mar 2015 12:27:10

Generated On: 20 Jul 2016 22:42:34

Date of withdrawal	04 JUN 2014 DD/MMM/YYYY
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Did the subject withdraw it's consent from the main study?	Yes <input type="radio"/>
--	---------------------------

If available, please provide details	THE SUBJECTS DECISION TO WITHDRAW CONSENT
--------------------------------------	--

Did the subject withdraw from the Protected Health Information (PHI)?	No <input type="radio"/>
---	--------------------------

Did the subject confirm that samples collected up to the time of withdrawal can be analysed?	Yes <input type="radio"/>
--	---------------------------
