

Subject Case Report Forms

1002 (Prod: Covance Clinical Development Services, Daytona Beach, Florida)

Generated On: 20 Jul 2016 10:56:43

All time stamps listed in this document are displayed in GMT

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Form: Subject

Data signed: (hfarmer1) 26 Mar 2015 13:37:06

Generated On: 20 Jul 2016 10:56:43

Screening number	1002
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Site number	DAY
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Subject Status

Form: Subject Status

Data signed: (hfarmer1) 26 Mar 2015 13:37:44

Generated On: 20 Jul 2016 10:56:43

Date of 'Screen Failed' Event

Date of 'Discontinued From
Enrollment' Event

Randomization Date

16 JAN 2014
DD/MMM/YYYY

Randomization Time

11:21
hour:min 24-hour clock

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Screening

Form: Date of Visit

Data signed: (hfarmer1) 26 Mar 2015 13:37:51

Generated On: 20 Jul 2016 10:56:43

Date of Visit

17 DEC 2013
DD/MMM/YYYY

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Screening

Form: Additional Informed Consent

Data signed: (hfarmer1) 26 Mar 2015 13:37:45

Generated On: 20 Jul 2016 10:56:43

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

Yes ☒

Consent Date

17 DEC 2013
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

17 DEC 2013
DD/MMM/YYYY

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Screening

Form: Inclusion Criteria

Data signed: (hfarmer1) 26 Mar 2015 13:37:46

Generated On: 20 Jul 2016 10:56:43

*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: 1002**

Folder: Screening

Form: Inclusion Criteria (1)

Data signed: (hfarmer1) 26 Mar 2015 13:37:46

Generated On: 20 Jul 2016 10:56:43

Inclusion Criterion Number	1
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Inclusion Criterion	Subject has signed the ICF and is able to understand the information provided in the Subject Information Sheet and ICF.
---------------------	---

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Screening

Form: Inclusion Criteria (2)

Data signed: (hfarmer1) 26 Mar 2015 13:37:46

Generated On: 20 Jul 2016 10:56:43

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

*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: 1002**

Folder: Screening

Form: Inclusion Criteria (3)

Data signed: (hfarmer1) 26 Mar 2015 13:37:46

Generated On: 20 Jul 2016 10:56:43

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: 1002

Folder: Screening

Form: Inclusion Criteria (4)

Data signed: (hfarmer1) 26 Mar 2015 13:37:46

Generated On: 20 Jul 2016 10:56:43

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

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Screening

Form: Inclusion Criteria (5)

Data signed: (hfarmer1) 26 Mar 2015 13:37:46

Generated On: 20 Jul 2016 10:56:43

Inclusion Criterion Number	5
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Inclusion Criterion	The subject does not plan to quit smoking within the next 6 months as assessed by the Prochaska 'Stage of Change' questionnaire.
---------------------	--

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Screening

Form: Inclusion Criteria (6)

Data signed: (hfarmer1) 26 Mar 2015 13:37:46

Generated On: 20 Jul 2016 10:56:43

Inclusion Criterion Number	6
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Inclusion Criterion	The subject is ready to comply with study protocol (e.g readiness to accept interruptions of smoking for up to 91 days and to use THS 2.2 Menthol).
---------------------	---

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Screening

Form: Exclusion Criteria

Data signed: (hfarmer1) 26 Mar 2015 13:37:45

Generated On: 20 Jul 2016 10:56:43

*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: 1002**

Folder: Screening

Form: Exclusion Criteria (1)

Data signed: (hfarmer1) 26 Mar 2015 13:37:45

Generated On: 20 Jul 2016 10:56:43

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: 1002

Folder: Screening

Form: Exclusion Criteria (2)

Data signed: (hfarmer1) 26 Mar 2015 13:37:45

Generated On: 20 Jul 2016 10:56:43

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: 1002

Folder: Screening

Form: Exclusion Criteria (3)

Data signed: (hfarmer1) 26 Mar 2015 13:37:45

Generated On: 20 Jul 2016 10:56:43

Exclusion Criterion Number	3
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Exclusion Criterion	The subject has clinically relevant diseases which required medications (including but not limited to gastrointestinal, renal, hepatic, neurological, hematological, endocrine, oncological, urological, immunological, pulmonary, and cardiovascular disease or any other medical condition (including safety laboratory as per CTCAE), which in the opinion of the Investigator would jeopardize the safety of the subject.
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Result	No <input checked="" type="radio"/>
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*If any has been answered Yes, subject must not be included in the study.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Screening

Form: Exclusion Criteria (4)

Data signed: (hfarmer1) 26 Mar 2015 13:37:45

Generated On: 20 Jul 2016 10:56:43

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

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

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1002

Folder: Screening

Form: Exclusion Criteria (5)

Data signed: (hfarmer1) 26 Mar 2015 13:37:45

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Screening

Form: Exclusion Criteria (6)

Data signed: (hfarmer1) 26 Mar 2015 13:37:45

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Screening

Form: Exclusion Criteria (7)

Data signed: (hfarmer1) 26 Mar 2015 13:37:45

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Screening

Form: Exclusion Criteria (8)

Data signed: (hfarmer1) 26 Mar 2015 13:37:45

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Screening

Form: Exclusion Criteria (9)

Data signed: (hfarmer1) 26 Mar 2015 13:37:45

Generated On: 20 Jul 2016 10:56:43

Exclusion Criterion Number	9
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Exclusion Criterion	Any subject with an history of adverse events linked to caffeine or caffeine containing drugs (e.g., Vivarin), such as but not limited to hypersensitivity or allergy.
---------------------	--

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

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1002

Folder: Screening

Form: Exclusion Criteria (10)

Data signed: (hfarmer1) 26 Mar 2015 13:37:45

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Screening

Form: Exclusion Criteria (11)

Data signed: (hfarmer1) 26 Mar 2015 13:37:45

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Screening

Form: Exclusion Criteria (12)

Data signed: (hfarmer1) 26 Mar 2015 13:37:45

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Screening

Form: Exclusion Criteria (13)

Data signed: (hfarmer1) 26 Mar 2015 13:37:45

Generated On: 20 Jul 2016 10:56:43

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
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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: 1002**

Folder: Screening

Form: Exclusion Criteria (14)

Data signed: (hfarmer1) 26 Mar 2015 13:37:45

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Screening

Form: Exclusion Criteria (15)

Data signed: (hfarmer1) 26 Mar 2015 13:37:45

Generated On: 20 Jul 2016 10:56:43

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Screening

Form: Exclusion Criteria (16)

Data signed: (hfarmer1) 26 Mar 2015 13:37:45

Generated On: 20 Jul 2016 10:56:43

Exclusion Criterion Number	17
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Exclusion Criterion	Donation or receipt of whole blood or blood products within 3 months prior to Admission.	<input checked="" type="radio"/>
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Result	No	<input checked="" type="radio"/>
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*If any has been answered Yes, subject must not be included in the study.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Screening

Form: Exclusion Criteria (17)

Data signed: (hfarmer1) 26 Mar 2015 13:37:45

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Screening

Form: Exclusion Criteria (18)

Data signed: (hfarmer1) 26 Mar 2015 13:37:45

Generated On: 20 Jul 2016 10:56:43

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
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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: 1002**

Folder: Screening

Form: Exclusion Criteria (19)

Data signed: (hfarmer1) 26 Mar 2015 13:37:45

Generated On: 20 Jul 2016 10:56:43

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

*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: 1002**

Folder: Screening

Form: Exclusion Criteria (20)

Data signed: (hfarmer1) 26 Mar 2015 13:37:45

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Screening

Form: Exclusion Criteria (21)

Data signed: (hfarmer1) 26 Mar 2015 13:37:45

Generated On: 20 Jul 2016 10:56:43

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
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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: 1002**

Folder: Screening

Form: Demographics

Data signed: (hfarmer1) 26 Mar 2015 13:37:44

Generated On: 20 Jul 2016 10:56:43

Date of Birth	(b) (6)
Sex	Female <input checked="" type="radio"/>
Race	White <input checked="" type="radio"/>
Other, specify	
Ethnicity	Not Hispanic <input checked="" type="radio"/>
Date the Subject signed the Informed Consent	17 DEC 2013 DD/MMM/YYYY
Time the Subject signed the Informed Consent	10:04 hour:min 24-hour clock
Age(Derived)	23

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Screening

Form: Medical History/Concomitant Disease

Data signed: (hfarmer1) 26 Mar 2015 13:37:47

Generated On: 20 Jul 2016 10:56:43

Date of collection

17 DEC 2013
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: 1002**

Folder: Screening

Form: Medical History/Concomitant Disease (1)

Data signed: (hfarmer1) 26 Mar 2015 13:37:47

Generated On: 20 Jul 2016 10:56:43

Date of collection	17 DEC 2013 DD/MMM/YYYY
--------------------	----------------------------

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

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

Diagnosis Description	FOOD ALLERGIES
-----------------------	----------------

Onset Date DD/MMM/YYYY	UN UNK 2010
---------------------------	-------------

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

Ongoing?	True
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Screening

Form: Medical History/Concomitant Disease (2)

Data signed: (hfarmer1) 26 Mar 2015 13:37:47

Generated On: 20 Jul 2016 10:56:43

Date of collection	17 DEC 2013 DD/MMM/YYYY
--------------------	----------------------------

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

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

Diagnosis Description	INSECT STING ALLERGIES
-----------------------	------------------------

Onset Date DD/MMM/YYYY	UN UNK 2006
---------------------------	-------------

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

Ongoing?	True
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Screening

Form: Medical History/Concomitant Disease (3)

Data signed: (hfarmer1) 26 Mar 2015 13:37:47

Generated On: 20 Jul 2016 10:56:43

Date of collection	17 DEC 2013 DD/MMM/YYYY
--------------------	----------------------------

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

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

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

Onset Date DD/MMM/YYYY	UN UNK 2010
---------------------------	-------------

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

Ongoing?	True
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Screening

Form: Medical History/Concomitant Disease (4)

Data signed: (hfarmer1) 26 Mar 2015 13:37:47

Generated On: 20 Jul 2016 10:56:43

Date of collection	17 DEC 2013 DD/MMM/YYYY
--------------------	----------------------------

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

Number	4
--------	---

Diagnosis Description	RIGHT ELBOW REPAIR
-----------------------	--------------------

Onset Date DD/MMM/YYYY	UN UNK 1995
---------------------------	-------------

Stop Date DD/MMM/YYYY	UN UNK 1995
--------------------------	-------------

Ongoing?	False
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Screening

Form: Vital Signs<Screening/<

Data signed: (hfarmer1) 26 Mar 2015 13:37:51

Generated On: 20 Jul 2016 10:56:43

Were Vitals Signs assessed?

Yes ☒

If No, please specify the reason: _____

Has the subject smoked within 15 minutes prior to
assessment

No ☒

Date of assessment

17 DEC 2013
DD/MMM/YYYY

Time of assessment

11:38
hour:min 24-hour clock

Pulse rate

57
beats per minute

Respiratory rate

16
breaths per minute

Blood Pressure (systolic)

108
mmHg

Blood Pressure (diastolic)

65
mmHg

Vital Signs Position of Subject

Supine ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Screening

Form: Physical Examination

Data signed: (hfarmer1) 26 Mar 2015 13:37:48

Generated On: 20 Jul 2016 10:56:43

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

17 DEC 2013
DD/MMM/YYYY

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Screening

Form: Physical Examination (1)

Data signed: (hfarmer1) 26 Mar 2015 13:37:48

Generated On: 20 Jul 2016 10:56:43

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of assessment 17 DEC 2013
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: 1002**

Folder: Screening

Form: Physical Examination (2)

Data signed: (hfarmer1) 26 Mar 2015 13:37:48

Generated On: 20 Jul 2016 10:56:43

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

17 DEC 2013
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: 1002**

Folder: Screening

Form: Physical Examination (3)

Data signed: (hfarmer1) 26 Mar 2015 13:37:48

Generated On: 20 Jul 2016 10:56:43

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of assessment 17 DEC 2013
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: 1002**

Folder: Screening

Form: Physical Examination (4)

Data signed: (hfarmer1) 26 Mar 2015 13:37:48

Generated On: 20 Jul 2016 10:56:43

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of assessment 17 DEC 2013
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: 1002**

Folder: Screening

Form: Physical Examination (5)

Data signed: (hfarmer1) 26 Mar 2015 13:37:48

Generated On: 20 Jul 2016 10:56:43

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of assessment 17 DEC 2013
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: 1002**

Folder: Screening

Form: Physical Examination (6)

Data signed: (hfarmer1) 26 Mar 2015 13:37:48

Generated On: 20 Jul 2016 10:56:43

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of assessment 17 DEC 2013
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: 1002**

Folder: Screening

Form: Physical Examination (7)

Data signed: (hfarmer1) 26 Mar 2015 13:37:48

Generated On: 20 Jul 2016 10:56:43

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of assessment 17 DEC 2013
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: 1002**

Folder: Screening

Form: Physical Examination (8)

Data signed: (hfarmer1) 26 Mar 2015 13:37:48

Generated On: 20 Jul 2016 10:56:43

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of assessment 17 DEC 2013
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: 1002**

Folder: Screening

Form: Physical Examination (9)

Data signed: (hfarmer1) 26 Mar 2015 13:37:48

Generated On: 20 Jul 2016 10:56:43

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of assessment 17 DEC 2013
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: 1002**

Folder: Screening

Form: Physical Examination (10)

Data signed: (hfarmer1) 26 Mar 2015 13:37:48

Generated On: 20 Jul 2016 10:56:43

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

17 DEC 2013
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: 1002**

Folder: Screening

Form: Physical Examination (11)

Data signed: (hfarmer1) 26 Mar 2015 13:37:48

Generated On: 20 Jul 2016 10:56:43

Was the physical examination performed? Yes ☐

If No, please specify the reason: _____

Date of assessment 17 DEC 2013
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: 1002**

Folder: Screening

Form: Physical Examination (12)

Data signed: (hfarmer1) 26 Mar 2015 13:37:48

Generated On: 20 Jul 2016 10:56:43

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of assessment 17 DEC 2013
DD/MMM/YYYY

System Musculoskeletal ☒

Outcome Abnormal ☒

Abnormal, please specify RIGHT ELBOW DEFORMITY

Clinically significant No ☒

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Screening

Form: Physical Examination (13)

Data signed: (hfarmer1) 26 Mar 2015 13:37:48

Generated On: 20 Jul 2016 10:56:43

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

17 DEC 2013
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: 1002**

Folder: Screening

Form: Physical Examination (14)

Data signed: (hfarmer1) 26 Mar 2015 13:37:48

Generated On: 20 Jul 2016 10:56:43

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of assessment 17 DEC 2013
DD/MMM/YYYY

System Dentition ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Screening

Form: Physical Examination (15)

Data signed: (hfarmer1) 26 Mar 2015 13:37:48

Generated On: 20 Jul 2016 10:56:43

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

17 DEC 2013
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: 1002**

Folder: Screening

Form: Physical Examination (16)

Data signed: (hfarmer1) 26 Mar 2015 13:37:48

Generated On: 20 Jul 2016 10:56:43

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

17 DEC 2013
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: 1002**

Folder: Screening

Form: Physical Examination (17)

Data signed: (hfarmer1) 26 Mar 2015 13:37:48

Generated On: 20 Jul 2016 10:56:43

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

17 DEC 2013
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: 1002**

Folder: Screening

Form: Physical Examination (18)

Data signed: (hfarmer1) 26 Mar 2015 13:37:48

Generated On: 20 Jul 2016 10:56:43

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

17 DEC 2013
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: 1002**

Folder: Screening

Form: Physical Examination (19)

Data signed: (hfarmer1) 26 Mar 2015 13:37:48

Generated On: 20 Jul 2016 10:56:43

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

17 DEC 2013
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: 1002**

Folder: Screening

Form: Advice on the risk of smoking and debriefing

Data signed: (hfarmer1) 26 Mar 2015 13:37:51

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Screening

Form: Identification of Current Cigarette Brand

Data signed: (hfarmer1) 26 Mar 2015 13:37:51

Generated On: 20 Jul 2016 10:56:43

Date

17 DEC 2013
DD/MMM/YYYY

Brand name

305 MENTHOL 100'S

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Screening

Form: THS 2.2 menthol product demonstration

Data signed: (hfarmer1) 26 Mar 2015 13:37:51

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Screening

Form: Smoking History

Data signed: (hfarmer1) 26 Mar 2015 13:37:51

Generated On: 20 Jul 2016 10:56:43

Date of Assessment

17 DEC 2013
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: 1002**

Folder: Screening

Form: Weight and Height

Data signed: (hfarmer1) 26 Mar 2015 13:37:52

Generated On: 20 Jul 2016 10:56:43

Measurement(s) assessed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

17 DEC 2013
DD/MMM/YYYY

Weight

65.5
kg

Height

161.7
cm

BMI (Derived)

25.1
kg/m2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Screening

Form: ECG (12-Lead Standard)

Data signed: (hfarmer1) 26 Mar 2015 13:37:44

Generated On: 20 Jul 2016 10:56:43

Was the ECG performed? Yes ☒

If No, please specify the reason: _____

Date of assessment: 17 DEC 2013
DD/MMM/YYYY

Position Supine ☒

Heart Rate 54
beats per minute

QRS Interval 83
msec

QT Interval 410
msec

QTcB Interval 390
msec

QTcF Interval 396
msec

PR Interval 198
msec

Interpretation Normal ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Screening

Form: ECG (12-Lead Standard)

Data signed: (hfarmer1) 26 Mar 2015 13:37:44

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Screening

Form: Spirometry (1)

Data signed: (hfarmer1) 26 Mar 2015 13:37:50

Generated On: 20 Jul 2016 10:56:43

Was the spirometry performed? Yes ☒

If No, please specify the reason: _____

Category Without short-acting ☒
bronchodilator

Position SITTING

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

Date of assessment 17 DEC 2013
DD/MMM/YYYY

Time of assessment 12:28

Predicted FVC value 3.76
L

Best measured FVC value 4.83
L

Percent of predicted FVC value 128
%

Best measured FEV1 value 3.25
L

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Screening

Form: Spirometry (1)

Data signed: (hfarmer1) 26 Mar 2015 13:37:50

Generated On: 20 Jul 2016 10:56:43

Predicted FEV1 value	3.26 L
----------------------	-----------

Percent of predicted FEV1 value	100 %
---------------------------------	----------

Calculated ratio between FEV1/FVC	0.67
-----------------------------------	------

MEF 25/75 value	02.12 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: 1002**

Folder: Screening

Form: Spirometry (2)

Data signed: (hfarmer1) 26 Mar 2015 13:37:50

Generated On: 20 Jul 2016 10:56:43

Was the spirometry performed? Yes ☒

If No, please specify the reason: _____

Category With short-acting ☒
bronchodilator

Position SITTING

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

Date of assessment 17 DEC 2013
DD/MMM/YYYY

Time of assessment 12:54

Name of bronchodilator ALBUTEROL SULFATE

Dose 180MCG

Predicted FVC value 3.76
L

Best measured FVC value 4.19
L

Percent of predicted FVC value 111
%

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Screening

Form: Spirometry (2)

Data signed: (hfarmer1) 26 Mar 2015 13:37:50

Generated On: 20 Jul 2016 10:56:43

Best measured FEV1 value	3.24 L
Predicted FEV1 value	3.26 L
Percent of predicted FEV1 value	99 %
Calculated ratio between FEV1/FVC	0.77
MEF 25/75 value	02.79 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: 1002**

Folder: Screening

Form: Chest X-Ray

Data signed: (hfarmer1) 26 Mar 2015 13:37:52

Generated On: 20 Jul 2016 10:56:43

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

Yes ☒

If No, please specify the reason: _____

Date of assessment

30 DEC 2013
DD/MMM/YYYY

System

Chest ☒

Interpretation

Normal ☒

Clinically significant _____

Abnormal, please specify: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Screening

Form: Haematology

Data signed: (hfarmer1) 26 Mar 2015 13:37:47

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Screening

Form: Clinical Chemistry

Data signed: (hfarmer1) 26 Mar 2015 13:37:46

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Screening

Form: Urine analysis

Data signed: (hfarmer1) 26 Mar 2015 13:37:47

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Screening

Form: Serology for HIV and Hepatitis B and C

Data signed: (hfarmer1) 26 Mar 2015 13:37:47

Generated On: 20 Jul 2016 10:56:43

Category

Serology ☒

Not Done

False

If Not Done, please specify the reason:

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1002

Folder: Screening

Form: Urine Drug Screen

Data signed: (hfarmer1) 26 Mar 2015 13:37:46

Generated On: 20 Jul 2016 10:56:43

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

If Not Done, please specify the reason: _____

Date of sample collection	17 DEC 2013 DD/MMM/YYYY
---------------------------	----------------------------

Time of sample collection	11:26 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: 1002

Folder: Screening

Form: Urine Drug Screen (4)

Data signed: (hfarmer1) 26 Mar 2015 13:37:46

Generated On: 20 Jul 2016 10:56:43

Drug type	Result
Cannabinoids	Negative
Cocaine	Negative
Opiates	Negative

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Screening

Form: Alcohol Test

Data signed: (hfarmer1) 26 Mar 2015 13:37:46

Generated On: 20 Jul 2016 10:56:43

Was the alcohol test performed? Yes ☒

If No, please specify the reason: _____

Method used Breath test ☒

Date of assessment 17 DEC 2013
DD/MMM/YYYY

Time of assessment 11:31
hour:min 24-hour clock

Result Negative ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Screening

Form: Urine Pregnancy Test

Generated On: 20 Jul 2016 10:56:43

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

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

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

Date of Test	17 DEC 2013 DD/MMM/YYYY
--------------	----------------------------

Time of Test	11:45 hour:min 24-hour clock
--------------	---------------------------------

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

If unclear, please confirm with FSH test

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Screening

Form: Urine Cotinine Test

Data signed: (hfarmer1) 26 Mar 2015 13:37:46

Generated On: 20 Jul 2016 10:56:43

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

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

If Not Done, please specify the reason: _____

Date of Sample Collection	17 DEC 2013 DD/MMM/YYYY
---------------------------	----------------------------

Time of Sample Collection	11:26 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: 1002**

Folder: Screening

Form: Lab-BU-LabCorp CHEMISTRY(17 DEC 2013)

Data signed: (hfarmer1) 26 Mar 2015 13:37:53

Generated On: 20 Jul 2016 10:56:43

Experiment Type

CHEMISTRY

Date of Sample Collection
YYYY/MM/DD

17 DEC 2013

Please document clinically relevant abnormalities in the AE form

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Screening

Form: Lab-BU-LabCorp CHEMISTRY(17 DEC 2013)

Data signed: (hfarmer1) 26 Mar 2015 13:37:53

Generated On: 20 Jul 2016 10:56:43

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

Date of Sample Collection YYYY/MM/DD	17 DEC 2013
---	-------------

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

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

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

Time of Sample Collection	12:07
---------------------------	-------

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

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

Result	71
--------	----

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

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

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

Flag	
------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Screening

Form: Lab-BU-LabCorp CHEMISTRY(17 DEC 2013)

Data signed: (hfarmer1) 26 Mar 2015 13:37:53

Generated On: 20 Jul 2016 10:56:43

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

35157100020

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Screening

Form: Lab-BU-LabCorp (2)

Data signed: (hfarmer1) 26 Mar 2015 13:37:53

Generated On: 20 Jul 2016 10:56:43

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

Date of Sample Collection YYYY/MM/DD	17 DEC 2013
---	-------------

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

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

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

Time of Sample Collection	12:07
---------------------------	-------

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

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

Result	11
--------	----

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

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

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

Flag	
------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Screening

Form: Lab-BU-LabCorp (2)

Data signed: (hfarmer1) 26 Mar 2015 13:37:53

Generated On: 20 Jul 2016 10:56:43

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

35157100020

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Screening

Form: Lab-BU-LabCorp (3)

Data signed: (hfarmer1) 26 Mar 2015 13:37:53

Generated On: 20 Jul 2016 10:56:43

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

Date of Sample Collection YYYY/MM/DD	17 DEC 2013
---	-------------

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

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

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

Time of Sample Collection	12:07
---------------------------	-------

Analyte Name	CHOLESTEROL, TOTAL
--------------	--------------------

Code	001065
------	--------

Result	221
--------	-----

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

Lower limit	100
-------------	-----

Upper limit	189
-------------	-----

Flag	High <input checked="" type="radio"/>
------	---------------------------------------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Screening

Form: Lab-BU-LabCorp (3)

Data signed: (hfarmer1) 26 Mar 2015 13:37:53

Generated On: 20 Jul 2016 10:56:43

Clinically Significant?

No ☒

Comment

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

35157100020

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Screening

Form: Lab-BU-LabCorp (4)

Data signed: (hfarmer1) 26 Mar 2015 13:37:53

Generated On: 20 Jul 2016 10:56:43

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

Date of Sample Collection YYYY/MM/DD	17 DEC 2013
---	-------------

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

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

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

Time of Sample Collection	12:07
---------------------------	-------

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

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

Result	6.8
--------	-----

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

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

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

Flag	
------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Screening

Form: Lab-BU-LabCorp (4)

Data signed: (hfarmer1) 26 Mar 2015 13:37:53

Generated On: 20 Jul 2016 10:56:43

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

35157100020

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Screening

Form: Lab-BU-LabCorp (5)

Data signed: (hfarmer1) 26 Mar 2015 13:37:53

Generated On: 20 Jul 2016 10:56:43

Experiment Type

CHEMISTRY

Date of Sample Collection
YYYY/MM/DD

17 DEC 2013

Subject Number

Date of Birth

(b) (6)

Gender

Female ☒

Time of Sample Collection

12:07

Analyte Name

ALBUMIN, SERUM

Code

001081

Result

3.8

Unit

G/DL

Lower limit

3.5

Upper limit

5.5

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Screening

Form: Lab-BU-LabCorp (5)

Data signed: (hfarmer1) 26 Mar 2015 13:37:53

Generated On: 20 Jul 2016 10:56:43

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

35157100020

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Screening

Form: Lab-BU-LabCorp (6)

Data signed: (hfarmer1) 26 Mar 2015 13:37:53

Generated On: 20 Jul 2016 10:56:43

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

Date of Sample Collection YYYY/MM/DD	17 DEC 2013
---	-------------

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

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

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

Time of Sample Collection	12:07
---------------------------	-------

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

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

Result	0.3
--------	-----

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

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

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

Flag	
------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Screening

Form: Lab-BU-LabCorp (6)

Data signed: (hfarmer1) 26 Mar 2015 13:37:53

Generated On: 20 Jul 2016 10:56:43

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

35157100020

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Screening

Form: Lab-BU-LabCorp (7)

Data signed: (hfarmer1) 26 Mar 2015 13:37:53

Generated On: 20 Jul 2016 10:56:43

Experiment Type

CHEMISTRY

Date of Sample Collection
YYYY/MM/DD

17 DEC 2013

Subject Number

Date of Birth

(b) (6)

Gender

Female ☒

Time of Sample Collection

12:07

Analyte Name

ALKALINE PHOSPHATASE, S

Code

001107

Result

107

Unit

IU/L

Lower limit

39

Upper limit

117

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Screening

Form: Lab-BU-LabCorp (7)

Data signed: (hfarmer1) 26 Mar 2015 13:37:53

Generated On: 20 Jul 2016 10:56:43

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

35157100020

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Screening

Form: Lab-BU-LabCorp (8)

Data signed: (hfarmer1) 26 Mar 2015 13:37:53

Generated On: 20 Jul 2016 10:56:43

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

Date of Sample Collection YYYY/MM/DD	17 DEC 2013
---	-------------

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

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

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

Time of Sample Collection	12:07
---------------------------	-------

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

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

Result	126
--------	-----

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

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

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

Flag	
------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Screening

Form: Lab-BU-LabCorp (8)

Data signed: (hfarmer1) 26 Mar 2015 13:37:53

Generated On: 20 Jul 2016 10:56:43

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

35157100020

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Screening

Form: Lab-BU-LabCorp (9)

Data signed: (hfarmer1) 26 Mar 2015 13:37:53

Generated On: 20 Jul 2016 10:56:43

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

Date of Sample Collection YYYY/MM/DD	17 DEC 2013
---	-------------

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

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

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

Time of Sample Collection	12:07
---------------------------	-------

Analyte Name	AST (SGOT)
--------------	------------

Code	001123
------	--------

Result	20
--------	----

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

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

Upper limit	40
-------------	----

Flag	
------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Screening

Form: Lab-BU-LabCorp (9)

Data signed: (hfarmer1) 26 Mar 2015 13:37:53

Generated On: 20 Jul 2016 10:56:43

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

35157100020

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Screening

Form: Lab-BU-LabCorp (10)

Data signed: (hfarmer1) 26 Mar 2015 13:37:53

Generated On: 20 Jul 2016 10:56:43

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

Date of Sample Collection YYYY/MM/DD	17 DEC 2013
---	-------------

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

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

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

Time of Sample Collection	12:07
---------------------------	-------

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

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

Result	94
--------	----

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

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

Upper limit	114
-------------	-----

Flag	
------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Screening

Form: Lab-BU-LabCorp (10)

Data signed: (hfarmer1) 26 Mar 2015 13:37:53

Generated On: 20 Jul 2016 10:56:43

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

35157100020

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Screening

Form: Lab-BU-LabCorp (11)

Data signed: (hfarmer1) 26 Mar 2015 13:37:53

Generated On: 20 Jul 2016 10:56:43

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

Date of Sample Collection YYYY/MM/DD	17 DEC 2013
---	-------------

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

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

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

Time of Sample Collection	12:07
---------------------------	-------

Analyte Name	POTASSIUM, SERUM
--------------	------------------

Code	001180
------	--------

Result	4.4
--------	-----

Unit	MMOL/L
------	--------

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

Upper limit	5.2
-------------	-----

Flag	
------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Screening

Form: Lab-BU-LabCorp (11)

Data signed: (hfarmer1) 26 Mar 2015 13:37:53

Generated On: 20 Jul 2016 10:56:43

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

35157100020

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Screening

Form: Lab-BU-LabCorp (12)

Data signed: (hfarmer1) 26 Mar 2015 13:37:53

Generated On: 20 Jul 2016 10:56:43

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

Date of Sample Collection YYYY/MM/DD	17 DEC 2013
---	-------------

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

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

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

Time of Sample Collection	12:07
---------------------------	-------

Analyte Name	SODIUM, SERUM
--------------	---------------

Code	001198
------	--------

Result	140
--------	-----

Unit	MMOL/L
------	--------

Lower limit	134
-------------	-----

Upper limit	144
-------------	-----

Flag	
------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Screening

Form: Lab-BU-LabCorp (12)

Data signed: (hfarmer1) 26 Mar 2015 13:37:53

Generated On: 20 Jul 2016 10:56:43

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

35157100020

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Screening

Form: Lab-BU-LabCorp (13)

Data signed: (hfarmer1) 26 Mar 2015 13:37:53

Generated On: 20 Jul 2016 10:56:43

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

Date of Sample Collection YYYY/MM/DD	17 DEC 2013
---	-------------

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

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

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

Time of Sample Collection	12:07
---------------------------	-------

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: 1002**

Folder: Screening

Form: Lab-BU-LabCorp (13)

Data signed: (hfarmer1) 26 Mar 2015 13:37:53

Generated On: 20 Jul 2016 10:56:43

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

35157100020

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Screening

Form: Lab-BU-LabCorp (14)

Data signed: (hfarmer1) 26 Mar 2015 13:37:53

Generated On: 20 Jul 2016 10:56:43

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

Date of Sample Collection YYYY/MM/DD	17 DEC 2013
---	-------------

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

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

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

Time of Sample Collection	12:07
---------------------------	-------

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

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

Result	0.75
--------	------

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

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

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

Flag	
------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Screening

Form: Lab-BU-LabCorp (14)

Data signed: (hfarmer1) 26 Mar 2015 13:37:53

Generated On: 20 Jul 2016 10:56:43

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

35157100020

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Screening

Form: Lab-BU-LabCorp (15)

Data signed: (hfarmer1) 26 Mar 2015 13:37:53

Generated On: 20 Jul 2016 10:56:43

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

Date of Sample Collection YYYY/MM/DD	17 DEC 2013
---	-------------

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

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

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

Time of Sample Collection	12:07
---------------------------	-------

Analyte Name	ALT (SGPT)
--------------	------------

Code	001545
------	--------

Result	19
--------	----

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

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

Upper limit	32
-------------	----

Flag	
------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Screening

Form: Lab-BU-LabCorp (15)

Data signed: (hfarmer1) 26 Mar 2015 13:37:53

Generated On: 20 Jul 2016 10:56:43

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

35157100020

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Screening

Form: Lab-BU-LabCorp (16)

Data signed: (hfarmer1) 26 Mar 2015 13:37:53

Generated On: 20 Jul 2016 10:56:43

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

Date of Sample Collection YYYY/MM/DD	17 DEC 2013
---	-------------

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

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

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

Time of Sample Collection	12:07
---------------------------	-------

Analyte Name	GGT
--------------	-----

Code	001958
------	--------

Result	7
--------	---

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

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

Upper limit	60
-------------	----

Flag	
------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Screening

Form: Lab-BU-LabCorp (16)

Data signed: (hfarmer1) 26 Mar 2015 13:37:53

Generated On: 20 Jul 2016 10:56:43

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

35157100020

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Screening

Form: Lab-BU-LabCorp (17)

Data signed: (hfarmer1) 26 Mar 2015 13:37:53

Generated On: 20 Jul 2016 10:56:43

Experiment Type

CHEMISTRY

Date of Sample Collection
YYYY/MM/DD

17 DEC 2013

Subject Number

Date of Birth

(b) (6)

Gender

Female ☒

Time of Sample Collection

12:07

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: 1002**

Folder: Screening

Form: Lab-BU-LabCorp (17)

Data signed: (hfarmer1) 26 Mar 2015 13:37:53

Generated On: 20 Jul 2016 10:56:43

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

35157100020

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Screening

Form: Lab-BU-LabCorp SEROLOGY(17 DEC 2013)

Data signed: (hfarmer1) 26 Mar 2015 13:37:56

Generated On: 20 Jul 2016 10:56:43

Experiment Type

SEROLOGY

Date of Sample Collection
YYYY/MM/DD

17 DEC 2013

Please document clinically relevant abnormalities in the AE form

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Screening

Form: Lab-BU-LabCorp SEROLOGY(17 DEC 2013)

Data signed: (hfarmer1) 26 Mar 2015 13:37:56

Generated On: 20 Jul 2016 10:56:43

Experiment Type

SEROLOGY

Date of Sample Collection
YYYY/MM/DD

17 DEC 2013

Subject Number

Date of Birth

(b) (6)

Gender

Female ☒

Time of Sample Collection

12:07

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: 1002**

Folder: Screening

Form: Lab-BU-LabCorp SEROLOGY(17 DEC 2013)

Data signed: (hfarmer1) 26 Mar 2015 13:37:56

Generated On: 20 Jul 2016 10:56:43

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

35157100020

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Screening

Form: Lab-BU-LabCorp (2)

Data signed: (hfarmer1) 26 Mar 2015 13:37:56

Generated On: 20 Jul 2016 10:56:43

Experiment Type

SEROLOGY

Date of Sample Collection
YYYY/MM/DD

17 DEC 2013

Subject Number

Date of Birth

(b) (6)

Gender

Female ☒

Time of Sample Collection

12:07

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: 1002**

Folder: Screening

Form: Lab-BU-LabCorp (2)

Data signed: (hfarmer1) 26 Mar 2015 13:37:56

Generated On: 20 Jul 2016 10:56:43

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

35157100020

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Screening

Form: Lab-BU-LabCorp (3)

Data signed: (hfarmer1) 26 Mar 2015 13:37:56

Generated On: 20 Jul 2016 10:56:43

Experiment Type

SEROLOGY

Date of Sample Collection
YYYY/MM/DD

17 DEC 2013

Subject Number

Date of Birth

(b) (6)

Gender

Female ☒

Time of Sample Collection

12:07

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: 1002**

Folder: Screening

Form: Lab-BU-LabCorp (3)

Data signed: (hfarmer1) 26 Mar 2015 13:37:56

Generated On: 20 Jul 2016 10:56:43

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

35157100020

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Screening

Form: Lab-BU-LabCorp HEMATOLOGY(17 DEC 2013)

Data signed: (hfarmer1) 26 Mar 2015 13:37:56

Generated On: 20 Jul 2016 10:56:43

Experiment Type

HEMATOLOGY

Date of Sample Collection
YYYY/MM/DD

17 DEC 2013

Please document clinically relevant abnormalities in the AE form

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Screening

Form: Lab-BU-LabCorp HEMATOLOGY(17 DEC 2013)

Data signed: (hfarmer1) 26 Mar 2015 13:37:56

Generated On: 20 Jul 2016 10:56:43

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

Date of Sample Collection YYYY/MM/DD	17 DEC 2013
---	-------------

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

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

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

Time of Sample Collection	12:07
---------------------------	-------

Analyte Name	WBC
--------------	-----

Code	005025
------	--------

Result	5.7
--------	-----

Unit	X10E3/UL
------	----------

Lower limit	3.4
-------------	-----

Upper limit	10.8
-------------	------

Flag	
------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Screening

Form: Lab-BU-LabCorp HEMATOLOGY(17 DEC 2013)

Data signed: (hfarmer1) 26 Mar 2015 13:37:56

Generated On: 20 Jul 2016 10:56:43

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

35157100020

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Screening

Form: Lab-BU-LabCorp (2)

Data signed: (hfarmer1) 26 Mar 2015 13:37:56

Generated On: 20 Jul 2016 10:56:43

Experiment Type

HEMATOLOGY

Date of Sample Collection
YYYY/MM/DD

17 DEC 2013

Subject Number

Date of Birth

(b) (6)

Gender

Female ☒

Time of Sample Collection

12:07

Analyte Name

RBC

Code

005033

Result

4.92

Unit

X10E6/UL

Lower limit

3.77

Upper limit

5.28

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Screening

Form: Lab-BU-LabCorp (2)

Data signed: (hfarmer1) 26 Mar 2015 13:37:56

Generated On: 20 Jul 2016 10:56:43

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

35157100020

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Screening

Form: Lab-BU-LabCorp (3)

Data signed: (hfarmer1) 26 Mar 2015 13:37:56

Generated On: 20 Jul 2016 10:56:43

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

Date of Sample Collection YYYY/MM/DD	17 DEC 2013
---	-------------

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

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

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

Time of Sample Collection	12:07
---------------------------	-------

Analyte Name	HEMOGLOBIN
--------------	------------

Code	005041
------	--------

Result	14.2
--------	------

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

Lower limit	11.1
-------------	------

Upper limit	15.9
-------------	------

Flag	
------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Screening

Form: Lab-BU-LabCorp (3)

Data signed: (hfarmer1) 26 Mar 2015 13:37:56

Generated On: 20 Jul 2016 10:56:43

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

35157100020

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Screening

Form: Lab-BU-LabCorp (4)

Data signed: (hfarmer1) 26 Mar 2015 13:37:56

Generated On: 20 Jul 2016 10:56:43

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

Date of Sample Collection YYYY/MM/DD	17 DEC 2013
---	-------------

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

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

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

Time of Sample Collection	12:07
---------------------------	-------

Analyte Name	HEMATOCRIT
--------------	------------

Code	005058
------	--------

Result	42.9
--------	------

Unit	%
------	---

Lower limit	34.0
-------------	------

Upper limit	46.6
-------------	------

Flag	
------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Screening

Form: Lab-BU-LabCorp (4)

Data signed: (hfarmer1) 26 Mar 2015 13:37:56

Generated On: 20 Jul 2016 10:56:43

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

35157100020

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Screening

Form: Lab-BU-LabCorp (5)

Data signed: (hfarmer1) 26 Mar 2015 13:37:56

Generated On: 20 Jul 2016 10:56:43

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

Date of Sample Collection YYYY/MM/DD	17 DEC 2013
---	-------------

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

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

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

Time of Sample Collection	12:07
---------------------------	-------

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

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

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

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

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

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

Flag	
------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Screening

Form: Lab-BU-LabCorp (5)

Data signed: (hfarmer1) 26 Mar 2015 13:37:56

Generated On: 20 Jul 2016 10:56:43

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

35157100020

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Screening

Form: Lab-BU-LabCorp (6)

Data signed: (hfarmer1) 26 Mar 2015 13:37:56

Generated On: 20 Jul 2016 10:56:43

Experiment Type

HEMATOLOGY

Date of Sample Collection
YYYY/MM/DD

17 DEC 2013

Subject Number

Date of Birth

(b) (6)

Gender

Female ☒

Time of Sample Collection

12:07

Analyte Name

MCH

Code

015073

Result

28.9

Unit

PG

Lower limit

26.6

Upper limit

33.0

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Screening

Form: Lab-BU-LabCorp (6)

Data signed: (hfarmer1) 26 Mar 2015 13:37:56

Generated On: 20 Jul 2016 10:56:43

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

35157100020

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Screening

Form: Lab-BU-LabCorp (7)

Data signed: (hfarmer1) 26 Mar 2015 13:37:56

Generated On: 20 Jul 2016 10:56:43

Experiment Type

HEMATOLOGY

Date of Sample Collection
YYYY/MM/DD

17 DEC 2013

Subject Number

Date of Birth

(b) (6)

Gender

Female ☒

Time of Sample Collection

12:07

Analyte Name

MCHC

Code

015081

Result

33.1

Unit

G/DL

Lower limit

31.5

Upper limit

35.7

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Screening

Form: Lab-BU-LabCorp (7)

Data signed: (hfarmer1) 26 Mar 2015 13:37:56

Generated On: 20 Jul 2016 10:56:43

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

35157100020

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Screening

Form: Lab-BU-LabCorp (8)

Data signed: (hfarmer1) 26 Mar 2015 13:37:56

Generated On: 20 Jul 2016 10:56:43

Experiment Type

HEMATOLOGY

Date of Sample Collection
YYYY/MM/DD

17 DEC 2013

Subject Number

Date of Birth

(b) (6)

Gender

Female ☒

Time of Sample Collection

12:07

Analyte Name

NEUTROPHILS

Code

015107

Result

49

Unit

%

Lower limit

40

Upper limit

74

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Screening

Form: Lab-BU-LabCorp (8)

Data signed: (hfarmer1) 26 Mar 2015 13:37:56

Generated On: 20 Jul 2016 10:56:43

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

35157100020

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Screening

Form: Lab-BU-LabCorp (9)

Data signed: (hfarmer1) 26 Mar 2015 13:37:56

Generated On: 20 Jul 2016 10:56:43

Experiment Type

HEMATOLOGY

Date of Sample Collection
YYYY/MM/DD

17 DEC 2013

Subject Number

Date of Birth

(b) (6)

Gender

Female ☒

Time of Sample Collection

12:07

Analyte Name

LYMPHS

Code

015123

Result

40

Unit

%

Lower limit

14

Upper limit

46

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Screening

Form: Lab-BU-LabCorp (9)

Data signed: (hfarmer1) 26 Mar 2015 13:37:56

Generated On: 20 Jul 2016 10:56:43

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

35157100020

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Screening

Form: Lab-BU-LabCorp (10)

Data signed: (hfarmer1) 26 Mar 2015 13:37:56

Generated On: 20 Jul 2016 10:56:43

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

Date of Sample Collection YYYY/MM/DD	17 DEC 2013
---	-------------

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

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

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

Time of Sample Collection	12:07
---------------------------	-------

Analyte Name	MONOCYTES
--------------	-----------

Code	015131
------	--------

Result	6
--------	---

Unit	%
------	---

Lower limit	4
-------------	---

Upper limit	12
-------------	----

Flag	
------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Screening

Form: Lab-BU-LabCorp (10)

Data signed: (hfarmer1) 26 Mar 2015 13:37:56

Generated On: 20 Jul 2016 10:56:43

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

35157100020

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Screening

Form: Lab-BU-LabCorp (11)

Data signed: (hfarmer1) 26 Mar 2015 13:37:56

Generated On: 20 Jul 2016 10:56:43

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

Date of Sample Collection YYYY/MM/DD	17 DEC 2013
---	-------------

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

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

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

Time of Sample Collection	12:07
---------------------------	-------

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: 1002**

Folder: Screening

Form: Lab-BU-LabCorp (11)

Data signed: (hfarmer1) 26 Mar 2015 13:37:56

Generated On: 20 Jul 2016 10:56:43

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

35157100020

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Screening

Form: Lab-BU-LabCorp (12)

Data signed: (hfarmer1) 26 Mar 2015 13:37:56

Generated On: 20 Jul 2016 10:56:43

Experiment Type

HEMATOLOGY

Date of Sample Collection
YYYY/MM/DD

17 DEC 2013

Subject Number

Date of Birth

(b) (6)

Gender

Female ☒

Time of Sample Collection

12:07

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: 1002**

Folder: Screening

Form: Lab-BU-LabCorp (12)

Data signed: (hfarmer1) 26 Mar 2015 13:37:56

Generated On: 20 Jul 2016 10:56:43

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

35157100020

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Screening

Form: Lab-BU-LabCorp (13)

Data signed: (hfarmer1) 26 Mar 2015 13:37:56

Generated On: 20 Jul 2016 10:56:43

Experiment Type

HEMATOLOGY

Date of Sample Collection
YYYY/MM/DD

17 DEC 2013

Subject Number

Date of Birth

(b) (6)

Gender

Female ☒

Time of Sample Collection

12:07

Analyte Name

PLATELETS

Code

015172

Result

360

Unit

X10E3/UL

Lower limit

155

Upper limit

379

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Screening

Form: Lab-BU-LabCorp (13)

Data signed: (hfarmer1) 26 Mar 2015 13:37:56

Generated On: 20 Jul 2016 10:56:43

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

35157100020

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Screening

Form: Lab-BU-LabCorp (14)

Data signed: (hfarmer1) 26 Mar 2015 13:37:56

Generated On: 20 Jul 2016 10:56:43

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

Date of Sample Collection YYYY/MM/DD	17 DEC 2013
---	-------------

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

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

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

Time of Sample Collection	12:07
---------------------------	-------

Analyte Name	NEUTROPHILS (ABSOLUTE)
--------------	------------------------

Code	015909
------	--------

Result	2.8
--------	-----

Unit	X10E3/UL
------	----------

Lower limit	1.4
-------------	-----

Upper limit	7.0
-------------	-----

Flag	
------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Screening

Form: Lab-BU-LabCorp (14)

Data signed: (hfarmer1) 26 Mar 2015 13:37:56

Generated On: 20 Jul 2016 10:56:43

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

35157100020

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Screening

Form: Lab-BU-LabCorp (15)

Data signed: (hfarmer1) 26 Mar 2015 13:37:56

Generated On: 20 Jul 2016 10:56:43

Experiment Type	HEMATOLOGY
Date of Sample Collection YYYY/MM/DD	17 DEC 2013
Subject Number	
Date of Birth	(b) (6)
Gender	Female <input checked="" type="radio"/>
Time of Sample Collection	12:07
Analyte Name	LYMPHS (ABSOLUTE)
Code	015917
Result	2.3
Unit	X10E3/UL
Lower limit	0.7
Upper limit	3.1
Flag	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Screening

Form: Lab-BU-LabCorp (15)

Data signed: (hfarmer1) 26 Mar 2015 13:37:56

Generated On: 20 Jul 2016 10:56:43

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

35157100020

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Screening

Form: Lab-BU-LabCorp (16)

Data signed: (hfarmer1) 26 Mar 2015 13:37:56

Generated On: 20 Jul 2016 10:56:43

Experiment Type

HEMATOLOGY

Date of Sample Collection
YYYY/MM/DD

17 DEC 2013

Subject Number

Date of Birth

(b) (6)

Gender

Female ☒

Time of Sample Collection

12:07

Analyte Name

MONOCYTES(ABSOLUTE)

Code

015925

Result

0.3

Unit

X10E3/UL

Lower limit

0.1

Upper limit

0.9

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Screening

Form: Lab-BU-LabCorp (16)

Data signed: (hfarmer1) 26 Mar 2015 13:37:56

Generated On: 20 Jul 2016 10:56:43

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

35157100020

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Screening

Form: Lab-BU-LabCorp (17)

Data signed: (hfarmer1) 26 Mar 2015 13:37:56

Generated On: 20 Jul 2016 10:56:43

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

Date of Sample Collection YYYY/MM/DD	17 DEC 2013
---	-------------

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

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

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

Time of Sample Collection	12:07
---------------------------	-------

Analyte Name	EOS (ABSOLUTE)
--------------	----------------

Code	015933
------	--------

Result	0.2
--------	-----

Unit	X10E3/UL
------	----------

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

Upper limit	0.4
-------------	-----

Flag	
------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Screening

Form: Lab-BU-LabCorp (17)

Data signed: (hfarmer1) 26 Mar 2015 13:37:56

Generated On: 20 Jul 2016 10:56:43

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

35157100020

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Screening

Form: Lab-BU-LabCorp (18)

Data signed: (hfarmer1) 26 Mar 2015 13:37:56

Generated On: 20 Jul 2016 10:56:43

Experiment Type

HEMATOLOGY

Date of Sample Collection
YYYY/MM/DD

17 DEC 2013

Subject Number

Date of Birth

(b) (6)

Gender

Female ☒

Time of Sample Collection

12:07

Analyte Name

BASO (ABSOLUTE)

Code

015941

Result

0.0

Unit

X10E3/UL

Lower limit

0.0

Upper limit

0.2

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Screening

Form: Lab-BU-LabCorp (18)

Data signed: (hfarmer1) 26 Mar 2015 13:37:56

Generated On: 20 Jul 2016 10:56:43

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

35157100020

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Screening

Form: Lab-BU-LabCorp URINALYSIS(17 DEC 2013)

Data signed: (hfarmer1) 26 Mar 2015 13:37:59

Generated On: 20 Jul 2016 10:56:43

Experiment Type

URINALYSIS

Date of Sample Collection
YYYY/MM/DD

17 DEC 2013

Please document clinically relevant abnormalities in the AE form

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Screening

Form: Lab-BU-LabCorp URINALYSIS(17 DEC 2013)

Data signed: (hfarmer1) 26 Mar 2015 13:37:59

Generated On: 20 Jul 2016 10:56:43

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

Date of Sample Collection YYYY/MM/DD	17 DEC 2013
---	-------------

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

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

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

Time of Sample Collection	11:41
---------------------------	-------

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

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

Result	1.02
--------	------

Unit	
------	--

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

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

Flag	
------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Screening

Form: Lab-BU-LabCorp URINALYSIS(17 DEC 2013)

Data signed: (hfarmer1) 26 Mar 2015 13:37:59

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Screening

Form: Lab-BU-LabCorp (2)

Data signed: (hfarmer1) 26 Mar 2015 13:37:59

Generated On: 20 Jul 2016 10:56:43

Experiment Type	URINALYSIS
Date of Sample Collection YYYY/MM/DD	17 DEC 2013
Subject Number	
Date of Birth	(b) (6)
Gender	Female <input checked="" type="radio"/>
Time of Sample Collection	11:41
Analyte Name	PH
Code	13078
Result	5
Unit	
Lower limit	5
Upper limit	8
Flag	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Screening

Form: Lab-BU-LabCorp (2)

Data signed: (hfarmer1) 26 Mar 2015 13:37:59

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Screening

Form: Lab-BU-LabCorp (3)

Data signed: (hfarmer1) 26 Mar 2015 13:37:59

Generated On: 20 Jul 2016 10:56:43

Experiment Type

URINALYSIS

Date of Sample Collection
YYYY/MM/DD

17 DEC 2013

Subject Number

Date of Birth

(b) (6)

Gender

Female ☒

Time of Sample Collection

11:41

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: 1002**

Folder: Screening

Form: Lab-BU-LabCorp (3)

Data signed: (hfarmer1) 26 Mar 2015 13:37:59

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Screening

Form: Lab-BU-LabCorp (4)

Data signed: (hfarmer1) 26 Mar 2015 13:37:59

Generated On: 20 Jul 2016 10:56:43

Experiment Type

URINALYSIS

Date of Sample Collection
YYYY/MM/DD

17 DEC 2013

Subject Number

Date of Birth

(b) (6)

Gender

Female ☒

Time of Sample Collection

11:41

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: 1002**

Folder: Screening

Form: Lab-BU-LabCorp (4)

Data signed: (hfarmer1) 26 Mar 2015 13:37:59

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Screening

Form: Lab-BU-LabCorp (5)

Data signed: (hfarmer1) 26 Mar 2015 13:37:59

Generated On: 20 Jul 2016 10:56:43

Experiment Type

URINALYSIS

Date of Sample Collection
YYYY/MM/DD

17 DEC 2013

Subject Number

Date of Birth

(b) (6)

Gender

Female ☒

Time of Sample Collection

11:41

Analyte Name

OCCULT BLOOD

Code

13102

Result

TRACE

Unit

Lower limit

NEGATIVE

Upper limit

Flag

High ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Screening

Form: Lab-BU-LabCorp (5)

Data signed: (hfarmer1) 26 Mar 2015 13:37:59

Generated On: 20 Jul 2016 10:56:43

Clinically Significant?

No ☒

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: 1002**

Folder: Screening

Form: Lab-BU-LabCorp (6)

Data signed: (hfarmer1) 26 Mar 2015 13:37:59

Generated On: 20 Jul 2016 10:56:43

Experiment Type

URINALYSIS

Date of Sample Collection
YYYY/MM/DD

17 DEC 2013

Subject Number

Date of Birth

(b) (6)

Gender

Female ☒

Time of Sample Collection

11:41

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: 1002**

Folder: Screening

Form: Lab-BU-LabCorp (6)

Data signed: (hfarmer1) 26 Mar 2015 13:37:59

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Screening

Form: Lab-BU-LabCorp (7)

Data signed: (hfarmer1) 26 Mar 2015 13:37:59

Generated On: 20 Jul 2016 10:56:43

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

Date of Sample Collection YYYY/MM/DD	17 DEC 2013
---	-------------

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

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

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

Time of Sample Collection	11:41
---------------------------	-------

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: 1002**

Folder: Screening

Form: Lab-BU-LabCorp (7)

Data signed: (hfarmer1) 26 Mar 2015 13:37:59

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Screening

Form: FTND Questionnaire

Generated On: 20 Jul 2016 10:56:43

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

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

Date of assessment	2013 DEC 17
DD/MMM/YYYY	DD/MMM/YYYY

Time of assessment	13:19
	hour:min 24-hour clock

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

1. How soon after you wake up do you smoke your first cigarette?	Within 5 minutes <input checked="" type="radio"/>
--	---

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

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

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

5. Do you smoke more frequently during the first hours after awakening than during the rest of the day?	Yes <input checked="" type="radio"/>
---	--------------------------------------

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Screening

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

Data signed: (hfarmer1) 26 Mar 2015 13:37:51

Generated On: 20 Jul 2016 10:56:43

Was paper questionnaire used? Yes ☒

Reason not done _____

Type PROCHASKA STAGE OF
CHANGE QUESTIONNAIRE:
INTENTION TO QUIT
SMOKING

Date of assessment 17 DEC 2013
DD/MMM/YYYY

Time of assessment 10:17
hour:min 24-hour clock

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

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

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Admission (Day -2)

Form: Date of Visit

Data signed: (hfarmer1) 26 Mar 2015 13:38:05

Generated On: 20 Jul 2016 10:56:43

Date of Visit

14 JAN 2014
DD/MMM/YYYY

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Admission (Day -2)

Form: Inclusion Criteria

Data signed: (hfarmer1) 26 Mar 2015 13:38:02

Generated On: 20 Jul 2016 10:56:43

*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: 1002

Folder: Admission (Day -2)

Form: Inclusion Criteria (1)

Data signed: (hfarmer1) 26 Mar 2015 13:38:02

Generated On: 20 Jul 2016 10:56:43

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: 1002

Folder: Admission (Day -2)

Form: Inclusion Criteria (2)

Data signed: (hfarmer1) 26 Mar 2015 13:38:02

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Admission (Day -2)

Form: Inclusion Criteria (3)

Data signed: (hfarmer1) 26 Mar 2015 13:38:02

Generated On: 20 Jul 2016 10:56:43

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: 1002

Folder: Admission (Day -2)

Form: Inclusion Criteria (4)

Data signed: (hfarmer1) 26 Mar 2015 13:38:02

Generated On: 20 Jul 2016 10:56:43

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

Inclusion Criterion	The subject is ready to comply with study protocol (e.g readiness to accept interruptions of smoking for up to 91 days and to use THS 2.2 Menthol).	<input checked="" type="radio"/>
---------------------	--	----------------------------------

Result	Yes	<input checked="" type="radio"/>
--------	-----	----------------------------------

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Admission (Day -2)

Form: Exclusion Criteria

Data signed: (hfarmer1) 26 Mar 2015 13:38:00

Generated On: 20 Jul 2016 10:56:43

*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: 1002**

Folder: Admission (Day -2)

Form: Exclusion Criteria (1)

Data signed: (hfarmer1) 26 Mar 2015 13:38:00

Generated On: 20 Jul 2016 10:56:43

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: 1002

Folder: Admission (Day -2)

Form: Exclusion Criteria (2)

Data signed: (hfarmer1) 26 Mar 2015 13:38:00

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Admission (Day -2)

Form: Exclusion Criteria (3)

Data signed: (hfarmer1) 26 Mar 2015 13:38:00

Generated On: 20 Jul 2016 10:56:43

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

Exclusion Criterion	The subject has a body mass index (BMI) <18.5 or ≥35 kg/m2.
---------------------	---

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: 1002**

Folder: Admission (Day -2)

Form: Exclusion Criteria (4)

Data signed: (hfarmer1) 26 Mar 2015 13:38:00

Generated On: 20 Jul 2016 10:56:43

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: 1002

Folder: Admission (Day -2)

Form: Exclusion Criteria (5)

Data signed: (hfarmer1) 26 Mar 2015 13:38:00

Generated On: 20 Jul 2016 10:56:43

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: 1002

Folder: Admission (Day -2)

Form: Exclusion Criteria (6)

Data signed: (hfarmer1) 26 Mar 2015 13:38:00

Generated On: 20 Jul 2016 10:56:43

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

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

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

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

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1002

Folder: Admission (Day -2)

Form: Exclusion Criteria (7)

Data signed: (hfarmer1) 26 Mar 2015 13:38:00

Generated On: 20 Jul 2016 10:56:43

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: 1002

Folder: Admission (Day -2)

Form: Exclusion Criteria (8)

Data signed: (hfarmer1) 26 Mar 2015 13:38:00

Generated On: 20 Jul 2016 10:56:43

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

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

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

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Admission (Day -2)

Form: Exclusion Criteria (9)

Data signed: (hfarmer1) 26 Mar 2015 13:38:00

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Admission (Day -2)

Form: Exclusion Criteria (10)

Data signed: (hfarmer1) 26 Mar 2015 13:38:00

Generated On: 20 Jul 2016 10:56:43

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

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

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

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Admission (Day -2)

Form: Exclusion Criteria (11)

Data signed: (hfarmer1) 26 Mar 2015 13:38:00

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Admission (Day -2)

Form: Exclusion Criteria (12)

Data signed: (hfarmer1) 26 Mar 2015 13:38:00

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Admission (Day -2)

Form: Exclusion Criteria (13)

Data signed: (hfarmer1) 26 Mar 2015 13:38:00

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Admission (Day -2)

Form: Exclusion Criteria (14)

Data signed: (hfarmer1) 26 Mar 2015 13:38:00

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Admission (Day -2)

Form: Vital Signs

Data signed: (hfarmer1) 26 Mar 2015 13:38:05

Generated On: 20 Jul 2016 10:56:43

Were Vitals Signs assessed? Yes ☒

If No, please specify the reason: _____

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

Time of assessment 15:19
hour:min 24-hour clock

Pulse rate 57
beats per minute

Respiratory rate 12
breaths per minute

Blood Pressure (systolic) 104
mmHg

Blood Pressure (diastolic) 62
mmHg

Vital Signs Position of Subject Supine ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Admission (Day -2)

Form: Product preference

Data signed: (hfarmer1) 26 Mar 2015 13:38:05

Generated On: 20 Jul 2016 10:56:43

Which Product Arm would you prefer to be randomized
to:

mCC 

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Admission (Day -2)

Form: Advice on the risk of smoking and debriefing

Data signed: (hfarmer1) 26 Mar 2015 13:38:05

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Admission (Day -2)

Form: Physical Examination

Data signed: (hfarmer1) 26 Mar 2015 13:38:03

Generated On: 20 Jul 2016 10:56:43

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Admission (Day -2)

Form: Physical Examination (1)

Data signed: (hfarmer1) 26 Mar 2015 13:38:03

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Admission (Day -2)

Form: Physical Examination (2)

Data signed: (hfarmer1) 26 Mar 2015 13:38:03

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Admission (Day -2)

Form: Physical Examination (3)

Data signed: (hfarmer1) 26 Mar 2015 13:38:03

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Admission (Day -2)

Form: Physical Examination (4)

Data signed: (hfarmer1) 26 Mar 2015 13:38:03

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Admission (Day -2)

Form: Physical Examination (5)

Data signed: (hfarmer1) 26 Mar 2015 13:38:03

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Admission (Day -2)

Form: Physical Examination (6)

Data signed: (hfarmer1) 26 Mar 2015 13:38:03

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Admission (Day -2)

Form: Physical Examination (7)

Data signed: (hfarmer1) 26 Mar 2015 13:38:03

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Admission (Day -2)

Form: Physical Examination (8)

Data signed: (hfarmer1) 26 Mar 2015 13:38:03

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Admission (Day -2)

Form: Physical Examination (9)

Data signed: (hfarmer1) 26 Mar 2015 13:38:03

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Admission (Day -2)

Form: Physical Examination (10)

Data signed: (hfarmer1) 26 Mar 2015 13:38:03

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Admission (Day -2)

Form: Physical Examination (11)

Data signed: (hfarmer1) 26 Mar 2015 13:38:03

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Admission (Day -2)

Form: Physical Examination (12)

Data signed: (hfarmer1) 26 Mar 2015 13:38:03

Generated On: 20 Jul 2016 10:56:43

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

System Musculoskeletal ☒

Outcome Abnormal ☒

Abnormal, please specify RIGHT ELBOW DEFORMITY

Clinically significant No ☒

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Admission (Day -2)

Form: Physical Examination (13)

Data signed: (hfarmer1) 26 Mar 2015 13:38:03

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Admission (Day -2)

Form: Physical Examination (14)

Data signed: (hfarmer1) 26 Mar 2015 13:38:03

Generated On: 20 Jul 2016 10:56:43

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

System Dentition ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Admission (Day -2)

Form: Physical Examination (15)

Data signed: (hfarmer1) 26 Mar 2015 13:38:03

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Admission (Day -2)

Form: Physical Examination (16)

Data signed: (hfarmer1) 26 Mar 2015 13:38:03

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Admission (Day -2)

Form: Physical Examination (17)

Data signed: (hfarmer1) 26 Mar 2015 13:38:03

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Admission (Day -2)

Form: Physical Examination (18)

Data signed: (hfarmer1) 26 Mar 2015 13:38:03

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Admission (Day -2)

Form: Physical Examination (19)

Data signed: (hfarmer1) 26 Mar 2015 13:38:03

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Admission (Day -2)

Form: Identification of Current Cigarette Brand

Data signed: (hfarmer1) 26 Mar 2015 13:38:05

Generated On: 20 Jul 2016 10:56:43

Brand name

305 MENTHOL 100'S

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1002

Folder: Admission (Day -2)

Form: THS 2.2 menthol product test

Data signed: (hfarmer1) 26 Mar 2015 13:38:05

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Admission (Day -2)

Form: Smoking History

Data signed: (hfarmer1) 26 Mar 2015 13:38:05

Generated On: 20 Jul 2016 10:56:43

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

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

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

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Admission (Day -2)

Form: Weight

Data signed: (hfarmer1) 26 Mar 2015 13:38:05

Generated On: 20 Jul 2016 10:56:43

Measurement(s) assessed?

Yes ☒

If No, please specify the reason: _____

Time of assessment

14:55
hour:min 24-hour clock

Weight

64.3
kg

Waist circumference

33
cm

BMI

24.6

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1002

Folder: Admission (Day -2)

Form: Urine Drug Screen

Data signed: (hfarmer1) 26 Mar 2015 13:38:02

Generated On: 20 Jul 2016 10:56:43

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

If Not Done, please specify the reason: _____

Time of sample collection	14:53 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: 1002

Folder: Admission (Day -2)

Form: Urine Drug Screen (6)

Data signed: (hfarmer1) 26 Mar 2015 13:38:02

Generated On: 20 Jul 2016 10:56:43

Drug type	Result
Opiates	Negative

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Admission (Day -2)

Form: Alcohol Test

Data signed: (hfarmer1) 26 Mar 2015 13:38:02

Generated On: 20 Jul 2016 10:56:43

Was the alcohol test performed? Yes ☒

If No, please specify the reason: _____

Method used Breath test ☒

Time of assessment 14:58
hour:min 24-hour clock

Result Negative ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Admission (Day -2)

Form: Urine Pregnancy Test

Generated On: 20 Jul 2016 10:56:43

Not Done False

If Not Done, specify reason _____

Time of Test 15:14
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: 1002**

Folder: Admission (Day -2)

Form: CO Breath Test

Data signed: (hfarmer1) 26 Mar 2015 13:38:00

Generated On: 20 Jul 2016 10:56:43

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

If Not Done, please specify the reason: _____

Actual Time of Assessment	14:57
	hour:min 24-hour clock

Result	22
	ppm

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Admission (Day -2)

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

Data signed: (hfarmer1) 26 Mar 2015 13:38:05

Generated On: 20 Jul 2016 10:56:43

Was paper questionnaire used? Yes ☒

Reason not done _____

Type PROCHASKA STAGE OF
CHANGE QUESTIONNAIRE:
INTENTION TO QUIT
SMOKING

Date of assessment 14 JAN 2014
DD/MMM/YYYY

Time of assessment 14:49
hour:min 24-hour clock

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

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

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day -1)

Form: Date of Visit

Data signed: (hfarmer1) 26 Mar 2015 13:38:10

Generated On: 20 Jul 2016 10:56:43

Date of Visit

15 JAN 2014
DD/MMM/YYYY

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day -1)

Form: Vital Signs

Data signed: (hfarmer1) 26 Mar 2015 13:38:10

Generated On: 20 Jul 2016 10:56:43

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 09:25
hour:min 24-hour clock

Pulse rate 54
beats per minute

Respiratory rate 16
breaths per minute

Blood Pressure (systolic) 104
mmHg

Blood Pressure (diastolic) 59
mmHg

Vital Signs Position of Subject Supine ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day -1)

Form: CoHb Blood Sample

Data signed: (hfarmer1) 26 Mar 2015 13:38:06

Generated On: 20 Jul 2016 10:56:43

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

If Not Done, please specify the reason: _____

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

Timepoint	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: 1002**

Folder: Baseline (Day -1)

Form: CO Breath Test (1)

Data signed: (hfarmer1) 26 Mar 2015 13:38:05

Generated On: 20 Jul 2016 10:56:43

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day -1)

Form: CO Breath Test (2)

Data signed: (hfarmer1) 26 Mar 2015 13:38:05

Generated On: 20 Jul 2016 10:56:43

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	12:04
---	-------

Result(ppm)	25
-------------	----

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day -1)

Form: CO Breath Test (3)

Data signed: (hfarmer1) 26 Mar 2015 13:38:05

Generated On: 20 Jul 2016 10:56:43

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

If Not Done, please specify the reason: _____

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

Actual Time of Assessment hour:min 24-hour clock	16:05
---	-------

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day -1)

Form: CO Breath Test (4)

Data signed: (hfarmer1) 26 Mar 2015 13:38:05

Generated On: 20 Jul 2016 10:56:43

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	20:29
---	-------

Result(ppm)	35
-------------	----

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day -1)

Form: 4 hour urine collection

Data signed: (hfarmer1) 26 Mar 2015 13:38:10

Generated On: 20 Jul 2016 10:56:43

Start Time	09:50
	hour:min 24-hour clock

End Time	13:48
	hour:min 24-hour clock

Volume	257
	mL

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day -1)

Form: Sample Urine Collection (4 Hour collection)

Data signed: (hfarmer1) 26 Mar 2015 13:38:10

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Baseline (Day -1)

Form: Lab_BU_COHB (1)

Data signed: (hfarmer1) 26 Mar 2015 13:38:11

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05115150000017
----------------	----------------

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

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

Result	8.60
--------	------

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

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

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

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

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

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

Day of Visit	-1
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Celerion Study Number	AA99128-16
-----------------------	------------

Date of Collection	2014-JAN-15
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Timepoint-minutes	
-------------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day -1)

Form: Lab_BU_COHB (1)

Data signed: (hfarmer1) 26 Mar 2015 13:38:11

Generated On: 20 Jul 2016 10:56:43

Start Day (24 hour urine only)

End Day (24 hour Urine Only)

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day -1)

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)

Data signed: (hfarmer1) 26 Mar 2015 13:38:10

Generated On: 20 Jul 2016 10:56:43

Date of Birth	(b) (6)
Date of assessment DD/MMM/YYYY	2014 JAN 15 DD/MMM/YYYY
Time of assessment	20:22 hour:min 24-hour clock
Assessment Status	Completed
1. Was smoking satisfying?	A lot
2. Did cigarettes taste good?	Moderately
3. Did you enjoy the sensation in your throat and chest?	Moderately
4. Did smoking calm you down?	Moderately
5. Did smoking make you feel more awake?	Moderately
6. Did smoking make you feel less irritable?	A lot
7. Did smoking help you concentrate?	Little
8. Did smoking reduce your hunger for food?	Very little

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day -1)

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)

Data signed: (hfarmer1) 26 Mar 2015 13:38:10

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Baseline (Day -1)

Form: Behavioral Risk Factor Surveillance System Questionnaire

Data signed: (hfarmer1) 26 Mar 2015 13:38:06

Generated On: 20 Jul 2016 10:56:43

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

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

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

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

Time of assessment	20:25 hour:min 24-hour clock
--------------------	---------------------------------

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

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

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

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day -1)

Form: Behavioral Risk Factor Surveillance System Questionnaire

Data signed: (hfarmer1) 26 Mar 2015 13:38:06

Generated On: 20 Jul 2016 10:56:43

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: 1002

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ)

Data signed: (hfarmer1) 26 Mar 2015 13:38:06

Generated On: 20 Jul 2016 10:56:43

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

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

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

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

Time of assessment	20:27 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?	19 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: 1002**

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ)

Data signed: (hfarmer1) 26 Mar 2015 13:38:06

Generated On: 20 Jul 2016 10:56:43

Months

Days

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

Years

Months

Days

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

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1002

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (1)

Data signed: (hfarmer1) 26 Mar 2015 13:38:06

Generated On: 20 Jul 2016 10:56:43

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

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

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

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

Time of assessment	20:27 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?	19 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: 1002

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (1)

Data signed: (hfarmer1) 26 Mar 2015 13:38:06

Generated On: 20 Jul 2016 10:56:43

Months _____

Days _____

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

Years _____

Months _____

Days _____

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

Time

Currently (last 3 months) ☒

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

Manufactured Cigarettes
per day

18

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

Hand-rolled Cigarettes
per day

10

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (1)

Data signed: (hfarmer1) 26 Mar 2015 13:38:06

Generated On: 20 Jul 2016 10:56:43

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: 1002

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (2)

Data signed: (hfarmer1) 26 Mar 2015 13:38:06

Generated On: 20 Jul 2016 10:56:43

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

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

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

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

Time of assessment	20:27 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?	19 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: 1002

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (2)

Data signed: (hfarmer1) 26 Mar 2015 13:38:06

Generated On: 20 Jul 2016 10:56:43

Months _____

Days _____

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

Years _____

Months _____

Days _____

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

Time

1 year ago ☒

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

Manufactured Cigarettes
per day

15

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: 1002**

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (2)

Data signed: (hfarmer1) 26 Mar 2015 13:38:06

Generated On: 20 Jul 2016 10:56:43

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: 1002

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (3)

Data signed: (hfarmer1) 26 Mar 2015 13:38:06

Generated On: 20 Jul 2016 10:56:43

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

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

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

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

Time of assessment	20:27 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?	19 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: 1002**

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (3)

Data signed: (hfarmer1) 26 Mar 2015 13:38:06

Generated On: 20 Jul 2016 10:56:43

Months _____

Days _____

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

Years _____

Months _____

Days _____

7. What brand of cigarettes/hand-rolled tobacco did you predominantly smoke in the last 12 months of smoking? 305 MENTHOL 100'S

Time

5 years ago ☒

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

None ☒

Manufactured Cigarettes
per day _____

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

None ☒

Hand-rolled Cigarettes
per day _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (3)

Data signed: (hfarmer1) 26 Mar 2015 13:38:06

Generated On: 20 Jul 2016 10:56:43

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: 1002

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (4)

Data signed: (hfarmer1) 26 Mar 2015 13:38:06

Generated On: 20 Jul 2016 10:56:43

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

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

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

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

Time of assessment	20:27 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?	19 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: 1002

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (4)

Data signed: (hfarmer1) 26 Mar 2015 13:38:06

Generated On: 20 Jul 2016 10:56:43

Months _____

Days _____

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

Years _____

Months _____

Days _____

7. What brand of cigarettes/hand-rolled tobacco did you predominantly smoke in the last 12 months of smoking? 305 MENTHOL 100'S

Time

10 years ago ☒

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

None ☒

Manufactured Cigarettes
per day _____

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

None ☒

Hand-rolled Cigarettes
per day _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (4)

Data signed: (hfarmer1) 26 Mar 2015 13:38:06

Generated On: 20 Jul 2016 10:56:43

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: 1002

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (5)

Data signed: (hfarmer1) 26 Mar 2015 13:38:06

Generated On: 20 Jul 2016 10:56:43

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

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

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

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

Time of assessment	20:27 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?	19 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: 1002**

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (5)

Data signed: (hfarmer1) 26 Mar 2015 13:38:06

Generated On: 20 Jul 2016 10:56:43

Months

Days

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

Years

Months

Days

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

Time

15 years ago ☒

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

None ☒

Manufactured Cigarettes
per day

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

None ☒

Hand-rolled Cigarettes
per day

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (5)

Data signed: (hfarmer1) 26 Mar 2015 13:38:06

Generated On: 20 Jul 2016 10:56:43

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: 1002

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (6)

Data signed: (hfarmer1) 26 Mar 2015 13:38:06

Generated On: 20 Jul 2016 10:56:43

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

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

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

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

Time of assessment	20:27 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?	19 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: 1002**

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (6)

Data signed: (hfarmer1) 26 Mar 2015 13:38:06

Generated On: 20 Jul 2016 10:56:43

Months _____

Days _____

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

Years _____

Months _____

Days _____

7. What brand of cigarettes/hand-rolled tobacco did you predominantly smoke in the last 12 months of smoking? 305 MENTHOL 100'S

Time

20 years ago ☒

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

None ☒

Manufactured Cigarettes
per day _____

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

None ☒

Hand-rolled Cigarettes
per day _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (6)

Data signed: (hfarmer1) 26 Mar 2015 13:38:06

Generated On: 20 Jul 2016 10:56:43

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: 1002

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (7)

Data signed: (hfarmer1) 26 Mar 2015 13:38:06

Generated On: 20 Jul 2016 10:56:43

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

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

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

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

Time of assessment	20:27 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?	19 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: 1002**

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (7)

Data signed: (hfarmer1) 26 Mar 2015 13:38:06

Generated On: 20 Jul 2016 10:56:43

Months _____

Days _____

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

Years _____

Months _____

Days _____

7. What brand of cigarettes/hand-rolled tobacco did you predominantly smoke in the last 12 months of smoking? 305 MENTHOL 100'S

Time

More than 20 years ago ☒

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

None ☐

Manufactured Cigarettes
per day _____

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

None ☐

Hand-rolled Cigarettes
per day _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (7)

Data signed: (hfarmer1) 26 Mar 2015 13:38:06

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Baseline (Day -1)

Form: Supplemental Questions

Data signed: (hfarmer1) 26 Mar 2015 13:38:09

Generated On: 20 Jul 2016 10:56:43

Was paper questionnaire used?

Yes ☒

Reason not done

Date of Assessment

15 JAN 2014
DD/MMM/YYYY

Time of assessment

20:28

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

02 minutes

Comments (open-end)

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day -1)

Form: Supplemental Questions (1)

Data signed: (hfarmer1) 26 Mar 2015 13:38:09

Generated On: 20 Jul 2016 10:56:43

Was paper questionnaire used? Yes ☒

Reason not done _____

Date of Assessment 15 JAN 2014
DD/MMM/YYYY

Time of assessment 20:28

1. How long it takes for the subject to complete the SQ 02 minutes

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

Answer No ☒

Comments (open-end) _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day -1)

Form: Supplemental Questions (2)

Data signed: (hfarmer1) 26 Mar 2015 13:38:09

Generated On: 20 Jul 2016 10:56:43

Was paper questionnaire used? Yes ☐

Reason not done _____

Date of Assessment 15 JAN 2014
DD/MMM/YYYY

Time of assessment 20:28

1. How long it takes for the subject to complete the SQ 02 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: 1002**

Folder: Baseline (Day -1)

Form: Supplemental Questions (3)

Data signed: (hfarmer1) 26 Mar 2015 13:38:09

Generated On: 20 Jul 2016 10:56:43

Was paper questionnaire used? Yes ☐

Reason not done _____

Date of Assessment 15 JAN 2014
DD/MMM/YYYY

Time of assessment 20:28

1. How long it takes for the subject to complete the SQ 02 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: 1002**

Folder: Baseline (Day -1)

Form: Supplemental Questions (4)

Data signed: (hfarmer1) 26 Mar 2015 13:38:09

Generated On: 20 Jul 2016 10:56:43

Was paper questionnaire used? Yes ☐

Reason not done _____

Date of Assessment 15 JAN 2014
DD/MMM/YYYY

Time of assessment 20:28

1. How long it takes for the subject to complete the SQ 02 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: 1002**

Folder: Baseline (Day -1)

Form: Supplemental Questions (5)

Data signed: (hfarmer1) 26 Mar 2015 13:38:09

Generated On: 20 Jul 2016 10:56:43

Was paper questionnaire used? Yes ☐

Reason not done _____

Date of Assessment 15 JAN 2014
DD/MMM/YYYY

Time of assessment 20:28

1. How long it takes for the subject to complete the SQ 02 minutes

Question 6. Was the SQ self-explaining? ☐

Answer Yes ☐

Comments (open-end) _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day -1)

Form: Supplemental Questions (6)

Data signed: (hfarmer1) 26 Mar 2015 13:38:09

Generated On: 20 Jul 2016 10:56:43

Was paper questionnaire used? Yes ☐

Reason not done _____

Date of Assessment 15 JAN 2014
DD/MMM/YYYY

Time of assessment 20:28

1. How long it takes for the subject to complete the SQ 02 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: 1002**

Folder: Baseline (Day -1)

Form: Questionnaire on smoking urges (QSU)

Data signed: (hfarmer1) 26 Mar 2015 13:38:11

Generated On: 20 Jul 2016 10:56:43

Type	QSU
Date of Birth	(b) (6)
Date of assessment DD/MMM/YYYY	2014 JAN 15
Time of assessment hour:min 24-hour clock	20:21
Assessment Status	Completed <input type="radio"/>
1. I have a desire for a cigarette right now	Disagree <input type="radio"/>
2. Nothing would be better than smoking a cigarette right now	Disagree <input type="radio"/>
3. If it were possible I would probably smoke now	Disagree <input type="radio"/>
4. I could control things better right now if I could smoke	Disagree <input type="radio"/>
5. All I want right now is a cigarette	Disagree <input type="radio"/>
6. I have an urge for a cigarette	Disagree <input type="radio"/>

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day -1)

Form: Questionnaire on smoking urges (QSU)

Data signed: (hfarmer1) 26 Mar 2015 13:38:11

Generated On: 20 Jul 2016 10:56:43

7. A cigarette would taste good now Disagree ☐

8. I would do almost anything for a cigarette now Disagree ☐

9. Smoking would make me less depressed Disagree ☐

10. I am going to smoke as soon as possible Disagree ☐

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day -1)

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

Data signed: (hfarmer1) 26 Mar 2015 13:38:12

Generated On: 20 Jul 2016 10:56:43

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day -1)

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

Data signed: (hfarmer1) 26 Mar 2015 13:38:12

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05112450000012
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Analyte	HPMA
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Sample type	URINE
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Result	732
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Result Unit	NG/ML
-------------	-------

Lab Status	OK
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Sample comment	
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Detection method	LC-MS/MS
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Planned time point (Hour)	0
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Day of Visit	-1
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Celerion Study Number	AA99128-03
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Date of Collection	2014-JAN-15
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Timepoint-minutes	
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Urine Start Day	
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day -1)

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

Data signed: (hfarmer1) 26 Mar 2015 13:38:12

Generated On: 20 Jul 2016 10:56:43

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (2)

Data signed: (hfarmer1) 26 Mar 2015 13:38:12

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05112450000012
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Analyte	CEMA
---------	------

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

Result	186
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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	-1
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Celerion Study Number	AA99128-03
-----------------------	------------

Date of Collection	2014-JAN-15
--------------------	-------------

Timepoint-minutes	
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Urine Start Day	
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (2)

Data signed: (hfarmer1) 26 Mar 2015 13:38:12

Generated On: 20 Jul 2016 10:56:43

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (3)

Data signed: (hfarmer1) 26 Mar 2015 13:38:12

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05112450000012
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Analyte	HBMA
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Sample type	URINE
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Result	290
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Result Unit	NG/ML
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Lab Status	OK
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Sample comment	
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Detection method	LC-MS/MS
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Planned time point (Hour)	0
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Day of Visit	-1
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Celerion Study Number	AA99128-03
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Date of Collection	2014-JAN-15
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Timepoint-minutes	
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Urine Start Day	
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (3)

Data signed: (hfarmer1) 26 Mar 2015 13:38:12

Generated On: 20 Jul 2016 10:56:43

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (NNN, NNAL)

Data signed: (hfarmer1) 26 Mar 2015 13:38:11

Generated On: 20 Jul 2016 10:56:43

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (NNN, NNAL) (1)

Data signed: (hfarmer1) 26 Mar 2015 13:38:11

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05112460000012
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Analyte	NNAL
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Sample type	URINE
-------------	-------

Result	790
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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
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Day of Visit	-1
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Celerion Study Number	AA99128-04
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Date of Collection	2014-JAN-15
--------------------	-------------

Timepoint-minutes	
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Urine Start Day	
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (NNN, NNAL) (1)

Data signed: (hfarmer1) 26 Mar 2015 13:38:11

Generated On: 20 Jul 2016 10:56:43

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (NNN, NNAL) (2)

Data signed: (hfarmer1) 26 Mar 2015 13:38:11

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05112460000012
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Analyte	NNN
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Sample type	URINE
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Result	10.7
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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
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Planned time point (Hour)	0
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Day of Visit	-1
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Celerion Study Number	AA99128-04
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Date of Collection	2014-JAN-15
--------------------	-------------

Timepoint-minutes	
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Urine Start Day	
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (NNN, NNAL) (2)

Data signed: (hfarmer1) 26 Mar 2015 13:38:11

Generated On: 20 Jul 2016 10:56:43

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (HEMA)

Data signed: (hfarmer1) 26 Mar 2015 13:38:11

Generated On: 20 Jul 2016 10:56:43

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (HEMA) (1)

Data signed: (hfarmer1) 26 Mar 2015 13:38:11

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05112470000507
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Analyte	HEMA
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Sample type	URINE
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Result	9.28
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Result Unit	NG/ML
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Lab Status	OK
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Sample comment	
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Detection method	LC-MS/MS
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Planned time point (Hour)	0
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Day of Visit	-1
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Celerion Study Number	AA99128-05
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Date of Collection	2014-JAN-15
--------------------	-------------

Timepoint-minutes	
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Urine Start Day	
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (HEMA) (1)

Data signed: (hfarmer1) 26 Mar 2015 13:38:11

Generated On: 20 Jul 2016 10:56:43

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day -1)

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

Data signed: (hfarmer1) 26 Mar 2015 13:38:13

Generated On: 20 Jul 2016 10:56:43

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day -1)

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

Data signed: (hfarmer1) 26 Mar 2015 13:38:13

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05112480000012
Analyte	COT
Sample type	URINE
Result	1090
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-JAN-15
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day -1)

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

Data signed: (hfarmer1) 26 Mar 2015 13:38:13

Generated On: 20 Jul 2016 10:56:43

Urine Start Day

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day -1)

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

Data signed: (hfarmer1) 26 Mar 2015 13:38:13

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05112480000012
Analyte	COT-GLUC
Sample type	URINE
Result	8000
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-JAN-15
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day -1)

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

Data signed: (hfarmer1) 26 Mar 2015 13:38:13

Generated On: 20 Jul 2016 10:56:43

Urine Start Day

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day -1)

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(3)**

Data signed: (hfarmer1) 26 Mar 2015 13:38:13

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05112480000012
Analyte	NIC
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	-1
Celerion Study Number	AA99128-06
Date of Collection	2014-JAN-15
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day -1)

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(3)**

Data signed: (hfarmer1) 26 Mar 2015 13:38:13

Generated On: 20 Jul 2016 10:56:43

Urine Start Day

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day -1)

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

Data signed: (hfarmer1) 26 Mar 2015 13:38:13

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05112480000012
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Analyte	NIC-GLUC
---------	----------

Sample type	URINE
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Result	647
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Result Unit	NG/ML
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Lab Status	OK
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Sample comment	
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Detection method	LC-MS/MS
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Planned time point (Hour)	0
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Day of Visit	-1
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Celerion Study Number	AA99128-06
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Date of Collection	2014-JAN-15
--------------------	-------------

Timepoint-minutes	
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day -1)

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

Data signed: (hfarmer1) 26 Mar 2015 13:38:13

Generated On: 20 Jul 2016 10:56:43

Urine Start Day

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day -1)

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

Data signed: (hfarmer1) 26 Mar 2015 13:38:13

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05112480000012
Analyte	THCOT
Sample type	URINE
Result	4550
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-JAN-15
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day -1)

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

Data signed: (hfarmer1) 26 Mar 2015 13:38:13

Generated On: 20 Jul 2016 10:56:43

Urine Start Day

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day -1)

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

Data signed: (hfarmer1) 26 Mar 2015 13:38:13

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05112480000012
Analyte	THCOT-GLUC
Sample type	URINE
Result	4560
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-JAN-15
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day -1)

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

Data signed: (hfarmer1) 26 Mar 2015 13:38:13

Generated On: 20 Jul 2016 10:56:43

Urine Start Day

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (3-OH BaP)

Data signed: (hfarmer1) 26 Mar 2015 13:38:14

Generated On: 20 Jul 2016 10:56:43

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (3-OH BaP) (1)

Data signed: (hfarmer1) 26 Mar 2015 13:38:14

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05112490000507
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Analyte	3-OH BAP
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Sample type	URINE
-------------	-------

Result	532
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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	-1
--------------	----

Celerion Study Number	AA99128-07
-----------------------	------------

Date of Collection	2014-JAN-15
--------------------	-------------

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

Urine Start Day	
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (3-OH BaP) (1)

Data signed: (hfarmer1) 26 Mar 2015 13:38:14

Generated On: 20 Jul 2016 10:56:43

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP)

Data signed: (hfarmer1) 26 Mar 2015 13:38:14

Generated On: 20 Jul 2016 10:56:43

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (1)

Data signed: (hfarmer1) 26 Mar 2015 13:38:14

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05112510000012
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Analyte	1-NA
---------	------

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

Result	77.8
--------	------

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-JAN-15
--------------------	-------------

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

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (1)

Data signed: (hfarmer1) 26 Mar 2015 13:38:14

Generated On: 20 Jul 2016 10:56:43

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (2)

Data signed: (hfarmer1) 26 Mar 2015 13:38:14

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05112510000012
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Analyte	2-NA
---------	------

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

Result	29.7
--------	------

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-JAN-15
--------------------	-------------

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

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (2)

Data signed: (hfarmer1) 26 Mar 2015 13:38:14

Generated On: 20 Jul 2016 10:56:43

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (3)

Data signed: (hfarmer1) 26 Mar 2015 13:38:14

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05112510000012
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Analyte	4-ABP
---------	-------

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

Result	15.3
--------	------

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	-1
--------------	----

Celerion Study Number	AA99128-09
-----------------------	------------

Date of Collection	2014-JAN-15
--------------------	-------------

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

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (3)

Data signed: (hfarmer1) 26 Mar 2015 13:38:14

Generated On: 20 Jul 2016 10:56:43

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (4)

Data signed: (hfarmer1) 26 Mar 2015 13:38:14

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05112510000012
Analyte	O-TOL
Sample type	URINE
Result	166
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-JAN-15
Timepoint-minutes	
Urine Start Day	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (4)

Data signed: (hfarmer1) 26 Mar 2015 13:38:14

Generated On: 20 Jul 2016 10:56:43

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (11-dTXb2)

Data signed: (hfarmer1) 26 Mar 2015 13:38:11

Generated On: 20 Jul 2016 10:56:43

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (11-dTXb2) (1)

Data signed: (hfarmer1) 26 Mar 2015 13:38:11

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05112530000008
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Analyte	11-DTXB2
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Sample type	URINE
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Result	1150
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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	-1
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Celerion Study Number	AA99128-11
-----------------------	------------

Date of Collection	2014-JAN-15
--------------------	-------------

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

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (11-dTXb2) (1)

Data signed: (hfarmer1) 26 Mar 2015 13:38:11

Generated On: 20 Jul 2016 10:56:43

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (iPF2a-III)

Data signed: (hfarmer1) 26 Mar 2015 13:38:11

Generated On: 20 Jul 2016 10:56:43

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (iPF2a-III) (1)

Data signed: (hfarmer1) 26 Mar 2015 13:38:11

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05112540000008
----------------	----------------

Analyte	IPF2A-III
---------	-----------

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

Result	190
--------	-----

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-JAN-15
--------------------	-------------

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

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (iPF2a-III) (1)

Data signed: (hfarmer1) 26 Mar 2015 13:38:11

Generated On: 20 Jul 2016 10:56:43

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (1-OHP)

Data signed: (hfarmer1) 26 Mar 2015 13:38:14

Generated On: 20 Jul 2016 10:56:43

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (1-OHP) (1)

Data signed: (hfarmer1) 26 Mar 2015 13:38:14

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05115190001101
----------------	----------------

Analyte	1-OHP
---------	-------

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

Result	146
--------	-----

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-JAN-15
--------------------	-------------

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

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (1-OHP) (1)

Data signed: (hfarmer1) 26 Mar 2015 13:38:14

Generated On: 20 Jul 2016 10:56:43

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (SPMA, SBMA)

Data signed: (hfarmer1) 26 Mar 2015 13:38:11

Generated On: 20 Jul 2016 10:56:43

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (SPMA, SBMA) (1)

Data signed: (hfarmer1) 26 Mar 2015 13:38:11

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05115170003203
----------------	----------------

Analyte	SBMA
---------	------

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

Result	3.67
--------	------

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-JAN-15
--------------------	-------------

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

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (SPMA, SBMA) (1)

Data signed: (hfarmer1) 26 Mar 2015 13:38:11

Generated On: 20 Jul 2016 10:56:43

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (SPMA, SBMA) (2)

Data signed: (hfarmer1) 26 Mar 2015 13:38:11

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05115170003203
----------------	----------------

Analyte	SPMA
---------	------

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

Result	3.09
--------	------

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-JAN-15
--------------------	-------------

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

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (SPMA, SBMA) (2)

Data signed: (hfarmer1) 26 Mar 2015 13:38:11

Generated On: 20 Jul 2016 10:56:43

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (MHBMA)

Data signed: (hfarmer1) 26 Mar 2015 13:38:12

Generated On: 20 Jul 2016 10:56:43

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (MHBMA) (1)

Data signed: (hfarmer1) 26 Mar 2015 13:38:12

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05115180000012
----------------	----------------

Analyte	MHBMA
---------	-------

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

Result	1.52
--------	------

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-JAN-15
--------------------	-------------

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

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (MHBMA) (1)

Data signed: (hfarmer1) 26 Mar 2015 13:38:12

Generated On: 20 Jul 2016 10:56:43

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (Creatinine)

Data signed: (hfarmer1) 26 Mar 2015 13:38:14

Generated On: 20 Jul 2016 10:56:43

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (Creatinine) (1)

Data signed: (hfarmer1) 26 Mar 2015 13:38:14

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05115160000012
----------------	----------------

Analyte	CREATININE
---------	------------

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

Result	75.7
--------	------

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-JAN-15
--------------------	-------------

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

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (Creatinine) (1)

Data signed: (hfarmer1) 26 Mar 2015 13:38:14

Generated On: 20 Jul 2016 10:56:43

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day 0)

Form: Date of Visit

Data signed: (hfarmer1) 26 Mar 2015 13:38:16

Generated On: 20 Jul 2016 10:56:43

Date of Visit

16 JAN 2014
DD/MMM/YYYY

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day 0)

Form: Randomization

Data signed: (hfarmer1) 26 Mar 2015 13:38:16

Generated On: 20 Jul 2016 10:56:43

Randomization number (4 digits)	3002
---------------------------------	------

Allocation Arm	mCC <input checked="" type="radio"/>
----------------	--------------------------------------

Cigarette Consumption	10 – 19 conventional menthol cigarettesper day <input checked="" type="radio"/>
-----------------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day 0)

Form: Vital Signs

Data signed: (hfarmer1) 26 Mar 2015 13:38:16

Generated On: 20 Jul 2016 10:56:43

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 10:10
hour:min 24-hour clock

Pulse rate 75
beats per minute

Respiratory rate 14
breaths per minute

Blood Pressure (systolic) 105
mmHg

Blood Pressure (diastolic) 67
mmHg

Vital Signs Position of Subject Supine ☒

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1002

Folder: Baseline (Day 0)

Form: Gas Transfer

Data signed: (hfarmer1) 26 Mar 2015 13:38:15

Generated On: 20 Jul 2016 10:56:43

Was the Gas Transfer performed? Yes ☒

If No, please specify the reason: _____

Category _____

Position SITTING

Time of assessment 06:35

DLCO value 17.17
ml/min/mmHg

KCO value 1.11
mmol/min/kPa/L

DLCO/VA value 3.33
mL/min/mmHg/L

Interpretation Abnormal ☒

If Abnormal, Clinical Significance Not clinically significant ☒

If Not Clinically Significant or Clinically Significant, Please MILD DECREASE IN DLCO specify the finding(s)

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1002

Folder: Baseline (Day 0)

Form: Lung Volume Measurements

Data signed: (hfarmer1) 26 Mar 2015 13:38:15

Generated On: 20 Jul 2016 10:56:43

Were the Lung Volume Measurements performed? Yes ☒

If No, please specify the reason: _____

Category _____

Position SITTING

Time of assessment 06:52

VC value 4.47
L

TLC value 5.36
L

IC value 2.85
L

FRC value 2.51
L

Interpretation Abnormal ☒

If Abnormal, Clinical Significance Not clinically significant ☒

If Not Clinically Significant or Clinically Significant, Please specify the finding(s) MILD DECREASE IN RESIDUAL VOLUME (RV)

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1002

Folder: Baseline (Day 0)

Form: Spirometry with a short-acting bronchodilator

Data signed: (hfarmer1) 26 Mar 2015 13:38:16

Generated On: 20 Jul 2016 10:56:43

Was the Spirometry with a short-acting bronchodilator performed?	Yes <input checked="" type="radio"/>
--	--------------------------------------

If No, please specify the reason:	<hr/>
-----------------------------------	-------

Category	With short-acting bronchodilator <input checked="" type="radio"/>
----------	---

Position	SITTING
----------	---------

Time of assessment	07:30
--------------------	-------

Name of bronchodilator	ALBUTEROL SULFATE
------------------------	-------------------

Dose	180 MCG
------	---------

Predicted FVC value	3.76 L
---------------------	-----------

Best measured FVC value	4.47 L
-------------------------	-----------

Percent of predicted FVC value	120 %
--------------------------------	----------

Best measured FEV1 value	3.08 L
--------------------------	-----------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day 0)

Form: Spirometry with a short-acting bronchodilator

Data signed: (hfarmer1) 26 Mar 2015 13:38:16

Generated On: 20 Jul 2016 10:56:43

Predicted FEV1 value	3.26 L
----------------------	-----------

Percent of predicted FEV1 value	104 %
---------------------------------	----------

Calculated ratio between FEV1/FVC	_____
-----------------------------------	-------

MEF 25/75 value	2.14 L/s
-----------------	-------------

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

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

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day 0)

Form: Haematology

Data signed: (hfarmer1) 26 Mar 2015 13:38:15

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Baseline (Day 0)

Form: Clinical Chemistry

Data signed: (hfarmer1) 26 Mar 2015 13:38:15

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Baseline (Day 0)

Form: Urine analysis

Data signed: (hfarmer1) 26 Mar 2015 13:38:15

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Baseline (Day 0)

Form: Plasma Nicotine Sample

Data signed: (hfarmer1) 26 Mar 2015 13:38:15

Generated On: 20 Jul 2016 10:56:43

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

If Not Done, please specify the reason: _____

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

Time hour:min 24-hour clock	20:34
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day 0)

Form: Plasma Cotinine Sample

Data signed: (hfarmer1) 26 Mar 2015 13:38:15

Generated On: 20 Jul 2016 10:56:43

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

If Not Done, please specify the reason: _____

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

Time hour:min 24-hour clock	20:34
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day 0)

Form: CoHb Blood Sample <D0> (1)

Data signed: (hfarmer1) 26 Mar 2015 13:38:15

Generated On: 20 Jul 2016 10:56:43

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

If Not Done, please specify the reason: _____

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

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

Time hour:min 24-hour clock	05:31
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day 0)

Form: CoHb Blood Sample <D0> (2)

Data signed: (hfarmer1) 26 Mar 2015 13:38:15

Generated On: 20 Jul 2016 10:56:43

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

If Not Done, please specify the reason: _____

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

Timepoint	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: 1002**

Folder: Baseline (Day 0)

Form: Oxysterols

Data signed: (hfarmer1) 26 Mar 2015 13:38:15

Generated On: 20 Jul 2016 10:56:43

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	16 JAN 2014
---------------------	-------------

Time hour:min 24-hour clock	05:31
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day 0)

Form: CO Breath Test (1)

Data signed: (hfarmer1) 26 Mar 2015 13:38:14

Generated On: 20 Jul 2016 10:56:43

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	07:40
---	-------

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day 0)

Form: CO Breath Test (2)

Data signed: (hfarmer1) 26 Mar 2015 13:38:14

Generated On: 20 Jul 2016 10:56:43

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	12:04
---	-------

Result(ppm)	43
-------------	----

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day 0)

Form: CO Breath Test (3)

Data signed: (hfarmer1) 26 Mar 2015 13:38:14

Generated On: 20 Jul 2016 10:56:43

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)	40
-------------	----

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day 0)

Form: CO Breath Test (4)

Data signed: (hfarmer1) 26 Mar 2015 13:38:14

Generated On: 20 Jul 2016 10:56:43

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	20:24
---	-------

Result(ppm)	48
-------------	----

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1002

Folder: Baseline (Day 0)

Form: CYP2A6 activity Sample

Data signed: (hfarmer1) 26 Mar 2015 13:38:15

Generated On: 20 Jul 2016 10:56:43

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

If Not Done, please specify the reason: _____

Date of sample collection
DD/MMM/YYYY

Time of sample collection
hour:min 24-hour clock

Parameter

16 JAN 2014

05:31

trans-3'-hydroxyc
otinine

16 JAN 2014

05:31

cotinine

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1002

Folder: Baseline (Day 0)

Form: CYP1A2 activity Sample

Data signed: (hfarmer1) 26 Mar 2015 13:38:15

Generated On: 20 Jul 2016 10:56:43

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
16 JAN 2014	16:04	Caffeine
16 JAN 2014	16:04	Paraxanthine

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day 0)

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

Data signed: (hfarmer1) 26 Mar 2015 13:38:15

Generated On: 20 Jul 2016 10:56:43

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

If Not Done, please specify the reason: _____

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

Time hour:min 24-hour clock	05:31
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day 0)

Form: 24 hour urine collections

Data signed: (hfarmer1) 26 Mar 2015 13:38:16

Generated On: 20 Jul 2016 10:56:43

Start Date	16 JAN 2014 DD/MMM/YYYY
------------	----------------------------

Start Time	06:07 hour:min 24-hour clock
------------	---------------------------------

End Date	17 JAN 2014 DD/MMM/YYYY
----------	----------------------------

End Time	06:26 hour:min 24-hour clock
----------	---------------------------------

Volume	1972 mL
--------	------------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day 0)

Form: Sample Urine Collection

Data signed: (hfarmer1) 26 Mar 2015 13:38:16

Generated On: 20 Jul 2016 10:56:43

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: 1002

Folder: Baseline (Day 0)

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Data signed: (hfarmer1) 26 Mar 2015 13:38:17

Generated On: 20 Jul 2016 10:56:43

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

Date of assessment DD/MMM/YYYY	2014 JAN 16 DD/MMM/YYYY
-----------------------------------	----------------------------

Time of assessment	05:51 hour:min 24-hour clock
--------------------	---------------------------------

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

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

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

1. Angry, irritable, frustrated

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

2. Anxious, nervous

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

3. Depressed Mood, sad

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

4. Desire or craving to smoke

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day 0)

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Data signed: (hfarmer1) 26 Mar 2015 13:38:17

Generated On: 20 Jul 2016 10:56:43

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? Slight ☐

7. Insomnia, sleep problems, awakening at night

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

8. Restless

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

9. Impatient

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

10. Constipation

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

11. Dizziness

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

12. Coughing

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day 0)

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Data signed: (hfarmer1) 26 Mar 2015 13:38:17

Generated On: 20 Jul 2016 10:56:43

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?

Mild ☐

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: 1002

Folder: Baseline (Day 0)

Form: Cough Assessment

Data signed: (hfarmer1) 26 Mar 2015 13:38:18

Generated On: 20 Jul 2016 10:56:43

Date of Birth

(b) (6)

Date of assessment
DD/MMM/YYYY

2014 JAN 16
DD/MMM/YYYY

Time of assessment

05:49
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?

24

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

Mild ☒

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

Sometimes ☒

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: 1002**

Folder: Baseline (Day 0)

Form: Bio-banking (Transcriptomics)

Data signed: (hfarmer1) 26 Mar 2015 13:38:17

Generated On: 20 Jul 2016 10:56:43

Was a Bio-banking sample for transcriptomics taken?

Yes ☒

Time of Sample Collection

05:31
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: 1002**

Folder: Baseline (Day 0)

Form: Bio-banking (Biomarkers of exposure and risk markers)

Data signed: (hfarmer1) 26 Mar 2015 13:38:16

Generated On: 20 Jul 2016 10:56:43

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

Yes ☒

Time of Sample Collection

05:31
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: 1002**

Folder: Baseline (Day 0)

Form: Bio-banking (nasal epithelial collection/buccal collection)

Data signed: (hfarmer1) 26 Mar 2015 13:38:17

Generated On: 20 Jul 2016 10:56:43

Was a Bio-banking sample for nasal epithelial collection/buccal collection taken?	Yes <input checked="" type="radio"/>
---	--------------------------------------

Time of Buccal Collection	17:35
	hour:min 24-hour clock

Time of Nasal Epithelial Collection	17:32
	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: 1002**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (1)

Data signed: (hfarmer1) 26 Mar 2015 13:38:18

Generated On: 20 Jul 2016 10:56:43

Transmission Type Cumulative ☐

Subject ID or Number _____

Subject Sex F

Subject Date of Birth (b) (6) 

Visit Name _____

Visit Type Scheduled ☐

Accession ID V225571

Actual Collection Date 2014 01 16

Actual Collection Time 05:31

Specimen Condition _____

Battery ID RC1029

Battery Name TRIGLYCERIDES

Lab Test ID RCT19

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (1)

Data signed: (hfarmer1) 26 Mar 2015 13:38:18

Generated On: 20 Jul 2016 10:56:43

Lab Test Name	TRIGLYCERIDES (GPO)
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	154
Reported Numeric Result	154
Reference Range low	36
Reference Range high	144
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: 1002**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (1)

Data signed: (hfarmer1) 26 Mar 2015 13:38:18

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (2)

Data signed: (hfarmer1) 26 Mar 2015 13:38:18

Generated On: 20 Jul 2016 10:56:43

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex F

Subject Date of Birth (b) (6) 

Visit Name _____

Visit Type Scheduled ☒

Accession ID V225571

Actual Collection Date 2014 01 16

Actual Collection Time 05:31

Specimen Condition _____

Battery ID RC1092

Battery Name FASTING GLUCOSE

Lab Test ID RCT142

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (2)

Data signed: (hfarmer1) 26 Mar 2015 13:38:18

Generated On: 20 Jul 2016 10:56:43

Lab Test Name	FASTING GLUCOSE
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	83
Reported Numeric Result	83
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: 1002**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (2)

Data signed: (hfarmer1) 26 Mar 2015 13:38:18

Generated On: 20 Jul 2016 10:56:43

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (3)

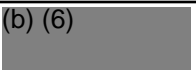
Data signed: (hfarmer1) 26 Mar 2015 13:38:18

Generated On: 20 Jul 2016 10:56:43

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex F

Subject Date of Birth (b) (6) 

Visit Name _____

Visit Type Scheduled ☒

Accession ID V225571

Actual Collection Date 2014 01 16

Actual Collection Time 05:31

Specimen Condition _____

Battery ID RC272

Battery Name TOTAL CHOLESTEROL

Lab Test ID RCT20

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (3)

Data signed: (hfarmer1) 26 Mar 2015 13:38:18

Generated On: 20 Jul 2016 10:56:43

Lab Test Name	CHOLESTEROL (HIGH PERFORMANCE)
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	217
Reported Numeric Result	217
Reference Range low	128
Reference Range high	218
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: 1002**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (3)

Data signed: (hfarmer1) 26 Mar 2015 13:38:18

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (4)

Data signed: (hfarmer1) 26 Mar 2015 13:38:18

Generated On: 20 Jul 2016 10:56:43

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	V225571
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Actual Collection Date	2014 01 16
------------------------	------------

Actual Collection Time	05:31
------------------------	-------

Specimen Condition	<hr/>
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Battery ID	RC9255
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Battery Name	CHEMISTRY PANEL
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Lab Test ID	RCT1
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (4)

Data signed: (hfarmer1) 26 Mar 2015 13:38:18

Generated On: 20 Jul 2016 10:56:43

Lab Test Name	TOTAL BILIRUBIN
Test ID	
Test Status	Done <input checked="" 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: 1002**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (4)

Data signed: (hfarmer1) 26 Mar 2015 13:38:18

Generated On: 20 Jul 2016 10:56:43

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (5)

Data signed: (hfarmer1) 26 Mar 2015 13:38:18

Generated On: 20 Jul 2016 10:56:43

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex F

Subject Date of Birth (b) (6)

Visit Name _____

Visit Type Scheduled ☒

Accession ID V225571

Actual Collection Date 2014 01 16

Actual Collection Time 05:31

Specimen Condition _____

Battery ID RC9255

Battery Name CHEMISTRY PANEL

Lab Test ID RCT12

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (5)

Data signed: (hfarmer1) 26 Mar 2015 13:38:18

Generated On: 20 Jul 2016 10:56:43

Lab Test Name	TOTAL PROTEIN
Test ID	
Test Status	Done <input type="checkbox"/>
Reported Text Result	7.4
Reported Numeric Result	7.4
Reference Range low	6.1
Reference Range high	8.4
Range Units	G/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (5)

Data signed: (hfarmer1) 26 Mar 2015 13:38:18

Generated On: 20 Jul 2016 10:56:43

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (6)

Data signed: (hfarmer1) 26 Mar 2015 13:38:18

Generated On: 20 Jul 2016 10:56:43

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex F

Subject Date of Birth (b) (6) 

Visit Name _____

Visit Type Scheduled ☒

Accession ID V225571

Actual Collection Date 2014 01 16

Actual Collection Time 05:31

Specimen Condition _____

Battery ID RC9255

Battery Name CHEMISTRY PANEL

Lab Test ID RCT13

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (6)

Data signed: (hfarmer1) 26 Mar 2015 13:38:18

Generated On: 20 Jul 2016 10:56:43

Lab Test Name	ALBUMIN
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	4.2
Reported Numeric Result	4.2
Reference Range low	3.3
Reference Range high	4.9
Range Units	G/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (6)

Data signed: (hfarmer1) 26 Mar 2015 13:38:18

Generated On: 20 Jul 2016 10:56:43

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (7)

Data signed: (hfarmer1) 26 Mar 2015 13:38:18

Generated On: 20 Jul 2016 10:56:43

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex F

Subject Date of Birth (b) (6) ☒

Visit Name _____

Visit Type Scheduled ☒

Accession ID V225571

Actual Collection Date 2014 01 16

Actual Collection Time 05:31

Specimen Condition _____

Battery ID RC9255

Battery Name CHEMISTRY PANEL

Lab Test ID RCT1407

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (7)

Data signed: (hfarmer1) 26 Mar 2015 13:38:18

Generated On: 20 Jul 2016 10:56:43

Lab Test Name	ALKALINE PHOSPHATASE
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	78
Reported Numeric Result	78
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: 1002**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (7)

Data signed: (hfarmer1) 26 Mar 2015 13:38:18

Generated On: 20 Jul 2016 10:56:43

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (8)

Data signed: (hfarmer1) 26 Mar 2015 13:38:18

Generated On: 20 Jul 2016 10:56:43

Transmission Type Cumulative ☒

Subject ID or Number

Subject Sex F

Subject Date of Birth (b) (6) 

Visit Name

Visit Type Scheduled ☒

Accession ID V225571

Actual Collection Date 2014 01 16

Actual Collection Time 05:31

Specimen Condition

Battery ID RC9255

Battery Name CHEMISTRY PANEL

Lab Test ID RCT1408

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (8)

Data signed: (hfarmer1) 26 Mar 2015 13:38:18

Generated On: 20 Jul 2016 10:56:43

Lab Test Name	LDH
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	108
Reported Numeric Result	108
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: 1002**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (8)

Data signed: (hfarmer1) 26 Mar 2015 13:38:18

Generated On: 20 Jul 2016 10:56:43

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (9)

Data signed: (hfarmer1) 26 Mar 2015 13:38:18

Generated On: 20 Jul 2016 10:56:43

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex F

Subject Date of Birth (b) (6) _____

Visit Name _____

Visit Type Scheduled ☒

Accession ID V225571

Actual Collection Date 2014 01 16

Actual Collection Time 05:31

Specimen Condition _____

Battery ID RC9255

Battery Name CHEMISTRY PANEL

Lab Test ID RCT15

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (9)

Data signed: (hfarmer1) 26 Mar 2015 13:38:18

Generated On: 20 Jul 2016 10:56:43

Lab Test Name	SERUM SODIUM
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	145
Reported Numeric Result	145
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: 1002**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (9)

Data signed: (hfarmer1) 26 Mar 2015 13:38:18

Generated On: 20 Jul 2016 10:56:43

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (10)

Data signed: (hfarmer1) 26 Mar 2015 13:38:18

Generated On: 20 Jul 2016 10:56:43

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex F

Subject Date of Birth (b) (6) 

Visit Name _____

Visit Type Scheduled ☒

Accession ID V225571

Actual Collection Date 2014 01 16

Actual Collection Time 05:31

Specimen Condition _____

Battery ID RC9255

Battery Name CHEMISTRY PANEL

Lab Test ID RCT16

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1002

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (10)

Data signed: (hfarmer1) 26 Mar 2015 13:38:18

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (10)

Data signed: (hfarmer1) 26 Mar 2015 13:38:18

Generated On: 20 Jul 2016 10:56:43

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (11)

Data signed: (hfarmer1) 26 Mar 2015 13:38:18

Generated On: 20 Jul 2016 10:56:43

Transmission Type Cumulative ☐

Subject ID or Number _____

Subject Sex F

Subject Date of Birth (b) (6)

Visit Name _____

Visit Type Scheduled ☐

Accession ID V225571

Actual Collection Date 2014 01 16

Actual Collection Time 05:31

Specimen Condition _____

Battery ID RC9255

Battery Name CHEMISTRY PANEL

Lab Test ID RCT29

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (11)

Data signed: (hfarmer1) 26 Mar 2015 13:38:18

Generated On: 20 Jul 2016 10:56:43

Lab Test Name	DIRECT BILIRUBIN
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	0.1
Reported Numeric Result	0.1
Reference Range low	0.0
Reference Range high	0.4
Range Units	MG/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (11)

Data signed: (hfarmer1) 26 Mar 2015 13:38:18

Generated On: 20 Jul 2016 10:56:43

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (12)

Data signed: (hfarmer1) 26 Mar 2015 13:38:18

Generated On: 20 Jul 2016 10:56:43

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex F

Subject Date of Birth (b) (6)

Visit Name _____

Visit Type Scheduled ☒

Accession ID V225571

Actual Collection Date 2014 01 16

Actual Collection Time 05:31

Specimen Condition _____

Battery ID RC9255

Battery Name CHEMISTRY PANEL

Lab Test ID RCT3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (12)

Data signed: (hfarmer1) 26 Mar 2015 13:38:18

Generated On: 20 Jul 2016 10:56:43

Lab Test Name	GGT
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	7
Reported Numeric Result	7
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: 1002**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (12)

Data signed: (hfarmer1) 26 Mar 2015 13:38:18

Generated On: 20 Jul 2016 10:56:43

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (13)

Data signed: (hfarmer1) 26 Mar 2015 13:38:18

Generated On: 20 Jul 2016 10:56:43

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex F

Subject Date of Birth (b) (6) ☒

Visit Name _____

Visit Type Scheduled ☒

Accession ID V225571

Actual Collection Date 2014 01 16

Actual Collection Time 05:31

Specimen Condition _____

Battery ID RC9255

Battery Name CHEMISTRY PANEL

Lab Test ID RCT392

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (13)

Data signed: (hfarmer1) 26 Mar 2015 13:38:18

Generated On: 20 Jul 2016 10:56:43

Lab Test Name	CREATININE (RATE BLANKED)
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Test ID	<hr/>
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Test Status	Done <input checked="" type="radio"/>
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Reported Text Result	0.9
----------------------	-----

Reported Numeric Result	0.9
-------------------------	-----

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/>
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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: 1002**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (13)

Data signed: (hfarmer1) 26 Mar 2015 13:38:18

Generated On: 20 Jul 2016 10:56:43

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (14)

Data signed: (hfarmer1) 26 Mar 2015 13:38:18

Generated On: 20 Jul 2016 10:56:43

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/>
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	V225571
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Actual Collection Date	2014 01 16
------------------------	------------

Actual Collection Time	05:31
------------------------	-------

Specimen Condition	<hr/>
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Battery ID	RC9255
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Battery Name	CHEMISTRY PANEL
--------------	-----------------

Lab Test ID	RCT4
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (14)

Data signed: (hfarmer1) 26 Mar 2015 13:38:18

Generated On: 20 Jul 2016 10:56:43

Lab Test Name	ALT (SGPT)
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	14
Reported Numeric Result	14
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: 1002**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (14)

Data signed: (hfarmer1) 26 Mar 2015 13:38:18

Generated On: 20 Jul 2016 10:56:43

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (15)

Data signed: (hfarmer1) 26 Mar 2015 13:38:18

Generated On: 20 Jul 2016 10:56:43

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex F

Subject Date of Birth (b) (6) 

Visit Name _____

Visit Type Scheduled ☒

Accession ID V225571

Actual Collection Date 2014 01 16

Actual Collection Time 05:31

Specimen Condition _____

Battery ID RC9255

Battery Name CHEMISTRY PANEL

Lab Test ID RCT5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (15)

Data signed: (hfarmer1) 26 Mar 2015 13:38:18

Generated On: 20 Jul 2016 10:56:43

Lab Test Name	AST (SGOT)
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	16
Reported Numeric Result	16
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: 1002**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (15)

Data signed: (hfarmer1) 26 Mar 2015 13:38:18

Generated On: 20 Jul 2016 10:56:43

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (16)

Data signed: (hfarmer1) 26 Mar 2015 13:38:18

Generated On: 20 Jul 2016 10:56:43

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	V225571
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Actual Collection Date	2014 01 16
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Actual Collection Time	05:31
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Specimen Condition	<hr/>
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Battery ID	RC9255
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Battery Name	CHEMISTRY PANEL
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Lab Test ID	RCT6
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (16)

Data signed: (hfarmer1) 26 Mar 2015 13:38:18

Generated On: 20 Jul 2016 10:56:43

Lab Test Name	UREA NITROGEN
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	12
Reported Numeric Result	12
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: 1002**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (16)

Data signed: (hfarmer1) 26 Mar 2015 13:38:18

Generated On: 20 Jul 2016 10:56:43

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1002

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (17)

Data signed: (hfarmer1) 26 Mar 2015 13:38:18

Generated On: 20 Jul 2016 10:56:43

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex F

Subject Date of Birth (b) (6) 

Visit Name _____

Visit Type Scheduled ☒

Accession ID V225571

Actual Collection Date 2014 01 16

Actual Collection Time 05:31

Specimen Condition _____

Battery ID HM1604

Battery Name HEMATOLOGY
&DIFFERENTIAL PANEL

Lab Test ID HMT10

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (17)

Data signed: (hfarmer1) 26 Mar 2015 13:38:18

Generated On: 20 Jul 2016 10:56:43

Lab Test Name	MONOCYTES
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	0.26
Reported Numeric Result	0.26
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: 1002**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (17)

Data signed: (hfarmer1) 26 Mar 2015 13:38:18

Generated On: 20 Jul 2016 10:56:43

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1002

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (18)

Data signed: (hfarmer1) 26 Mar 2015 13:38:18

Generated On: 20 Jul 2016 10:56:43

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	V225571
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Actual Collection Date	2014 01 16
------------------------	------------

Actual Collection Time	05:31
------------------------	-------

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: 1002

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (18)

Data signed: (hfarmer1) 26 Mar 2015 13:38:18

Generated On: 20 Jul 2016 10:56:43

Lab Test Name	MCH
Test ID	
Test Status	Done <input type="checkbox"/>
Reported Text Result	28
Reported Numeric Result	28
Reference Range low	26
Reference Range high	34
Range Units	PG
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (18)

Data signed: (hfarmer1) 26 Mar 2015 13:38:18

Generated On: 20 Jul 2016 10:56:43

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (19)

Data signed: (hfarmer1) 26 Mar 2015 13:38:18

Generated On: 20 Jul 2016 10:56:43

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	V225571
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Actual Collection Date	2014 01 16
------------------------	------------

Actual Collection Time	05:31
------------------------	-------

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: 1002**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (19)

Data signed: (hfarmer1) 26 Mar 2015 13:38:18

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (19)

Data signed: (hfarmer1) 26 Mar 2015 13:38:18

Generated On: 20 Jul 2016 10:56:43

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (20)

Data signed: (hfarmer1) 26 Mar 2015 13:38:18

Generated On: 20 Jul 2016 10:56:43

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	V225571
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Actual Collection Date	2014 01 16
------------------------	------------

Actual Collection Time	05:31
------------------------	-------

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: 1002**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (20)

Data signed: (hfarmer1) 26 Mar 2015 13:38:18

Generated On: 20 Jul 2016 10:56:43

Lab Test Name	EOSINOPHILS
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	0.19
Reported Numeric Result	0.19
Reference Range low	0.00
Reference Range high	0.57
Range Units	X10^3/UL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (20)

Data signed: (hfarmer1) 26 Mar 2015 13:38:18

Generated On: 20 Jul 2016 10:56:43

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (21)

Data signed: (hfarmer1) 26 Mar 2015 13:38:18

Generated On: 20 Jul 2016 10:56:43

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	V225571
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Actual Collection Date	2014 01 16
------------------------	------------

Actual Collection Time	05:31
------------------------	-------

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: 1002

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (21)

Data signed: (hfarmer1) 26 Mar 2015 13:38:18

Generated On: 20 Jul 2016 10:56:43

Lab Test Name	BASOPHILS
Test ID	
Test Status	Done <input type="checkbox"/>
Reported Text Result	0.03
Reported Numeric Result	0.03
Reference Range low	0.00
Reference Range high	0.20
Range Units	X10^3/UL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (21)

Data signed: (hfarmer1) 26 Mar 2015 13:38:18

Generated On: 20 Jul 2016 10:56:43

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (22)

Data signed: (hfarmer1) 26 Mar 2015 13:38:18

Generated On: 20 Jul 2016 10:56:43

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	V225571
--------------	---------

Actual Collection Date	2014 01 16
------------------------	------------

Actual Collection Time	05:31
------------------------	-------

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: 1002**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (22)

Data signed: (hfarmer1) 26 Mar 2015 13:38:18

Generated On: 20 Jul 2016 10:56:43

Lab Test Name	PLATELETS
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	290
Reported Numeric Result	290
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: 1002**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (22)

Data signed: (hfarmer1) 26 Mar 2015 13:38:18

Generated On: 20 Jul 2016 10:56:43

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (23)

Data signed: (hfarmer1) 26 Mar 2015 13:38:18

Generated On: 20 Jul 2016 10:56:43

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	V225571
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Actual Collection Date	2014 01 16
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Actual Collection Time	05:31
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Specimen Condition	<hr/>
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Battery ID	HM1604
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Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
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Lab Test ID	HMT15
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1002

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (23)

Data signed: (hfarmer1) 26 Mar 2015 13:38:18

Generated On: 20 Jul 2016 10:56:43

Lab Test Name	NEUTROPHILS (%)
Test ID	
Test Status	Done <input checked="" type="checkbox"/>
Reported Text Result	45.0
Reported Numeric Result	45.0
Reference Range low	40.5
Reference Range high	75.0
Range Units	%
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (23)

Data signed: (hfarmer1) 26 Mar 2015 13:38:18

Generated On: 20 Jul 2016 10:56:43

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (24)

Data signed: (hfarmer1) 26 Mar 2015 13:38:18

Generated On: 20 Jul 2016 10:56:43

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	V225571
--------------	---------

Actual Collection Date	2014 01 16
------------------------	------------

Actual Collection Time	05:31
------------------------	-------

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: 1002**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (24)

Data signed: (hfarmer1) 26 Mar 2015 13:38:18

Generated On: 20 Jul 2016 10:56:43

Lab Test Name	LYMPHOCYTES (%)
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	47.7
Reported Numeric Result	47.7
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: 1002**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (24)

Data signed: (hfarmer1) 26 Mar 2015 13:38:18

Generated On: 20 Jul 2016 10:56:43

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (25)

Data signed: (hfarmer1) 26 Mar 2015 13:38:18

Generated On: 20 Jul 2016 10:56:43

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	V225571
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Actual Collection Date	2014 01 16
------------------------	------------

Actual Collection Time	05:31
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Specimen Condition	<hr/>
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Battery ID	HM1604
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Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
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Lab Test ID	HMT17
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (25)

Data signed: (hfarmer1) 26 Mar 2015 13:38:18

Generated On: 20 Jul 2016 10:56:43

Lab Test Name	MONOCYTES (%)
Test ID	
Test Status	Done <input checked="" type="checkbox"/>
Reported Text Result	4.0
Reported Numeric Result	4.0
Reference Range low	2.6
Reference Range high	10.1
Range Units	%
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (25)

Data signed: (hfarmer1) 26 Mar 2015 13:38:18

Generated On: 20 Jul 2016 10:56:43

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (26)

Data signed: (hfarmer1) 26 Mar 2015 13:38:18

Generated On: 20 Jul 2016 10:56:43

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex F

Subject Date of Birth (b) (6)

Visit Name _____

Visit Type Scheduled ☒

Accession ID V225571

Actual Collection Date 2014 01 16

Actual Collection Time 05:31

Specimen Condition _____

Battery ID HM1604

Battery Name HEMATOLOGY
&DIFFERENTIAL PANEL

Lab Test ID HMT18

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (26)

Data signed: (hfarmer1) 26 Mar 2015 13:38:18

Generated On: 20 Jul 2016 10:56:43

Lab Test Name	EOSINOPHILS (%)
Test ID	
Test Status	Done <input type="checkbox"/>
Reported Text Result	2.9
Reported Numeric Result	2.9
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: 1002**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (26)

Data signed: (hfarmer1) 26 Mar 2015 13:38:18

Generated On: 20 Jul 2016 10:56:43

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (27)

Data signed: (hfarmer1) 26 Mar 2015 13:38:18

Generated On: 20 Jul 2016 10:56:43

Transmission Type Cumulative ☐

Subject ID or Number _____

Subject Sex F

Subject Date of Birth (b) (6) [REDACTED]

Visit Name _____

Visit Type Scheduled ☐

Accession ID V225571

Actual Collection Date 2014 01 16

Actual Collection Time 05:31

Specimen Condition _____

Battery ID HM1604

Battery Name HEMATOLOGY
&DIFFERENTIAL PANEL

Lab Test ID HMT19

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (27)

Data signed: (hfarmer1) 26 Mar 2015 13:38:18

Generated On: 20 Jul 2016 10:56:43

Lab Test Name	BASOPHILS (%)
Test ID	
Test Status	Done <input checked="" type="checkbox"/>
Reported Text Result	0.4
Reported Numeric Result	0.4
Reference Range low	0.0
Reference Range high	2.0
Range Units	%
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (27)

Data signed: (hfarmer1) 26 Mar 2015 13:38:18

Generated On: 20 Jul 2016 10:56:43

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (28)

Data signed: (hfarmer1) 26 Mar 2015 13:38:18

Generated On: 20 Jul 2016 10:56:43

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex F

Subject Date of Birth (b) (6)

Visit Name _____

Visit Type Scheduled ☒

Accession ID V225571

Actual Collection Date 2014 01 16

Actual Collection Time 05:31

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: 1002

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (28)

Data signed: (hfarmer1) 26 Mar 2015 13:38:18

Generated On: 20 Jul 2016 10:56:43

Lab Test Name	HEMATOCRIT
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	47
Reported Numeric Result	47
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: 1002**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (28)

Data signed: (hfarmer1) 26 Mar 2015 13:38:18

Generated On: 20 Jul 2016 10:56:43

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (29)


Data signed: (hfarmer1) 26 Mar 2015 13:38:18

Generated On: 20 Jul 2016 10:56:43

Transmission Type Cumulative ☐

Subject ID or Number _____

Subject Sex F

Subject Date of Birth (b) (6) 

Visit Name _____

Visit Type Scheduled ☐

Accession ID V225571

Actual Collection Date 2014 01 16

Actual Collection Time 05:31

Specimen Condition _____

Battery ID HM1604

Battery Name HEMATOLOGY
&DIFFERENTIAL PANEL

Lab Test ID HMT3

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1002

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (29)

Data signed: (hfarmer1) 26 Mar 2015 13:38:18

Generated On: 20 Jul 2016 10:56:43

Lab Test Name	RBC
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	5.5
Reported Numeric Result	5.5
Reference Range low	4.1
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: 1002**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (29)

Data signed: (hfarmer1) 26 Mar 2015 13:38:18

Generated On: 20 Jul 2016 10:56:43

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (30)

Data signed: (hfarmer1) 26 Mar 2015 13:38:18

Generated On: 20 Jul 2016 10:56:43

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex F

Subject Date of Birth (b) (6) 

Visit Name _____

Visit Type Scheduled ☒

Accession ID V225571

Actual Collection Date 2014 01 16

Actual Collection Time 05:31

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: 1002**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (30)

Data signed: (hfarmer1) 26 Mar 2015 13:38:18

Generated On: 20 Jul 2016 10:56:43

Lab Test Name	MCV
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	86
Reported Numeric Result	86
Reference Range low	79
Reference Range high	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: 1002**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (30)

Data signed: (hfarmer1) 26 Mar 2015 13:38:18

Generated On: 20 Jul 2016 10:56:43

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (31)

Data signed: (hfarmer1) 26 Mar 2015 13:38:18

Generated On: 20 Jul 2016 10:56:43

Transmission Type Cumulative ☐

Subject ID or Number _____

Subject Sex F

Subject Date of Birth (b) (6) [REDACTED]

Visit Name _____

Visit Type Scheduled ☐

Accession ID V225571

Actual Collection Date 2014 01 16

Actual Collection Time 05:31

Specimen Condition _____

Battery ID HM1604

Battery Name HEMATOLOGY
&DIFFERENTIAL PANEL

Lab Test ID HMT40

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (31)

Data signed: (hfarmer1) 26 Mar 2015 13:38:18

Generated On: 20 Jul 2016 10:56:43

Lab Test Name	HEMOGLOBIN
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	15.6
Reported Numeric Result	15.6
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: 1002**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (31)

Data signed: (hfarmer1) 26 Mar 2015 13:38:18

Generated On: 20 Jul 2016 10:56:43

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (32)

Data signed: (hfarmer1) 26 Mar 2015 13:38:18

Generated On: 20 Jul 2016 10:56:43

Transmission Type Cumulative ☐

Subject ID or Number _____

Subject Sex F

Subject Date of Birth (b) (6) 

Visit Name _____

Visit Type Scheduled ☐

Accession ID V225571

Actual Collection Date 2014 01 16

Actual Collection Time 05:31

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: 1002**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (32)

Data signed: (hfarmer1) 26 Mar 2015 13:38:18

Generated On: 20 Jul 2016 10:56:43

Lab Test Name	WBC
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	6.61
Reported Numeric Result	6.61
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: 1002**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (32)

Data signed: (hfarmer1) 26 Mar 2015 13:38:18

Generated On: 20 Jul 2016 10:56:43

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (33)

Data signed: (hfarmer1) 26 Mar 2015 13:38:18

Generated On: 20 Jul 2016 10:56:43

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex F

Subject Date of Birth (b) (6) 

Visit Name _____

Visit Type Scheduled ☒

Accession ID V225571

Actual Collection Date 2014 01 16

Actual Collection Time 05:31

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: 1002**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (33)

Data signed: (hfarmer1) 26 Mar 2015 13:38:18


Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (33)

Data signed: (hfarmer1) 26 Mar 2015 13:38:18

Generated On: 20 Jul 2016 10:56:43

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (34)

Data signed: (hfarmer1) 26 Mar 2015 13:38:18

Generated On: 20 Jul 2016 10:56:43

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex F

Subject Date of Birth (b) (6) 

Visit Name _____

Visit Type Scheduled ☒

Accession ID V225571

Actual Collection Date 2014 01 16

Actual Collection Time 05:31

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: 1002**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (34)

Data signed: (hfarmer1) 26 Mar 2015 13:38:18

Generated On: 20 Jul 2016 10:56:43

Lab Test Name	NEUTROPHILS
Test ID	
Test Status	Done <input type="checkbox"/>
Reported Text Result	2.98
Reported Numeric Result	2.98
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: 1002**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (34)

Data signed: (hfarmer1) 26 Mar 2015 13:38:18

Generated On: 20 Jul 2016 10:56:43

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (35)

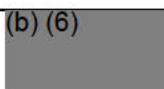
Data signed: (hfarmer1) 26 Mar 2015 13:38:18

Generated On: 20 Jul 2016 10:56:43

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex F

Subject Date of Birth (b) (6) 

Visit Name _____

Visit Type Scheduled ☒

Accession ID V225571

Actual Collection Date 2014 01 16

Actual Collection Time 05:31

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: 1002**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (35)

Data signed: (hfarmer1) 26 Mar 2015 13:38:18

Generated On: 20 Jul 2016 10:56:43

Lab Test Name	LYMPHOCYTES
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	3.15
Reported Numeric Result	3.15
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: 1002**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (35)

Data signed: (hfarmer1) 26 Mar 2015 13:38:18

Generated On: 20 Jul 2016 10:56:43

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (36)

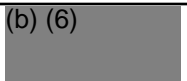
Data signed: (hfarmer1) 26 Mar 2015 13:38:18

Generated On: 20 Jul 2016 10:56:43

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex F

Subject Date of Birth (b) (6) 

Visit Name _____

Visit Type Scheduled ☒

Accession ID V225571

Actual Collection Date 2014 01 16

Actual Collection Time 05:31

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: 1002**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (36)

Data signed: (hfarmer1) 26 Mar 2015 13:38:18


Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (36)

Data signed: (hfarmer1) 26 Mar 2015 13:38:18

Generated On: 20 Jul 2016 10:56:43

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (37)

Data signed: (hfarmer1) 26 Mar 2015 13:38:18

Generated On: 20 Jul 2016 10:56:43

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	V225571
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Actual Collection Date	2014 01 16
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Actual Collection Time	05:31
------------------------	-------

Specimen Condition	<hr/>
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Battery ID	UA1538
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Battery Name	URINE MACRO PANEL
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Lab Test ID	UAT2
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (37)

Data signed: (hfarmer1) 26 Mar 2015 13:38:18

Generated On: 20 Jul 2016 10:56:43

Lab Test Name	UR SPECIFIC GRAVITY
Test ID	
Test Status	Done <input type="checkbox"/>
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: 1002**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (37)

Data signed: (hfarmer1) 26 Mar 2015 13:38:18

Generated On: 20 Jul 2016 10:56:43

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (38)

Data signed: (hfarmer1) 26 Mar 2015 13:38:18

Generated On: 20 Jul 2016 10:56:43

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex F

Subject Date of Birth (b) (6) ☒

Visit Name _____

Visit Type Scheduled ☒

Accession ID V225571

Actual Collection Date 2014 01 16

Actual Collection Time 05:31

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: 1002**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (38)

Data signed: (hfarmer1) 26 Mar 2015 13:38:18

Generated On: 20 Jul 2016 10:56:43

Lab Test Name	UR PH
Test ID	
Test Status	Done <input type="radio"/>
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: 1002**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (38)

Data signed: (hfarmer1) 26 Mar 2015 13:38:18

Generated On: 20 Jul 2016 10:56:43

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (39)

Data signed: (hfarmer1) 26 Mar 2015 13:38:18

Generated On: 20 Jul 2016 10:56:43

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	V225571
--------------	---------

Actual Collection Date	2014 01 16
------------------------	------------

Actual Collection Time	05:31
------------------------	-------

Specimen Condition	<hr/>
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Battery ID	UA1538
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Battery Name	URINE MACRO PANEL
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Lab Test ID	UAT43
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (39)

Data signed: (hfarmer1) 26 Mar 2015 13:38:18


Generated On: 20 Jul 2016 10:56:43

Lab Test Name

UR BLOOD

Test ID

Test Status

Done 

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: 1002**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (39)

Data signed: (hfarmer1) 26 Mar 2015 13:38:18

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (40)

Data signed: (hfarmer1) 26 Mar 2015 13:38:18

Generated On: 20 Jul 2016 10:56:43

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex F

Subject Date of Birth (b) (6)

Visit Name _____

Visit Type Scheduled ☒

Accession ID V225571

Actual Collection Date 2014 01 16

Actual Collection Time 05:31

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: 1002**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (40)

Data signed: (hfarmer1) 26 Mar 2015 13:38:18

Generated On: 20 Jul 2016 10:56:43

Lab Test Name	UR PROTEIN
Test ID	
Test Status	Done <input type="radio"/>
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: 1002**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (40)

Data signed: (hfarmer1) 26 Mar 2015 13:38:18

Generated On: 20 Jul 2016 10:56:43

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (41)


Data signed: (hfarmer1) 26 Mar 2015 13:38:18

Generated On: 20 Jul 2016 10:56:43

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex F

Subject Date of Birth (b) (6) 

Visit Name _____

Visit Type Scheduled ☒

Accession ID V225571

Actual Collection Date 2014 01 16

Actual Collection Time 05:31

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: 1002**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (41)

Data signed: (hfarmer1) 26 Mar 2015 13:38:18


Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (41)

Data signed: (hfarmer1) 26 Mar 2015 13:38:18

Generated On: 20 Jul 2016 10:56:43

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (42)

Data signed: (hfarmer1) 26 Mar 2015 13:38:18

Generated On: 20 Jul 2016 10:56:43

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex F

Subject Date of Birth (b) (6) 

Visit Name _____

Visit Type Scheduled ☒

Accession ID V225571

Actual Collection Date 2014 01 16

Actual Collection Time 05:31

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: 1002**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (42)

Data signed: (hfarmer1) 26 Mar 2015 13:38:18

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (42)

Data signed: (hfarmer1) 26 Mar 2015 13:38:18

Generated On: 20 Jul 2016 10:56:43

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day 0)

Form: Oxysterol results (1)

Generated On: 20 Jul 2016 10:56:43

Sample Accession number	3122557139
-------------------------	------------

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: 1002**

Folder: Baseline (Day 0)

Form: Oxysterol results (2)

Generated On: 20 Jul 2016 10:56:43

Sample Accession number	3122557139
-------------------------	------------

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: 1002**

Folder: Baseline (Day 0)

Form: Oxysterol results (3)

Generated On: 20 Jul 2016 10:56:43

Sample Accession number	3122557139
-------------------------	------------

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: 1002**

Folder: Baseline (Day 0)

Form: Oxysterol results (4)

Generated On: 20 Jul 2016 10:56:43

Sample Accession number	3122557139
-------------------------	------------

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: 1002**

Folder: Baseline (Day 0)

Form: Oxysterol results (5)

Generated On: 20 Jul 2016 10:56:43

Sample Accession number	3122557139
-------------------------	------------

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: 1002**

Folder: Baseline (Day 0)

Form: Oxysterol results (6)

Generated On: 20 Jul 2016 10:56:43

Sample Accession number	3122557139
-------------------------	------------

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: 1002**

Folder: Baseline (Day 0)

Form: Oxysterol results (7)

Generated On: 20 Jul 2016 10:56:43

Sample Accession number	3122557139
-------------------------	------------

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: 1002**

Folder: Baseline (Day 0)

Form: Oxysterol results (8)

Generated On: 20 Jul 2016 10:56:43

Sample Accession number	3122557139
-------------------------	------------

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: 1002**

Folder: Baseline (Day 0)

Form: Oxysterol results (9)

Generated On: 20 Jul 2016 10:56:43

Sample Accession number	3122557139
-------------------------	------------

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: 1002**

Folder: Baseline (Day 0)

Form: Oxysterol results (10)

Generated On: 20 Jul 2016 10:56:43

Sample Accession number	3122557139
-------------------------	------------

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: 1002**

Folder: Baseline (Day 0)

Form: Oxysterol results (11)

Generated On: 20 Jul 2016 10:56:43

Sample Accession number	3122557139
-------------------------	------------

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: 1002**

Folder: Baseline (Day 0)

Form: Oxysterol results (12)

Generated On: 20 Jul 2016 10:56:43

Sample Accession number	3122557139
-------------------------	------------

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: 1002**

Folder: Baseline (Day 0)

Form: Lab_BU_COHB (1)

Data signed: (hfarmer1) 26 Mar 2015 13:38:47

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05115150000018
----------------	----------------

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

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

Result	5.20
--------	------

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-JAN-16
--------------------	-------------

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day 0)

Form: Lab_BU_COHB (1)

Data signed: (hfarmer1) 26 Mar 2015 13:38:47

Generated On: 20 Jul 2016 10:56:43

Start Day (24 hour urine only) _____

End Day (24 hour Urine Only) _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day 0)

Form: Lab_BU_COHB (2)

Data signed: (hfarmer1) 26 Mar 2015 13:38:47

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05115150000019
----------------	----------------

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

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

Result	9.60
--------	------

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

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

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

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

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

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

Day of Visit	0
--------------	---

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

Date of Collection	2014-JAN-16
--------------------	-------------

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day 0)

Form: Lab_BU_COHB (2)

Data signed: (hfarmer1) 26 Mar 2015 13:38:47

Generated On: 20 Jul 2016 10:56:43

Start Day (24 hour urine only) _____

End Day (24 hour Urine Only) _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day 0)

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)

Data signed: (hfarmer1) 26 Mar 2015 13:38:17

Generated On: 20 Jul 2016 10:56:43

Date of Birth

(b) (6)

Date of assessment

2014 JAN 16

DD/MMM/YYYY

DD/MMM/YYYY

Time of assessment

20:10
hour:min 24-hour clock

Assessment Status

Completed ☒

1. Was smoking satisfying?

A lot ☒

2. Did cigarettes taste good?

A lot ☒

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

Little ☒

4. Did smoking calm you down?

A lot ☒

5. Did smoking make you feel more awake?

Moderately ☒

6. Did smoking make you feel less irritable?

Little ☒

7. Did smoking help you concentrate?

Little ☒

8. Did smoking reduce your hunger for food?

Very little ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day 0)

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)

Data signed: (hfarmer1) 26 Mar 2015 13:38:17

Generated On: 20 Jul 2016 10:56:43

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

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

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

12. Did you enjoy smoking? Quite a lot ☐

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1002

Folder: Baseline (Day 0)

Form: Human Smoking Topography Questionnaire

Data signed: (hfarmer1) 26 Mar 2015 13:38:16

Generated On: 20 Jul 2016 10:56:43

Type	HUMAN SMOKING TOPOGRAPHY QUESTIONNAIRE
------	--

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

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

Date of assessment	16 JAN 2014 DD/MMM/YYYY
--------------------	----------------------------

Time of assessment	20:15 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 checked="" type="radio"/>
--	--

If you agree or strongly agree, please describe :	THE DEVICE IS BULKY AND GETS IN THE WAY. IT DOESN'T FEEL THE SAME
---	---

2. You enjoy smoking with the device as much as without it.	Disagree <input type="radio"/>
---	--------------------------------

If you disagree or strongly disagree, please describe :	IT IS AWKWARD TO SMOKE WITH THE DEVICE
---	---

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1002

Folder: Baseline (Day 0)

Form: Human Smoking Topography Questionnaire

Data signed: (hfarmer1) 26 Mar 2015 13:38:16

Generated On: 20 Jul 2016 10:56:43

3. The taste of the conventional cigarettes/products is different with the device.

Disagree ☒

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.

Agree ☒

If you agree or strongly agree, please describe :

WITH THE DEVICE I CAN NOT SMOKE WHEN I WANT TO. I HAVE TO WAIT FOR THE MACHINE TO BE READY INSTEAD OF BEING ABLE TO SMOKE IMMEDIATELY WHEN I WANT TO.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day 0)

Form: Questionnaire on smoking urges (QSU)

Data signed: (hfarmer1) 26 Mar 2015 13:38:17

Generated On: 20 Jul 2016 10:56:43

Type	QSU
Date of Birth	(b) (6)
Date of assessment DD/MMM/YYYY	2014 JAN 16
Time of assessment hour:min 24-hour clock	20:09
Assessment Status	Completed <input type="radio"/>
1. I have a desire for a cigarette right now	Disagree <input type="radio"/>
2. Nothing would be better than smoking a cigarette right now	Disagree <input type="radio"/>
3. If it were possible I would probably smoke now	Disagree <input type="radio"/>
4. I could control things better right now if I could smoke	Disagree <input type="radio"/>
5. All I want right now is a cigarette	Disagree <input type="radio"/>
6. I have an urge for a cigarette	Disagree <input type="radio"/>

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day 0)

Form: Questionnaire on smoking urges (QSU)

Data signed: (hfarmer1) 26 Mar 2015 13:38:17

Generated On: 20 Jul 2016 10:56:43

7. A cigarette would taste good now Disagree ☐

8. I would do almost anything for a cigarette now Disagree ☐

9. Smoking would make me less depressed Somewhat disagree ☐

10. I am going to smoke as soon as possible Disagree ☐

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (1)

Data signed: (hfarmer1) 26 Mar 2015 13:38:40

Generated On: 20 Jul 2016 10:56:43

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	1002
----------------------	------

Subject Sex	F
-------------	---

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

Visit Name	DAY0
------------	------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	V225571
--------------	---------

Actual Collection Date	2014 01 16
------------------------	------------

Actual Collection Time	05:31
------------------------	-------

Specimen Condition	
--------------------	--

Battery ID	HM1054
------------	--------

Battery Name	HEMOGLOBIN A1C
--------------	----------------

Lab Test ID	HMT370
-------------	--------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (1)

Data signed: (hfarmer1) 26 Mar 2015 13:38:40

Generated On: 20 Jul 2016 10:56:43

Lab Test Name

HEMOGLOBIN
A1C,VARIANT(-70)

Test ID

Test Status

Done ☒

Reported Text Result

5.0

Reported Numeric Result

5.0

Reference Range low

Reference Range high

<6.5

Range Units

%

Conventional Text Result

Conventional Numeric Result

Conventional Reference Range Low

Conventional Reference Range High

Conventional Units

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (1)

Data signed: (hfarmer1) 26 Mar 2015 13:38:40

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (2)

Data signed: (hfarmer1) 26 Mar 2015 13:38:40

Generated On: 20 Jul 2016 10:56:43

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	1002
----------------------	------

Subject Sex	F
-------------	---

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

Visit Name	DAY0
------------	------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	V225571
--------------	---------

Actual Collection Date	2014 01 16
------------------------	------------

Actual Collection Time	05:31
------------------------	-------

Specimen Condition	
--------------------	--

Battery ID	RC6871
------------	--------

Battery Name	HDL
--------------	-----

Lab Test ID	RCT1684
-------------	---------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (2)

Data signed: (hfarmer1) 26 Mar 2015 13:38:40

Generated On: 20 Jul 2016 10:56:43

Lab Test Name

DIRECT HDL-C 3RD
GENERATION

Test ID

Test Status

Done ☒

Reported Text Result

57

Reported Numeric Result

57

Reference Range low

33

Reference Range high

79

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: 1002**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (2)

Data signed: (hfarmer1) 26 Mar 2015 13:38:40

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (3)

Data signed: (hfarmer1) 26 Mar 2015 13:38:40

Generated On: 20 Jul 2016 10:56:43

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	1002
----------------------	------

Subject Sex	F
-------------	---

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

Visit Name	DAY0
------------	------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	V225571
--------------	---------

Actual Collection Date	2014 01 16
------------------------	------------

Actual Collection Time	05:31
------------------------	-------

Specimen Condition	
--------------------	--

Battery ID	SC3249
------------	--------

Battery Name	HS-CRP
--------------	--------

Lab Test ID	SCT1528
-------------	---------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (3)

Data signed: (hfarmer1) 26 Mar 2015 13:38:40

Generated On: 20 Jul 2016 10:56:43

Lab Test Name	C-REACTIVE PROTEIN (N HS)-QT
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	0.049
Reported Numeric Result	0.049
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: 1002**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (3)

Data signed: (hfarmer1) 26 Mar 2015 13:38:40

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (4)

Data signed: (hfarmer1) 26 Mar 2015 13:38:40

Generated On: 20 Jul 2016 10:56:43

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	1002
----------------------	------

Subject Sex	F
-------------	---

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

Visit Name	DAY0
------------	------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	V225571
--------------	---------

Actual Collection Date	2014 01 16
------------------------	------------

Actual Collection Time	05:31
------------------------	-------

Specimen Condition	
--------------------	--

Battery ID	SC3582
------------	--------

Battery Name	APOLIPOPROTEIN
--------------	----------------

Lab Test ID	SCT3639
-------------	---------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (4)

Data signed: (hfarmer1) 26 Mar 2015 13:38:40

Generated On: 20 Jul 2016 10:56:43

Lab Test Name	APOLIPOPROTEIN A1, RAND
---------------	-------------------------

Test ID	<hr/>
---------	-------

Test Status	Done <input checked="" type="radio"/>
-------------	---------------------------------------

Reported Text Result	143
----------------------	-----

Reported Numeric Result	143
-------------------------	-----

Reference Range low	125
---------------------	-----

Reference Range high	215
----------------------	-----

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: 1002**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (4)

Data signed: (hfarmer1) 26 Mar 2015 13:38:40

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (5)

Data signed: (hfarmer1) 26 Mar 2015 13:38:40

Generated On: 20 Jul 2016 10:56:43

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	1002
----------------------	------

Subject Sex	F
-------------	---

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

Visit Name	DAY0
------------	------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	V225571
--------------	---------

Actual Collection Date	2014 01 16
------------------------	------------

Actual Collection Time	05:31
------------------------	-------

Specimen Condition	
--------------------	--

Battery ID	SC3582
------------	--------

Battery Name	APOLIPOPROTEIN
--------------	----------------

Lab Test ID	SCT3643
-------------	---------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (5)

Data signed: (hfarmer1) 26 Mar 2015 13:38:40

Generated On: 20 Jul 2016 10:56:43

Lab Test Name	APOLIPOPROTEIN B, RAND
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	99
Reported Numeric Result	99
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: 1002**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (5)

Data signed: (hfarmer1) 26 Mar 2015 13:38:40

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (6)

Data signed: (hfarmer1) 26 Mar 2015 13:38:40

Generated On: 20 Jul 2016 10:56:43

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	1002
----------------------	------

Subject Sex	F
-------------	---

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

Visit Name	DAY0
------------	------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	V225571
--------------	---------

Actual Collection Date	2014 01 16
------------------------	------------

Actual Collection Time	05:31
------------------------	-------

Specimen Condition	
--------------------	--

Battery ID	CG267
------------	-------

Battery Name	FIBRINOGEN
--------------	------------

Lab Test ID	CGT285
-------------	--------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (6)

Data signed: (hfarmer1) 26 Mar 2015 13:38:40

Generated On: 20 Jul 2016 10:56:43

Lab Test Name	FIBRINOGEN
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	246
Reported Numeric Result	246
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: 1002**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (6)

Data signed: (hfarmer1) 26 Mar 2015 13:38:40

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (7)

Data signed: (hfarmer1) 26 Mar 2015 13:38:40

Generated On: 20 Jul 2016 10:56:43

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	1002
----------------------	------

Subject Sex	F
-------------	---

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

Visit Name	DAY0
------------	------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	V225571
--------------	---------

Actual Collection Date	2014 01 16
------------------------	------------

Actual Collection Time	05:31
------------------------	-------

Specimen Condition	
--------------------	--

Battery ID	CN236
------------	-------

Battery Name	HOMOCYSTEINE
--------------	--------------

Lab Test ID	CNT145
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (7)

Data signed: (hfarmer1) 26 Mar 2015 13:38:40

Generated On: 20 Jul 2016 10:56:43

Lab Test Name	HOMOCYSTEINE, EDTAPL
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	9.62
Reported Numeric Result	9.62
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: 1002**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (7)

Data signed: (hfarmer1) 26 Mar 2015 13:38:40

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (8)

Data signed: (hfarmer1) 26 Mar 2015 13:38:40

Generated On: 20 Jul 2016 10:56:43

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	1002
----------------------	------

Subject Sex	F
-------------	---

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

Visit Name	DAY0
------------	------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	V225571
--------------	---------

Actual Collection Date	2014 01 16
------------------------	------------

Actual Collection Time	05:31
------------------------	-------

Specimen Condition	
--------------------	--

Battery ID	IM2293
------------	--------

Battery Name	SICAM-1
--------------	---------

Lab Test ID	IMT1768
-------------	---------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (8)

Data signed: (hfarmer1) 26 Mar 2015 13:38:40

Generated On: 20 Jul 2016 10:56:43

Lab Test Name	SICAM-1-RUO
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	273.7
Reported Numeric Result	273.7
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: 1002**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (8)

Data signed: (hfarmer1) 26 Mar 2015 13:38:40

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (9)

Data signed: (hfarmer1) 26 Mar 2015 13:38:40

Generated On: 20 Jul 2016 10:56:43

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	1002
----------------------	------

Subject Sex	F
-------------	---

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

Visit Name	DAY0
------------	------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	V225571
--------------	---------

Actual Collection Date	2014 01 16
------------------------	------------

Actual Collection Time	05:31
------------------------	-------

Specimen Condition	
--------------------	--

Battery ID	RC9267
------------	--------

Battery Name	LDL
--------------	-----

Lab Test ID	RCT2394
-------------	---------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (9)

Data signed: (hfarmer1) 26 Mar 2015 13:38:40

Generated On: 20 Jul 2016 10:56:43

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	136
----------------------	-----

Reported Numeric Result	136
-------------------------	-----

Reference Range low	60
---------------------	----

Reference Range high	148
----------------------	-----

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: 1002**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (9)

Data signed: (hfarmer1) 26 Mar 2015 13:38:40

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Baseline (Day 0)

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

Data signed: (hfarmer1) 26 Mar 2015 13:38:49

Generated On: 20 Jul 2016 10:56:43

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day 0)

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

Data signed: (hfarmer1) 26 Mar 2015 13:38:49

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05112450000014
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Analyte	HPMA
---------	------

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

Result	645
--------	-----

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-JAN-16
--------------------	-------------

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

Urine Start Day	0
-----------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day 0)

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

Data signed: (hfarmer1) 26 Mar 2015 13:38:49

Generated On: 20 Jul 2016 10:56:43

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (CEMA, HPMa, HBMA) (2)

Data signed: (hfarmer1) 26 Mar 2015 13:38:49

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05112450000014
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Analyte	CEMA
---------	------

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	0
--------------	---

Celerion Study Number	AA99128-03
-----------------------	------------

Date of Collection	2014-JAN-16
--------------------	-------------

Timepoint-minutes	
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Urine Start Day	0
-----------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (2)

Data signed: (hfarmer1) 26 Mar 2015 13:38:49

Generated On: 20 Jul 2016 10:56:43

Urine End Day	1
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (3)

Data signed: (hfarmer1) 26 Mar 2015 13:38:49

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05112450000014
Analyte	HBMA
Sample type	URINE
Result	336
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	0
Celerion Study Number	AA99128-03
Date of Collection	2014-JAN-16
Timepoint-minutes	
Urine Start Day	0

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (3)

Data signed: (hfarmer1) 26 Mar 2015 13:38:49

Generated On: 20 Jul 2016 10:56:43

Urine End Day	1
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (NNN, NNAL)

Data signed: (hfarmer1) 26 Mar 2015 13:38:47

Generated On: 20 Jul 2016 10:56:43

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (NNN, NNAL) (1)

Data signed: (hfarmer1) 26 Mar 2015 13:38:47

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05112460000014
Analyte	NNAL
Sample type	URINE
Result	525
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-JAN-16
Timepoint-minutes	
Urine Start Day	0

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (NNN, NNAL) (1)

Data signed: (hfarmer1) 26 Mar 2015 13:38:47

Generated On: 20 Jul 2016 10:56:43

Urine End Day

1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (NNN, NNAL) (2)

Data signed: (hfarmer1) 26 Mar 2015 13:38:47

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05112460000014
Analyte	NNN
Sample type	URINE
Result	16.8
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-JAN-16
Timepoint-minutes	
Urine Start Day	0

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (NNN, NNAL) (2)

Data signed: (hfarmer1) 26 Mar 2015 13:38:47

Generated On: 20 Jul 2016 10:56:43

Urine End Day

1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (HEMA)

Data signed: (hfarmer1) 26 Mar 2015 13:38:47

Generated On: 20 Jul 2016 10:56:43

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (HEMA) (1)

Data signed: (hfarmer1) 26 Mar 2015 13:38:47

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05112470000014
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Analyte	HEMA
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Sample type	URINE
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Result	8.61
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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	0
--------------	---

Celerion Study Number	AA99128-05
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Date of Collection	2014-JAN-16
--------------------	-------------

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

Urine Start Day	0
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (HEMA) (1)

Data signed: (hfarmer1) 26 Mar 2015 13:38:47

Generated On: 20 Jul 2016 10:56:43

Urine End Day

1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day 0)

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

Data signed: (hfarmer1) 26 Mar 2015 13:38:49

Generated On: 20 Jul 2016 10:56:43

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day 0)

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

Data signed: (hfarmer1) 26 Mar 2015 13:38:49

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05112480000014
Analyte	COT
Sample type	URINE
Result	861
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-JAN-17
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day 0)

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

Data signed: (hfarmer1) 26 Mar 2015 13:38:49

Generated On: 20 Jul 2016 10:56:43

Urine Start Day	0
<hr/>	
Urine End Day	1
<hr/>	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day 0)

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

Data signed: (hfarmer1) 26 Mar 2015 13:38:49

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05112480000014
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Analyte	COT-GLUC
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Sample type	URINE
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Result	4970
--------	------

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	0
--------------	---

Celerion Study Number	AA99128-06
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Date of Collection	2014-JAN-17
--------------------	-------------

Timepoint-minutes	
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day 0)

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

Data signed: (hfarmer1) 26 Mar 2015 13:38:49

Generated On: 20 Jul 2016 10:56:43

Urine Start Day	0
<hr/>	
Urine End Day	1
<hr/>	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day 0)

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(3)**

Data signed: (hfarmer1) 26 Mar 2015 13:38:49

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05112480000014
Analyte	NIC
Sample type	URINE
Result	719
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-JAN-17
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day 0)

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(3)**

Data signed: (hfarmer1) 26 Mar 2015 13:38:49

Generated On: 20 Jul 2016 10:56:43

Urine Start Day	0
<hr/>	
Urine End Day	1
<hr/>	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day 0)

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

Data signed: (hfarmer1) 26 Mar 2015 13:38:49

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05112480000014
Analyte	NIC-GLUC
Sample type	URINE
Result	923
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-JAN-17
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day 0)

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

Data signed: (hfarmer1) 26 Mar 2015 13:38:49

Generated On: 20 Jul 2016 10:56:43

Urine Start Day	0
<hr/>	
Urine End Day	1
<hr/>	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day 0)

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

Data signed: (hfarmer1) 26 Mar 2015 13:38:49

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05112480000014
Analyte	THCOT
Sample type	URINE
Result	2010
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-JAN-17
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day 0)

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

Data signed: (hfarmer1) 26 Mar 2015 13:38:49

Generated On: 20 Jul 2016 10:56:43

Urine Start Day	0
-----------------	---

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day 0)

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

Data signed: (hfarmer1) 26 Mar 2015 13:38:49

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05112480000014
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Analyte	THCOT-GLUC
---------	------------

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

Result	1960
--------	------

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-JAN-17
--------------------	-------------

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day 0)

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

Data signed: (hfarmer1) 26 Mar 2015 13:38:49

Generated On: 20 Jul 2016 10:56:43

Urine Start Day	0
<hr/>	
Urine End Day	1
<hr/>	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (3-OH BaP)

Data signed: (hfarmer1) 26 Mar 2015 13:38:49

Generated On: 20 Jul 2016 10:56:43

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (3-OH BaP) (1)

Data signed: (hfarmer1) 26 Mar 2015 13:38:49

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05112490000014
Analyte	3-OH BAP
Sample type	URINE
Result	117
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-JAN-16
Timepoint-minutes	
Urine Start Day	0

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (3-OH BaP) (1)

Data signed: (hfarmer1) 26 Mar 2015 13:38:49

Generated On: 20 Jul 2016 10:56:43

Urine End Day	1
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day 0)

Form: Biomarker-Plasma (Caffeine, Paraxanthine)

Generated On: 20 Jul 2016 10:56:43

Sample type

PLASMA

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day 0)

Form: Biomarker-Plasma (Caffeine, Paraxanthine) (1)

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05112500000004
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Analyte	CAFFEINE
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Sample type	PLASMA
-------------	--------

Result	1000
--------	------

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-JAN-16
--------------------	-------------

Timepoint-minutes	0
-------------------	---

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day 0)

Form: Biomarker-Plasma (Caffeine, Paraxanthine) (1)

Generated On: 20 Jul 2016 10:56:43

Urine End Day	0
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day 0)

Form: Biomarker-Plasma (Caffeine, Paraxanthine) (2)

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05112500000004
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Analyte	PARAXANTHINE
---------	--------------

Sample type	PLASMA
-------------	--------

Result	1410
--------	------

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-JAN-16
--------------------	-------------

Timepoint-minutes	0
-------------------	---

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day 0)

Form: Biomarker-Plasma (Caffeine, Paraxanthine) (2)

Generated On: 20 Jul 2016 10:56:43

Urine End Day	0
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP)

Data signed: (hfarmer1) 26 Mar 2015 13:38:50

Generated On: 20 Jul 2016 10:56:43

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (1)

Data signed: (hfarmer1) 26 Mar 2015 13:38:50

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05112510000014
Analyte	1-NA
Sample type	URINE
Result	95.3
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-JAN-16
Timepoint-minutes	
Urine Start Day	0

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (1)

Data signed: (hfarmer1) 26 Mar 2015 13:38:50

Generated On: 20 Jul 2016 10:56:43

Urine End Day	1
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (2)

Data signed: (hfarmer1) 26 Mar 2015 13:38:50

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05112510000014
Analyte	2-NA
Sample type	URINE
Result	28.3
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-JAN-16
Timepoint-minutes	
Urine Start Day	0

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (2)

Data signed: (hfarmer1) 26 Mar 2015 13:38:50

Generated On: 20 Jul 2016 10:56:43

Urine End Day	1
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (3)

Data signed: (hfarmer1) 26 Mar 2015 13:38:50

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05112510000014
Analyte	4-ABP
Sample type	URINE
Result	18.0
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-JAN-16
Timepoint-minutes	
Urine Start Day	0

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (3)

Data signed: (hfarmer1) 26 Mar 2015 13:38:50

Generated On: 20 Jul 2016 10:56:43

Urine End Day	1
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (4)

Data signed: (hfarmer1) 26 Mar 2015 13:38:50

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05112510000014
Analyte	O-TOL
Sample type	URINE
Result	144
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-JAN-16
Timepoint-minutes	
Urine Start Day	0

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (4)

Data signed: (hfarmer1) 26 Mar 2015 13:38:50

Generated On: 20 Jul 2016 10:56:43

Urine End Day	1
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (11-dTXb2)

Data signed: (hfarmer1) 26 Mar 2015 13:38:48

Generated On: 20 Jul 2016 10:56:43

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (11-dTXb2) (1)

Data signed: (hfarmer1) 26 Mar 2015 13:38:48

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05112530000010
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Analyte	11-DTXB2
---------	----------

Sample type	URINE
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Result	689
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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	AA99128-11
-----------------------	------------

Date of Collection	2014-JAN-16
--------------------	-------------

Timepoint-minutes	
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Urine Start Day	0
-----------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (11-dTXb2) (1)

Data signed: (hfarmer1) 26 Mar 2015 13:38:48

Generated On: 20 Jul 2016 10:56:43

Urine End Day

1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (iPF2a-III)

Data signed: (hfarmer1) 26 Mar 2015 13:38:48

Generated On: 20 Jul 2016 10:56:43

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (iPF2a-III) (1)

Data signed: (hfarmer1) 26 Mar 2015 13:38:48

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05112540000010
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Analyte	IPF2A-III
---------	-----------

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

Result	167
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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-JAN-16
--------------------	-------------

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

Urine Start Day	0
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (iPF2a-III) (1)

Data signed: (hfarmer1) 26 Mar 2015 13:38:48

Generated On: 20 Jul 2016 10:56:43

Urine End Day	1
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (Ames)

Data signed: (hfarmer1) 26 Mar 2015 13:38:50

Generated On: 20 Jul 2016 10:56:43

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (Ames) (1)

Data signed: (hfarmer1) 26 Mar 2015 13:38:50

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05113320000004
Analyte	AMES
Sample type	URINE
Result	33.4
Result Unit	REV/ML
Lab Status	OK
Sample comment	
Detection method	COUNT
Planned time point (Hour)	0
Day of Visit	0
Celerion Study Number	AA99128-15
Date of Collection	2014-JAN-16
Timepoint-minutes	
Urine Start Day	0

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (Ames) (1)

Data signed: (hfarmer1) 26 Mar 2015 13:38:50

Generated On: 20 Jul 2016 10:56:43

Urine End Day	1
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (1-OHP)

Data signed: (hfarmer1) 26 Mar 2015 13:38:50

Generated On: 20 Jul 2016 10:56:43

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (1-OHP) (1)

Data signed: (hfarmer1) 26 Mar 2015 13:38:50

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05115190001103
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Analyte	1-OHP
---------	-------

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

Result	116
--------	-----

Result Unit	PG/ML
-------------	-------

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

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

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	0
--------------	---

Celerion Study Number	AA99598-03
-----------------------	------------

Date of Collection	2014-JAN-16
--------------------	-------------

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

Urine Start Day	0
-----------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (1-OHP) (1)

Data signed: (hfarmer1) 26 Mar 2015 13:38:50

Generated On: 20 Jul 2016 10:56:43

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (SPMA, SBMA)

Data signed: (hfarmer1) 26 Mar 2015 13:38:48

Generated On: 20 Jul 2016 10:56:43

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (SPMA, SBMA) (1)

Data signed: (hfarmer1) 26 Mar 2015 13:38:48

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05115170001770
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Analyte	SBMA
---------	------

Sample type	URINE
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Result	3.24
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Result Unit	NG/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	0
--------------	---

Celerion Study Number	AA99598-01
-----------------------	------------

Date of Collection	2014-JAN-16
--------------------	-------------

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

Urine Start Day	0
-----------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (SPMA, SBMA) (1)

Data signed: (hfarmer1) 26 Mar 2015 13:38:48

Generated On: 20 Jul 2016 10:56:43

Urine End Day

1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (SPMA, SBMA) (2)

Data signed: (hfarmer1) 26 Mar 2015 13:38:48

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05115170001770
Analyte	SPMA
Sample type	URINE
Result	3.16
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-JAN-16
Timepoint-minutes	
Urine Start Day	0

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (SPMA, SBMA) (2)

Data signed: (hfarmer1) 26 Mar 2015 13:38:48

Generated On: 20 Jul 2016 10:56:43

Urine End Day	1
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (MHBMA)

Data signed: (hfarmer1) 26 Mar 2015 13:38:48

Generated On: 20 Jul 2016 10:56:43

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (MHBMA) (1)

Data signed: (hfarmer1) 26 Mar 2015 13:38:48

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05115180000014
Analyte	MHBMA
Sample type	URINE
Result	1.25
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-JAN-16
Timepoint-minutes	
Urine Start Day	0

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (MHBMA) (1)

Data signed: (hfarmer1) 26 Mar 2015 13:38:48

Generated On: 20 Jul 2016 10:56:43

Urine End Day	1
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (Creatinine)

Data signed: (hfarmer1) 26 Mar 2015 13:38:50

Generated On: 20 Jul 2016 10:56:43

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (Creatinine) (1)

Data signed: (hfarmer1) 26 Mar 2015 13:38:50

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05115160000014
----------------	----------------

Analyte	CREATININE
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Sample type	URINE
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Result	61.6
--------	------

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-JAN-16
--------------------	-------------

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

Urine Start Day	0
-----------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (Creatinine) (1)

Data signed: (hfarmer1) 26 Mar 2015 13:38:50

Generated On: 20 Jul 2016 10:56:43

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day 0)

Form: Biomarker-Plasma (Nic, Cot, tHCot)

Data signed: (hfarmer1) 26 Mar 2015 13:38:49

Generated On: 20 Jul 2016 10:56:43

Sample type

PLASMA

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day 0)

Form: Biomarker-Plasma (Nic, Cot, tHCot) (1)

Data signed: (hfarmer1) 26 Mar 2015 13:38:49

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05112430000020
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Analyte	COT
---------	-----

Sample type	PLASMA
-------------	--------

Result	211
--------	-----

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-JAN-16
--------------------	-------------

Timepoint-minutes	0
-------------------	---

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day 0)

Form: Biomarker-Plasma (Nic, Cot, tHCot) (1)

Data signed: (hfarmer1) 26 Mar 2015 13:38:49

Generated On: 20 Jul 2016 10:56:43

Urine End Day	0
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day 0)

Form: Biomarker-Plasma (Nic, Cot, tHCot) (2)

Data signed: (hfarmer1) 26 Mar 2015 13:38:49

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05112430000020
----------------	----------------

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)	0
---------------------------	---

Day of Visit	0
--------------	---

Celerion Study Number	AA99128-01
-----------------------	------------

Date of Collection	2014-JAN-16
--------------------	-------------

Timepoint-minutes	0
-------------------	---

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day 0)

Form: Biomarker-Plasma (Nic, Cot, tHCot) (2)

Data signed: (hfarmer1) 26 Mar 2015 13:38:49

Generated On: 20 Jul 2016 10:56:43

Urine End Day	0
---------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day 0)

Form: Biomarker-Plasma (Nic, Cot, tHCot) (3)

Data signed: (hfarmer1) 26 Mar 2015 13:38:49

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05112520000004
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Analyte	COT
---------	-----

Sample type	PLASMA
-------------	--------

Result	156
--------	-----

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-JAN-16
--------------------	-------------

Timepoint-minutes	0
-------------------	---

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day 0)

Form: Biomarker-Plasma (Nic, Cot, tHCot) (3)

Data signed: (hfarmer1) 26 Mar 2015 13:38:49

Generated On: 20 Jul 2016 10:56:43

Urine End Day	0
---------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day 0)

Form: Biomarker-Plasma (Nic, Cot, tHCot) (4)

Data signed: (hfarmer1) 26 Mar 2015 13:38:49

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05112520000004
----------------	----------------

Analyte	THCOT
---------	-------

Sample type	PLASMA
-------------	--------

Result	78.1
--------	------

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-JAN-16
--------------------	-------------

Timepoint-minutes	0
-------------------	---

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Baseline (Day 0)

Form: Biomarker-Plasma (Nic, Cot, tHCot) (4)

Data signed: (hfarmer1) 26 Mar 2015 13:38:49

Generated On: 20 Jul 2016 10:56:43

Urine End Day	0
---------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 1

Form: Date of Visit

Data signed: (hfarmer1) 26 Mar 2015 13:38:50

Generated On: 20 Jul 2016 10:56:43

Date of Visit

17 JAN 2014
DD/MMM/YYYY

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 1

Form: Vital Signs

Data signed: (hfarmer1) 26 Mar 2015 13:38:50

Generated On: 20 Jul 2016 10:56:43

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

10:19
hour:min 24-hour clock

Pulse rate

68
beats per minute

Respiratory rate

16
breaths per minute

Blood Pressure (systolic)

106
mmHg

Blood Pressure (diastolic)

63
mmHg

Vital Signs Position of Subject

Supine ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 1

Form: Plasma Nicotine Sample

Data signed: (hfarmer1) 26 Mar 2015 13:38:50

Generated On: 20 Jul 2016 10:56:43

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	17 JAN 2014
---------------------	-------------

Time hour:min 24-hour clock	20:34
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 1

Form: Plasma Cotinine Sample

Data signed: (hfarmer1) 26 Mar 2015 13:38:50

Generated On: 20 Jul 2016 10:56:43

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	17 JAN 2014
---------------------	-------------

Time hour:min 24-hour clock	20:34
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 1

Form: CoHb Blood Sample

Data signed: (hfarmer1) 26 Mar 2015 13:38:50

Generated On: 20 Jul 2016 10:56:43

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	17 JAN 2014
---------------------	-------------

Timepoint	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: 1002**

Folder: Day 1

Form: CO Breath Test (1)

Data signed: (hfarmer1) 26 Mar 2015 13:38:50

Generated On: 20 Jul 2016 10:56:43

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

If Not Done, please specify the reason: _____

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

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

Result(ppm)	18
-------------	----

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 1

Form: CO Breath Test (2)

Data signed: (hfarmer1) 26 Mar 2015 13:38:50

Generated On: 20 Jul 2016 10:56:43

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	12:04
---	-------

Result(ppm)	20
-------------	----

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 1

Form: CO Breath Test (3)

Data signed: (hfarmer1) 26 Mar 2015 13:38:50

Generated On: 20 Jul 2016 10:56:43

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

If Not Done, please specify the reason: _____

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

Actual Time of Assessment hour:min 24-hour clock	16:14
---	-------

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 1

Form: CO Breath Test (4)

Data signed: (hfarmer1) 26 Mar 2015 13:38:50

Generated On: 20 Jul 2016 10:56:43

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	20:24
---	-------

Result(ppm)	33
-------------	----

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 1

Form: 24 hour urine collections

Data signed: (hfarmer1) 26 Mar 2015 13:38:50

Generated On: 20 Jul 2016 10:56:43

Start Time	06:26
	hour:min 24-hour clock

End Date	18 JAN 2014
	DD/MMM/YYYY

End Time	06:01
	hour:min 24-hour clock

Volume	1516
	mL

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 1

Form: Sample Urine Collection

Data signed: (hfarmer1) 26 Mar 2015 13:38:50

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Day 1

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Data signed: (hfarmer1) 26 Mar 2015 13:38:50

Generated On: 20 Jul 2016 10:56:43

Date of Birth

(b) (6)

Date of assessment
DD/MMM/YYYY

2014 JAN 17
DD/MMM/YYYY

Time of assessment

06:35
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: 1002**

Folder: Day 1

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Data signed: (hfarmer1) 26 Mar 2015 13:38:50

Generated On: 20 Jul 2016 10:56:43

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? Mild ☐

12. Coughing

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 1

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Data signed: (hfarmer1) 26 Mar 2015 13:38:50

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Day 1

Form: Cough Assessment

Data signed: (hfarmer1) 26 Mar 2015 13:38:51

Generated On: 20 Jul 2016 10:56:43

Date of Birth

(b) (6)

Date of assessment
DD/MMM/YYYY

2014 JAN 17
DD/MMM/YYYY

Time of assessment

06:34
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?

19

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

Mild ☒

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

Sometimes ☒

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: 1002**

Folder: Day 1

Form: Lab_BU_COHB (1)

Data signed: (hfarmer1) 26 Mar 2015 13:38:51

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05115150000020
----------------	----------------

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

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

Result	7.80
--------	------

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

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	1
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Celerion Study Number	AA99128-16
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Date of Collection	2014-JAN-17
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Timepoint-minutes	
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 1

Form: Lab_BU_COHB (1)

Data signed: (hfarmer1) 26 Mar 2015 13:38:51

Generated On: 20 Jul 2016 10:56:43

Start Day (24 hour urine only) _____

End Day (24 hour Urine Only) _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 1

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)

Data signed: (hfarmer1) 26 Mar 2015 13:38:50

Generated On: 20 Jul 2016 10:56:43

Date of Birth

(b) (6)

Date of assessment

2014 JAN 17

DD/MMM/YYYY

DD/MMM/YYYY

Time of assessment

20:18
hour:min 24-hour clock

Assessment Status

Completed ☒

1. Was smoking satisfying?

Quite a lot ☒

2. Did cigarettes taste good?

A lot ☒

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

Little ☒

4. Did smoking calm you down?

Quite a lot ☒

5. Did smoking make you feel more awake?

Moderately ☒

6. Did smoking make you feel less irritable?

Moderately ☒

7. Did smoking help you concentrate?

Little ☒

8. Did smoking reduce your hunger for food?

Very little ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 1

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)

Data signed: (hfarmer1) 26 Mar 2015 13:38:50

Generated On: 20 Jul 2016 10:56:43

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

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

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

12. Did you enjoy smoking? Quite a lot ☐

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 1

Form: Questionnaire on smoking urges (QSU)

Data signed: (hfarmer1) 26 Mar 2015 13:38:50

Generated On: 20 Jul 2016 10:56:43

Type	QSU
Date of Birth	(b) (6)
Date of assessment DD/MMM/YYYY	2014 JAN 17
Time of assessment hour:min 24-hour clock	20:17
Assessment Status	Completed <input type="radio"/>
1. I have a desire for a cigarette right now	Disagree <input type="radio"/>
2. Nothing would be better than smoking a cigarette right now	Disagree <input type="radio"/>
3. If it were possible I would probably smoke now	Disagree <input type="radio"/>
4. I could control things better right now if I could smoke	Disagree <input type="radio"/>
5. All I want right now is a cigarette	Disagree <input type="radio"/>
6. I have an urge for a cigarette	Disagree <input type="radio"/>

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 1

Form: Questionnaire on smoking urges (QSU)

Data signed: (hfarmer1) 26 Mar 2015 13:38:50

Generated On: 20 Jul 2016 10:56:43

7. A cigarette would taste good now Disagree ☐

8. I would do almost anything for a cigarette now Disagree ☐

9. Smoking would make me less depressed Disagree ☐

10. I am going to smoke as soon as possible Disagree ☐

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 1

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

Data signed: (hfarmer1) 26 Mar 2015 13:38:51

Generated On: 20 Jul 2016 10:56:43

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 1

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

Data signed: (hfarmer1) 26 Mar 2015 13:38:51

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05112450000015
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Analyte	HPMA
---------	------

Sample type	URINE
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Result	501
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Result Unit	NG/ML
-------------	-------

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

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

Celerion Study Number	AA99128-03
-----------------------	------------

Date of Collection	2014-JAN-17
--------------------	-------------

Timepoint-minutes	
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Urine Start Day	1
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 1

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

Data signed: (hfarmer1) 26 Mar 2015 13:38:51

Generated On: 20 Jul 2016 10:56:43

Urine End Day

2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 1

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (2)

Data signed: (hfarmer1) 26 Mar 2015 13:38:51

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05112450000015
Analyte	CEMA
Sample type	URINE
Result	131
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-JAN-17
Timepoint-minutes	
Urine Start Day	1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 1

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (2)

Data signed: (hfarmer1) 26 Mar 2015 13:38:51

Generated On: 20 Jul 2016 10:56:43

Urine End Day

2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 1

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (3)

Data signed: (hfarmer1) 26 Mar 2015 13:38:51

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05112450000015
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Analyte	HBMA
---------	------

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

Result	283
--------	-----

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

Lab Status	OK
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Sample comment	
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Detection method	LC-MS/MS
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Planned time point (Hour)	0
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Day of Visit	1
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Celerion Study Number	AA99128-03
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Date of Collection	2014-JAN-17
--------------------	-------------

Timepoint-minutes	
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Urine Start Day	1
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 1

Form: Biomarker-Urine (CEMA, HPMa, HBMA) (3)

Data signed: (hfarmer1) 26 Mar 2015 13:38:51

Generated On: 20 Jul 2016 10:56:43

Urine End Day

2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 1

Form: Biomarker-Urine (NNN, NNAL)

Data signed: (hfarmer1) 26 Mar 2015 13:38:51

Generated On: 20 Jul 2016 10:56:43

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 1

Form: Biomarker-Urine (NNN, NNAL) (1)

Data signed: (hfarmer1) 26 Mar 2015 13:38:51

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05112460000015
Analyte	NNAL
Sample type	URINE
Result	589
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-JAN-17
Timepoint-minutes	
Urine Start Day	1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 1

Form: Biomarker-Urine (NNN, NNAL) (1)

Data signed: (hfarmer1) 26 Mar 2015 13:38:51

Generated On: 20 Jul 2016 10:56:43

Urine End Day

2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 1

Form: Biomarker-Urine (NNN, NNAL) (2)

Data signed: (hfarmer1) 26 Mar 2015 13:38:51

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05112460000015
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Analyte	NNN
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Sample type	URINE
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Result	11.7
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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
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Planned time point (Hour)	0
---------------------------	---

Day of Visit	1
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Celerion Study Number	AA99128-04
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Date of Collection	2014-JAN-17
--------------------	-------------

Timepoint-minutes	
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Urine Start Day	1
-----------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 1

Form: Biomarker-Urine (NNN, NNAL) (2)

Data signed: (hfarmer1) 26 Mar 2015 13:38:51

Generated On: 20 Jul 2016 10:56:43

Urine End Day

2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 1

Form: Biomarker-Urine (HEMA)

Data signed: (hfarmer1) 26 Mar 2015 13:38:51

Generated On: 20 Jul 2016 10:56:43

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 1

Form: Biomarker-Urine (HEMA) (1)

Data signed: (hfarmer1) 26 Mar 2015 13:38:51

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05112470000015
Analyte	HEMA
Sample type	URINE
Result	7.57
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-JAN-17
Timepoint-minutes	
Urine Start Day	1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 1

Form: Biomarker-Urine (HEMA) (1)

Data signed: (hfarmer1) 26 Mar 2015 13:38:51

Generated On: 20 Jul 2016 10:56:43

Urine End Day

2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 1

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

Data signed: (hfarmer1) 26 Mar 2015 13:38:51

Generated On: 20 Jul 2016 10:56:43

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 1

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

Data signed: (hfarmer1) 26 Mar 2015 13:38:51

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05112480000015
Analyte	COT
Sample type	URINE
Result	833
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-JAN-18
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 1

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

Data signed: (hfarmer1) 26 Mar 2015 13:38:51

Generated On: 20 Jul 2016 10:56:43

Urine Start Day	1
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Urine End Day	2
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 1

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

Data signed: (hfarmer1) 26 Mar 2015 13:38:51

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05112480000015
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Analyte	COT-GLUC
---------	----------

Sample type	URINE
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Result	5500
--------	------

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-JAN-18
--------------------	-------------

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 1

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

Data signed: (hfarmer1) 26 Mar 2015 13:38:51

Generated On: 20 Jul 2016 10:56:43

Urine Start Day	1
-----------------	---

Urine End Day	2
---------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 1

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(3)**

Data signed: (hfarmer1) 26 Mar 2015 13:38:51

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05112480000015
Analyte	NIC
Sample type	URINE
Result	370
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-JAN-18
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 1

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(3)**

Data signed: (hfarmer1) 26 Mar 2015 13:38:51

Generated On: 20 Jul 2016 10:56:43

Urine Start Day	1
-----------------	---

Urine End Day	2
---------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 1

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

Data signed: (hfarmer1) 26 Mar 2015 13:38:51

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05112480000015
----------------	----------------

Analyte	NIC-GLUC
---------	----------

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

Result	698
--------	-----

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-JAN-18
--------------------	-------------

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 1

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

Data signed: (hfarmer1) 26 Mar 2015 13:38:51

Generated On: 20 Jul 2016 10:56:43

Urine Start Day	1
-----------------	---

Urine End Day	2
---------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 1

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

Data signed: (hfarmer1) 26 Mar 2015 13:38:51

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05112480000015
Analyte	THCOT
Sample type	URINE
Result	2230
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-JAN-18
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 1

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

Data signed: (hfarmer1) 26 Mar 2015 13:38:51

Generated On: 20 Jul 2016 10:56:43

Urine Start Day	1
-----------------	---

Urine End Day	2
---------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 1

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

Data signed: (hfarmer1) 26 Mar 2015 13:38:51

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05112480000015
----------------	----------------

Analyte	THCOT-GLUC
---------	------------

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

Result	2280
--------	------

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-JAN-18
--------------------	-------------

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 1

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

Data signed: (hfarmer1) 26 Mar 2015 13:38:51

Generated On: 20 Jul 2016 10:56:43

Urine Start Day	1
-----------------	---

Urine End Day	2
---------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 1

Form: Biomarker-Urine (3-OH BaP)

Data signed: (hfarmer1) 26 Mar 2015 13:38:51

Generated On: 20 Jul 2016 10:56:43

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 1

Form: Biomarker-Urine (3-OH BaP) (1)

Data signed: (hfarmer1) 26 Mar 2015 13:38:51

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05112490000015
----------------	----------------

Analyte	3-OH BAP
---------	----------

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

Result	99.1
--------	------

Result Unit	FG/ML
-------------	-------

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

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

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

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

Celerion Study Number	AA99128-07
-----------------------	------------

Date of Collection	2014-JAN-17
--------------------	-------------

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

Urine Start Day	1
-----------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 1

Form: Biomarker-Urine (3-OH BaP) (1)

Data signed: (hfarmer1) 26 Mar 2015 13:38:51

Generated On: 20 Jul 2016 10:56:43

Urine End Day

2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 1

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP)

Data signed: (hfarmer1) 26 Mar 2015 13:38:51

Generated On: 20 Jul 2016 10:56:43

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 1

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (1)

Data signed: (hfarmer1) 26 Mar 2015 13:38:51

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05112510000015
----------------	----------------

Analyte	1-NA
---------	------

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

Result	54.0
--------	------

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-JAN-17
--------------------	-------------

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

Urine Start Day	1
-----------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 1

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (1)

Data signed: (hfarmer1) 26 Mar 2015 13:38:51

Generated On: 20 Jul 2016 10:56:43

Urine End Day

2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 1

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (2)

Data signed: (hfarmer1) 26 Mar 2015 13:38:51

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05112510000015
Analyte	2-NA
Sample type	URINE
Result	20.5
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-JAN-17
Timepoint-minutes	
Urine Start Day	1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 1

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (2)

Data signed: (hfarmer1) 26 Mar 2015 13:38:51

Generated On: 20 Jul 2016 10:56:43

Urine End Day

2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 1

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (3)

Data signed: (hfarmer1) 26 Mar 2015 13:38:51

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05112510000015
Analyte	4-ABP
Sample type	URINE
Result	16.1
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-JAN-17
Timepoint-minutes	
Urine Start Day	1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 1

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (3)

Data signed: (hfarmer1) 26 Mar 2015 13:38:51

Generated On: 20 Jul 2016 10:56:43

Urine End Day

2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 1

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (4)

Data signed: (hfarmer1) 26 Mar 2015 13:38:51

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05112510000015
Analyte	O-TOL
Sample type	URINE
Result	113
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-JAN-17
Timepoint-minutes	
Urine Start Day	1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 1

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (4)

Data signed: (hfarmer1) 26 Mar 2015 13:38:51

Generated On: 20 Jul 2016 10:56:43

Urine End Day

2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 1

Form: Biomarker-Urine (1-OHP)

Data signed: (hfarmer1) 26 Mar 2015 13:38:52

Generated On: 20 Jul 2016 10:56:43

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 1

Form: Biomarker-Urine (1-OHP) (1)

Data signed: (hfarmer1) 26 Mar 2015 13:38:52

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05115190001104
Analyte	1-OHP
Sample type	URINE
Result	88.2
Result Unit	PG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	1
Celerion Study Number	AA99598-03
Date of Collection	2014-JAN-17
Timepoint-minutes	
Urine Start Day	1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 1

Form: Biomarker-Urine (1-OHP) (1)

Data signed: (hfarmer1) 26 Mar 2015 13:38:52

Generated On: 20 Jul 2016 10:56:43

Urine End Day

2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 1

Form: Biomarker-Urine (SPMA, SBMA)

Data signed: (hfarmer1) 26 Mar 2015 13:38:51

Generated On: 20 Jul 2016 10:56:43

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 1

Form: Biomarker-Urine (SPMA, SBMA) (1)

Data signed: (hfarmer1) 26 Mar 2015 13:38:51

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05115170001771
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Analyte	SBMA
---------	------

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

Result	3.63
--------	------

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-JAN-17
--------------------	-------------

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

Urine Start Day	1
-----------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 1

Form: Biomarker-Urine (SPMA, SBMA) (1)

Data signed: (hfarmer1) 26 Mar 2015 13:38:51

Generated On: 20 Jul 2016 10:56:43

Urine End Day

2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 1

Form: Biomarker-Urine (SPMA, SBMA) (2)

Data signed: (hfarmer1) 26 Mar 2015 13:38:51

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05115170001771
Analyte	SPMA
Sample type	URINE
Result	3.70
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-JAN-17
Timepoint-minutes	
Urine Start Day	1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 1

Form: Biomarker-Urine (SPMA, SBMA) (2)

Data signed: (hfarmer1) 26 Mar 2015 13:38:51

Generated On: 20 Jul 2016 10:56:43

Urine End Day

2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 1

Form: Biomarker-Urine (MHBMA)

Data signed: (hfarmer1) 26 Mar 2015 13:38:51

Generated On: 20 Jul 2016 10:56:43

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 1

Form: Biomarker-Urine (MHBMA) (1)

Data signed: (hfarmer1) 26 Mar 2015 13:38:51

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05115180000015
----------------	----------------

Analyte	MHBMA
---------	-------

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

Result	1.05
--------	------

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-JAN-17
--------------------	-------------

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

Urine Start Day	1
-----------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 1

Form: Biomarker-Urine (MHBMA) (1)

Data signed: (hfarmer1) 26 Mar 2015 13:38:51

Generated On: 20 Jul 2016 10:56:43

Urine End Day

2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 1

Form: Biomarker-Urine (Creatinine)

Data signed: (hfarmer1) 26 Mar 2015 13:38:52

Generated On: 20 Jul 2016 10:56:43

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 1

Form: Biomarker-Urine (Creatinine) (1)

Data signed: (hfarmer1) 26 Mar 2015 13:38:52

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05115160000015
Analyte	CREATININE
Sample type	URINE
Result	66.5
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-JAN-17
Timepoint-minutes	
Urine Start Day	1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 1

Form: Biomarker-Urine (Creatinine) (1)

Data signed: (hfarmer1) 26 Mar 2015 13:38:52

Generated On: 20 Jul 2016 10:56:43

Urine End Day

2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 1

Form: Biomarker-Plasma (Nic, Cot, tHCot)

Data signed: (hfarmer1) 26 Mar 2015 13:38:51

Generated On: 20 Jul 2016 10:56:43

Sample type

PLASMA

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 1

Form: Biomarker-Plasma (Nic, Cot, tHCot) (1)

Data signed: (hfarmer1) 26 Mar 2015 13:38:51

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05112430000021
----------------	----------------

Analyte	COT
---------	-----

Sample type	PLASMA
-------------	--------

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

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-JAN-17
--------------------	-------------

Timepoint-minutes	0
-------------------	---

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 1

Form: Biomarker-Plasma (Nic, Cot, tHCot) (1)

Data signed: (hfarmer1) 26 Mar 2015 13:38:51

Generated On: 20 Jul 2016 10:56:43

Urine End Day

1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 1

Form: Biomarker-Plasma (Nic, Cot, tHCot) (2)

Data signed: (hfarmer1) 26 Mar 2015 13:38:51

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05112430000021
----------------	----------------

Analyte	NIC
---------	-----

Sample type	PLASMA
-------------	--------

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	1
--------------	---

Celerion Study Number	AA99128-01
-----------------------	------------

Date of Collection	2014-JAN-17
--------------------	-------------

Timepoint-minutes	0
-------------------	---

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 1

Form: Biomarker-Plasma (Nic, Cot, tHCot) (2)

Data signed: (hfarmer1) 26 Mar 2015 13:38:51

Generated On: 20 Jul 2016 10:56:43

Urine End Day

1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 2

Form: Date of Visit

Data signed: (hfarmer1) 26 Mar 2015 13:38:52

Generated On: 20 Jul 2016 10:56:43

Date of Visit

18 JAN 2014
DD/MMM/YYYY

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 2

Form: Vital Signs

Data signed: (hfarmer1) 26 Mar 2015 13:38:52

Generated On: 20 Jul 2016 10:56:43

Were Vitals Signs assessed?

Yes ☒

If No, please specify the reason: _____

Has the subject smoked within 15 minutes prior to
assessment

No ☒

Time of assessment

10:08
hour:min 24-hour clock

Pulse rate

68
beats per minute

Respiratory rate

16
breaths per minute

Blood Pressure (systolic)

98
mmHg

Blood Pressure (diastolic)

65
mmHg

Vital Signs Position of Subject

Supine ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 2

Form: Plasma Nicotine Sample

Data signed: (hfarmer1) 26 Mar 2015 13:38:52

Generated On: 20 Jul 2016 10:56:43

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	18 JAN 2014
---------------------	-------------

Time hour:min 24-hour clock	20:22
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 2

Form: Plasma Cotinine Sample

Data signed: (hfarmer1) 26 Mar 2015 13:38:52

Generated On: 20 Jul 2016 10:56:43

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	18 JAN 2014
---------------------	-------------

Time hour:min 24-hour clock	20:22
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 2

Form: CoHb Blood Sample

Data signed: (hfarmer1) 26 Mar 2015 13:38:52

Generated On: 20 Jul 2016 10:56:43

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	18 JAN 2014
---------------------	-------------

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

Time hour:min 24-hour clock	20:22
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 2

Form: CO Breath Test (1)

Data signed: (hfarmer1) 26 Mar 2015 13:38:52

Generated On: 20 Jul 2016 10:56:43

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

If Not Done, please specify the reason: _____

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

Actual Time of Assessment hour:min 24-hour clock	06:32
---	-------

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 2

Form: CO Breath Test (2)

Data signed: (hfarmer1) 26 Mar 2015 13:38:52

Generated On: 20 Jul 2016 10:56:43

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	12:10
---	-------

Result(ppm)	37
-------------	----

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 2

Form: CO Breath Test (3)

Data signed: (hfarmer1) 26 Mar 2015 13:38:52

Generated On: 20 Jul 2016 10:56:43

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

If Not Done, please specify the reason: _____

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

Actual Time of Assessment hour:min 24-hour clock	16:05
---	-------

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 2

Form: CO Breath Test (4)

Data signed: (hfarmer1) 26 Mar 2015 13:38:52

Generated On: 20 Jul 2016 10:56:43

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	20:16
---	-------

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 2

Form: 24 hour urine collections

Data signed: (hfarmer1) 26 Mar 2015 13:38:52

Generated On: 20 Jul 2016 10:56:43

Start Time	06:01
	hour:min 24-hour clock

End Date	19 JAN 2014
	DD/MMM/YYYY

End Time	06:14
	hour:min 24-hour clock

Volume	1747
	mL

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 2

Form: Sample Urine Collection

Data signed: (hfarmer1) 26 Mar 2015 13:38:52

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Day 2

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Data signed: (hfarmer1) 26 Mar 2015 13:38:52

Generated On: 20 Jul 2016 10:56:43

Date of Birth

(b) (6)

Date of assessment
DD/MMM/YYYY

2014 JAN 18
DD/MMM/YYYY

Time of assessment

06:15
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: 1002**

Folder: Day 2

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Data signed: (hfarmer1) 26 Mar 2015 13:38:52

Generated On: 20 Jul 2016 10:56:43

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

5. Difficulty concentrating

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

6. Increased appetite, hungry, weight gain

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

7. Insomnia, sleep problems, awakening at night

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

8. Restless

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

12. Coughing

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 2

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Data signed: (hfarmer1) 26 Mar 2015 13:38:52

Generated On: 20 Jul 2016 10:56:43

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: 1002

Folder: Day 2

Form: Cough Assessment

Data signed: (hfarmer1) 26 Mar 2015 13:38:53

Generated On: 20 Jul 2016 10:56:43

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

Date of assessment DD/MMM/YYYY	2014 JAN 18 DD/MMM/YYYY
-----------------------------------	----------------------------

Time of assessment	06:14 hour:min 24-hour clock
--------------------	---------------------------------

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

Have you experienced a regular need to cough e.g. coughing several times in the last 24 hrs?	Yes <input checked="" type="radio"/>
--	--------------------------------------

If YES, please answer the following questions:

First Question: Cough Impact Scale How much is your cough bothering you?	15
---	----

Second Question: Cough Intensity Scale: How intense is your cough?	Mild <input checked="" type="radio"/>
---	---------------------------------------

Third Question: Cough Frequency Scale: How frequently do you normally have to cough each day?	Sometimes <input checked="" type="radio"/>
--	--

Fourth Question: Sputum Production To what extent do you produce sputum when coughing?	No sputum <input checked="" type="radio"/>
---	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 2

Form: Lab_BU_COHB (1)

Data signed: (hfarmer1) 26 Mar 2015 13:38:53

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05115150000021
Analyte	CARBOXYHEMOGLOBIN
Sample type	BLOOD
Result	9.20
Result Unit	%
Lab Status	OK
Sample comment	
Detection method	SPECTROPHOTOMETRIC
Lower limit of quantification	0.500
Planned time point (Hour)	20
Day of Visit	2
Celerion Study Number	AA99128-16
Date of Collection	2014-JAN-18
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 2

Form: Lab_BU_COHB (1)

Data signed: (hfarmer1) 26 Mar 2015 13:38:53

Generated On: 20 Jul 2016 10:56:43

Start Day (24 hour urine only) _____

End Day (24 hour Urine Only) _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 2

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)

Data signed: (hfarmer1) 26 Mar 2015 13:38:53

Generated On: 20 Jul 2016 10:56:43

Date of Birth

(b) (6)

Date of assessment

2014 JAN 18

DD/MMM/YYYY

DD/MMM/YYYY

Time of assessment

20:12

hour:min 24-hour clock

Assessment Status

Completed

1. Was smoking satisfying?

A lot

2. Did cigarettes taste good?

A lot

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

Little

4. Did smoking calm you down?

Moderately

5. Did smoking make you feel more awake?

Little

6. Did smoking make you feel less irritable?

Little

7. Did smoking help you concentrate?

Little

8. Did smoking reduce your hunger for food?

Very little

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 2

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)

Data signed: (hfarmer1) 26 Mar 2015 13:38:53

Generated On: 20 Jul 2016 10:56:43

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

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

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

12. Did you enjoy smoking? A lot ☐

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 2

Form: Questionnaire on smoking urges (QSU)

Data signed: (hfarmer1) 26 Mar 2015 13:38:52

Generated On: 20 Jul 2016 10:56:43

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

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

Date of assessment	2014 JAN 18
--------------------	-------------

DD/MMM/YYYY

Time of assessment	20:11
--------------------	-------

hour:min 24-hour clock

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

1. I have a desire for a cigarette right now	Do not agree or disagree <input type="radio"/>
--	--

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

3. If it were possible I would probably smoke now	Do not agree or disagree <input type="radio"/>
---	--

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

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

6. I have an urge for a cigarette	Do not agree or disagree <input type="radio"/>
-----------------------------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 2

Form: Questionnaire on smoking urges (QSU)

Data signed: (hfarmer1) 26 Mar 2015 13:38:52

Generated On: 20 Jul 2016 10:56:43

7. A cigarette would taste good now Disagree ☐

8. I would do almost anything for a cigarette now Somewhat disagree ☐

9. Smoking would make me less depressed Disagree ☐

10. I am going to smoke as soon as possible Do not agree or disagree ☐

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 2

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

Data signed: (hfarmer1) 26 Mar 2015 13:38:55

Generated On: 20 Jul 2016 10:56:43

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 2

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

Data signed: (hfarmer1) 26 Mar 2015 13:38:55

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05112450000016
----------------	----------------

Analyte	HPMA
---------	------

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

Result	617
--------	-----

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-JAN-18
--------------------	-------------

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

Urine Start Day	2
-----------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 2

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

Data signed: (hfarmer1) 26 Mar 2015 13:38:55

Generated On: 20 Jul 2016 10:56:43

Urine End Day

3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 2

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (2)

Data signed: (hfarmer1) 26 Mar 2015 13:38:55

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05112450000016
Analyte	CEMA
Sample type	URINE
Result	137
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-JAN-18
Timepoint-minutes	
Urine Start Day	2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 2

Form: Biomarker-Urine (CEMA, HPMa, HBMA) (2)

Data signed: (hfarmer1) 26 Mar 2015 13:38:55

Generated On: 20 Jul 2016 10:56:43

Urine End Day

3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 2

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (3)

Data signed: (hfarmer1) 26 Mar 2015 13:38:55

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05112450000016
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Analyte	HBMA
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Sample type	URINE
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Result	291
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Result Unit	NG/ML
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Lab Status	OK
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Sample comment	
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Detection method	LC-MS/MS
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Planned time point (Hour)	0
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Day of Visit	2
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Celerion Study Number	AA99128-03
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Date of Collection	2014-JAN-18
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Timepoint-minutes	
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Urine Start Day	2
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 2

Form: Biomarker-Urine (CEMA, HPMa, HBMA) (3)

Data signed: (hfarmer1) 26 Mar 2015 13:38:55

Generated On: 20 Jul 2016 10:56:43

Urine End Day

3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 2

Form: Biomarker-Urine (NNN, NNAL)

Data signed: (hfarmer1) 26 Mar 2015 13:38:53

Generated On: 20 Jul 2016 10:56:43

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 2

Form: Biomarker-Urine (NNN, NNAL) (1)

Data signed: (hfarmer1) 26 Mar 2015 13:38:53

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05112460000016
Analyte	NNAL
Sample type	URINE
Result	469
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-JAN-18
Timepoint-minutes	
Urine Start Day	2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 2

Form: Biomarker-Urine (NNN, NNAL) (1)

Data signed: (hfarmer1) 26 Mar 2015 13:38:53

Generated On: 20 Jul 2016 10:56:43

Urine End Day

3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 2

Form: Biomarker-Urine (NNN, NNAL) (2)

Data signed: (hfarmer1) 26 Mar 2015 13:38:53

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05112460000016
Analyte	NNN
Sample type	URINE
Result	16.3
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-JAN-18
Timepoint-minutes	
Urine Start Day	2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 2

Form: Biomarker-Urine (NNN, NNAL) (2)

Data signed: (hfarmer1) 26 Mar 2015 13:38:53

Generated On: 20 Jul 2016 10:56:43

Urine End Day

3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 2

Form: Biomarker-Urine (HEMA)

Data signed: (hfarmer1) 26 Mar 2015 13:38:54

Generated On: 20 Jul 2016 10:56:43

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 2

Form: Biomarker-Urine (HEMA) (1)

Data signed: (hfarmer1) 26 Mar 2015 13:38:54

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05112470000016
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Analyte	HEMA
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Sample type	URINE
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Result	8.44
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Result Unit	NG/ML
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Lab Status	OK
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Sample comment	
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Detection method	LC-MS/MS
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Planned time point (Hour)	0
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Day of Visit	2
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Celerion Study Number	AA99128-05
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Date of Collection	2014-JAN-18
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Timepoint-minutes	
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Urine Start Day	2
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 2

Form: Biomarker-Urine (HEMA) (1)

Data signed: (hfarmer1) 26 Mar 2015 13:38:54

Generated On: 20 Jul 2016 10:56:43

Urine End Day

3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 2

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

Data signed: (hfarmer1) 26 Mar 2015 13:38:55

Generated On: 20 Jul 2016 10:56:43

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 2

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

Data signed: (hfarmer1) 26 Mar 2015 13:38:55

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05112480000016
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Analyte	COT
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Sample type	URINE
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Result	1060
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Result Unit	NG/ML
-------------	-------

Lab Status	OK
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Sample comment	
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Detection method	LC-MS/MS
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Planned time point (Hour)	0
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Day of Visit	2
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Celerion Study Number	AA99128-06
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Date of Collection	2014-JAN-19
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Timepoint-minutes	
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 2

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

Data signed: (hfarmer1) 26 Mar 2015 13:38:55

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Day 2

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

Data signed: (hfarmer1) 26 Mar 2015 13:38:55

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05112480000016
Analyte	COT-GLUC
Sample type	URINE
Result	5690
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-JAN-19
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 2

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

Data signed: (hfarmer1) 26 Mar 2015 13:38:55

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Day 2

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(3)**

Data signed: (hfarmer1) 26 Mar 2015 13:38:55

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05112480000016
Analyte	NIC
Sample type	URINE
Result	785
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-JAN-19
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 2

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(3)**

Data signed: (hfarmer1) 26 Mar 2015 13:38:55

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Day 2

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

Data signed: (hfarmer1) 26 Mar 2015 13:38:55

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05112480000016
Analyte	NIC-GLUC
Sample type	URINE
Result	1030
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-JAN-19
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 2

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

Data signed: (hfarmer1) 26 Mar 2015 13:38:55

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Day 2

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

Data signed: (hfarmer1) 26 Mar 2015 13:38:55

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05112480000016
Analyte	THCOT
Sample type	URINE
Result	2150
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-JAN-19
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 2

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

Data signed: (hfarmer1) 26 Mar 2015 13:38:55

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Day 2

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

Data signed: (hfarmer1) 26 Mar 2015 13:38:55

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05112480000016
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Analyte	THCOT-GLUC
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Sample type	URINE
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Result	1830
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Result Unit	NG/ML
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Lab Status	OK
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Sample comment	
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Detection method	LC-MS/MS
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Planned time point (Hour)	0
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Day of Visit	2
--------------	---

Celerion Study Number	AA99128-06
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Date of Collection	2014-JAN-19
--------------------	-------------

Timepoint-minutes	
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 2

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

Data signed: (hfarmer1) 26 Mar 2015 13:38:55

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Day 2

Form: Biomarker-Urine (3-OH BaP)

Data signed: (hfarmer1) 26 Mar 2015 13:38:56

Generated On: 20 Jul 2016 10:56:43

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 2

Form: Biomarker-Urine (3-OH BaP) (1)

Data signed: (hfarmer1) 26 Mar 2015 13:38:56

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05112490000016
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Analyte	3-OH BAP
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Sample type	URINE
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Result	103
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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	2
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Celerion Study Number	AA99128-07
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Date of Collection	2014-JAN-18
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Timepoint-minutes	
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Urine Start Day	2
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 2

Form: Biomarker-Urine (3-OH BaP) (1)

Data signed: (hfarmer1) 26 Mar 2015 13:38:56

Generated On: 20 Jul 2016 10:56:43

Urine End Day

3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 2

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP)

Data signed: (hfarmer1) 26 Mar 2015 13:38:56

Generated On: 20 Jul 2016 10:56:43

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 2

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (1)

Data signed: (hfarmer1) 26 Mar 2015 13:38:56

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05112510000016
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Analyte	1-NA
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Sample type	URINE
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Result	87.8
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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	2
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Celerion Study Number	AA99128-09
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Date of Collection	2014-JAN-18
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Timepoint-minutes	
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Urine Start Day	2
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 2

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (1)

Data signed: (hfarmer1) 26 Mar 2015 13:38:56

Generated On: 20 Jul 2016 10:56:43

Urine End Day

3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 2

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (2)

Data signed: (hfarmer1) 26 Mar 2015 13:38:56

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05112510000016
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Analyte	2-NA
---------	------

Sample type	URINE
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Result	28.1
--------	------

Result Unit	PG/ML
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Lab Status	OK
------------	----

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

Detection method	LC-MS/MS
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Planned time point (Hour)	0
---------------------------	---

Day of Visit	2
--------------	---

Celerion Study Number	AA99128-09
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Date of Collection	2014-JAN-18
--------------------	-------------

Timepoint-minutes	
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Urine Start Day	2
-----------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 2

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (2)

Data signed: (hfarmer1) 26 Mar 2015 13:38:56

Generated On: 20 Jul 2016 10:56:43

Urine End Day

3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 2

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (3)

Data signed: (hfarmer1) 26 Mar 2015 13:38:56

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05112510000016
Analyte	4-ABP
Sample type	URINE
Result	16.2
Result Unit	PG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	2
Celerion Study Number	AA99128-09
Date of Collection	2014-JAN-18
Timepoint-minutes	
Urine Start Day	2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 2

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (3)

Data signed: (hfarmer1) 26 Mar 2015 13:38:56

Generated On: 20 Jul 2016 10:56:43

Urine End Day

3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 2

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (4)

Data signed: (hfarmer1) 26 Mar 2015 13:38:56

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05112510000016
Analyte	O-TOL
Sample type	URINE
Result	144
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-JAN-18
Timepoint-minutes	
Urine Start Day	2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 2

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (4)

Data signed: (hfarmer1) 26 Mar 2015 13:38:56

Generated On: 20 Jul 2016 10:56:43

Urine End Day

3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 2

Form: Biomarker-Urine (1-OHP)

Data signed: (hfarmer1) 26 Mar 2015 13:38:56

Generated On: 20 Jul 2016 10:56:43

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 2

Form: Biomarker-Urine (1-OHP) (1)

Data signed: (hfarmer1) 26 Mar 2015 13:38:56

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05115190001105
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Analyte	1-OHP
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Sample type	URINE
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Result	112
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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	2
--------------	---

Celerion Study Number	AA99598-03
-----------------------	------------

Date of Collection	2014-JAN-18
--------------------	-------------

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

Urine Start Day	2
-----------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 2

Form: Biomarker-Urine (1-OHP) (1)

Data signed: (hfarmer1) 26 Mar 2015 13:38:56

Generated On: 20 Jul 2016 10:56:43

Urine End Day

3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 2

Form: Biomarker-Urine (SPMA, SBMA)

Data signed: (hfarmer1) 26 Mar 2015 13:38:54

Generated On: 20 Jul 2016 10:56:43

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 2

Form: Biomarker-Urine (SPMA, SBMA) (1)

Data signed: (hfarmer1) 26 Mar 2015 13:38:54

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05115170001772
Analyte	SBMA
Sample type	URINE
Result	3.28
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-JAN-18
Timepoint-minutes	
Urine Start Day	2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 2

Form: Biomarker-Urine (SPMA, SBMA) (1)

Data signed: (hfarmer1) 26 Mar 2015 13:38:54

Generated On: 20 Jul 2016 10:56:43

Urine End Day

3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 2

Form: Biomarker-Urine (SPMA, SBMA) (2)

Data signed: (hfarmer1) 26 Mar 2015 13:38:54

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05115170001772
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Analyte	SPMA
---------	------

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

Result	3.40
--------	------

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-JAN-18
--------------------	-------------

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

Urine Start Day	2
-----------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 2

Form: Biomarker-Urine (SPMA, SBMA) (2)

Data signed: (hfarmer1) 26 Mar 2015 13:38:54

Generated On: 20 Jul 2016 10:56:43

Urine End Day

3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 2

Form: Biomarker-Urine (MHBMA)

Data signed: (hfarmer1) 26 Mar 2015 13:38:54

Generated On: 20 Jul 2016 10:56:43

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 2

Form: Biomarker-Urine (MHBMA) (1)

Data signed: (hfarmer1) 26 Mar 2015 13:38:54

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05115180000016
Analyte	MHBMA
Sample type	URINE
Result	1.25
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-JAN-18
Timepoint-minutes	
Urine Start Day	2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 2

Form: Biomarker-Urine (MHBMA) (1)

Data signed: (hfarmer1) 26 Mar 2015 13:38:54

Generated On: 20 Jul 2016 10:56:43

Urine End Day

3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 2

Form: Biomarker-Urine (Creatinine)

Data signed: (hfarmer1) 26 Mar 2015 13:38:56

Generated On: 20 Jul 2016 10:56:43

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 2

Form: Biomarker-Urine (Creatinine) (1)

Data signed: (hfarmer1) 26 Mar 2015 13:38:56

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05115160000016
Analyte	CREATININE
Sample type	URINE
Result	60.8
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-JAN-18
Timepoint-minutes	
Urine Start Day	2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 2

Form: Biomarker-Urine (Creatinine) (1)

Data signed: (hfarmer1) 26 Mar 2015 13:38:56

Generated On: 20 Jul 2016 10:56:43

Urine End Day

3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 2

Form: Biomarker-Plasma (Nic, Cot, tHCot)

Data signed: (hfarmer1) 26 Mar 2015 13:38:55

Generated On: 20 Jul 2016 10:56:43

Sample type

PLASMA

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 2

Form: Biomarker-Plasma (Nic, Cot, tHCot) (1)

Data signed: (hfarmer1) 26 Mar 2015 13:38:55

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05112430000022
----------------	----------------

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	2
--------------	---

Celerion Study Number	AA99128-01
-----------------------	------------

Date of Collection	2014-JAN-18
--------------------	-------------

Timepoint-minutes	0
-------------------	---

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 2

Form: Biomarker-Plasma (Nic, Cot, tHCot) (1)

Data signed: (hfarmer1) 26 Mar 2015 13:38:55

Generated On: 20 Jul 2016 10:56:43

Urine End Day

2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 2

Form: Biomarker-Plasma (Nic, Cot, tHCot) (2)

Data signed: (hfarmer1) 26 Mar 2015 13:38:55

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05112430000022
----------------	----------------

Analyte	NIC
---------	-----

Sample type	PLASMA
-------------	--------

Result	18.8
--------	------

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-JAN-18
--------------------	-------------

Timepoint-minutes	0
-------------------	---

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 2

Form: Biomarker-Plasma (Nic, Cot, tHCot) (2)

Data signed: (hfarmer1) 26 Mar 2015 13:38:55

Generated On: 20 Jul 2016 10:56:43

Urine End Day

2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 3

Form: Date of Visit

Data signed: (hfarmer1) 26 Mar 2015 13:38:56

Generated On: 20 Jul 2016 10:56:43

Date of Visit

19 JAN 2014
DD/MMM/YYYY

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 3

Form: Vital Signs

Data signed: (hfarmer1) 26 Mar 2015 13:38:56

Generated On: 20 Jul 2016 10:56:43

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

09:39
hour:min 24-hour clock

Pulse rate

73
beats per minute

Respiratory rate

14
breaths per minute

Blood Pressure (systolic)

109
mmHg

Blood Pressure (diastolic)

66
mmHg

Vital Signs Position of Subject

Supine ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 3

Form: Plasma Nicotine Sample

Data signed: (hfarmer1) 26 Mar 2015 13:38:56

Generated On: 20 Jul 2016 10:56:43

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	19 JAN 2014
---------------------	-------------

Time hour:min 24-hour clock	20:38
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 3

Form: Plasma Cotinine Sample

Data signed: (hfarmer1) 26 Mar 2015 13:38:56

Generated On: 20 Jul 2016 10:56:43

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	19 JAN 2014
---------------------	-------------

Time hour:min 24-hour clock	20:38
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 3

Form: CoHb Blood Sample

Data signed: (hfarmer1) 26 Mar 2015 13:38:56

Generated On: 20 Jul 2016 10:56:43

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	19 JAN 2014
---------------------	-------------

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

Time hour:min 24-hour clock	20:38
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 3

Form: CO Breath Test (1)

Data signed: (hfarmer1) 26 Mar 2015 13:38:57

Generated On: 20 Jul 2016 10:56:43

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	06:37
---	-------

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 3

Form: CO Breath Test (2)

Data signed: (hfarmer1) 26 Mar 2015 13:38:57

Generated On: 20 Jul 2016 10:56:43

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)	27
-------------	----

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 3

Form: CO Breath Test (3)

Data signed: (hfarmer1) 26 Mar 2015 13:38:57

Generated On: 20 Jul 2016 10:56:43

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	16:39
---	-------

Result(ppm)	43
-------------	----

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 3

Form: CO Breath Test (4)

Data signed: (hfarmer1) 26 Mar 2015 13:38:57

Generated On: 20 Jul 2016 10:56:43

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	20:32
---	-------

Result(ppm)	37
-------------	----

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 3

Form: 24 hour urine collections

Data signed: (hfarmer1) 26 Mar 2015 13:38:56

Generated On: 20 Jul 2016 10:56:43

Start Time	06:14
	hour:min 24-hour clock

End Date	20 JAN 2014
	DD/MMM/YYYY

End Time	05:58
	hour:min 24-hour clock

Volume	1202
	mL

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 3

Form: Sample Urine Collection

Data signed: (hfarmer1) 26 Mar 2015 13:38:56

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Day 3

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Data signed: (hfarmer1) 26 Mar 2015 13:38:57

Generated On: 20 Jul 2016 10:56:43

Date of Birth

(b) (6)

Date of assessment
DD/MMM/YYYY

2014 JAN 19
DD/MMM/YYYY

Time of assessment

06:16
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: 1002**

Folder: Day 3

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Data signed: (hfarmer1) 26 Mar 2015 13:38:57

Generated On: 20 Jul 2016 10:56:43

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

5. Difficulty concentrating

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

6. Increased appetite, hungry, weight gain

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

7. Insomnia, sleep problems, awakening at night

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

8. Restless

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

12. Coughing

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 3

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Data signed: (hfarmer1) 26 Mar 2015 13:38:57

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Day 3

Form: Cough Assessment

Data signed: (hfarmer1) 26 Mar 2015 13:38:57

Generated On: 20 Jul 2016 10:56:43

Date of Birth

(b) (6)

Date of assessment
DD/MMM/YYYY

2014 JAN 19
DD/MMM/YYYY

Time of assessment

06:15
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?

13

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

Mild ☒

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

Sometimes ☒

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: 1002**

Folder: Day 3

Form: Lab_BU_COHB (1)

Data signed: (hfarmer1) 26 Mar 2015 13:38:57

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05115150000022
----------------	----------------

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

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

Result	10.8
--------	------

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

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

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

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

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

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

Day of Visit	3
--------------	---

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

Date of Collection	2014-JAN-19
--------------------	-------------

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 3

Form: Lab_BU_COHB (1)

Data signed: (hfarmer1) 26 Mar 2015 13:38:57

Generated On: 20 Jul 2016 10:56:43

Start Day (24 hour urine only) _____

End Day (24 hour Urine Only) _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 3

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)

Data signed: (hfarmer1) 26 Mar 2015 13:38:57

Generated On: 20 Jul 2016 10:56:43

Date of Birth

(b) (6)

Date of assessment

2014 JAN 19

DD/MMM/YYYY

DD/MMM/YYYY

Time of assessment

20:06

hour:min 24-hour clock

Assessment Status

Completed ☒

1. Was smoking satisfying?

A lot ☒

2. Did cigarettes taste good?

A lot ☒

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

Little ☒

4. Did smoking calm you down?

A lot ☒

5. Did smoking make you feel more awake?

Little ☒

6. Did smoking make you feel less irritable?

Very little ☒

7. Did smoking help you concentrate?

Very little ☒

8. Did smoking reduce your hunger for food?

Not at all ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 3

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)

Data signed: (hfarmer1) 26 Mar 2015 13:38:57

Generated On: 20 Jul 2016 10:56:43

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

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

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

12. Did you enjoy smoking? Quite a lot ☐

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 3

Form: Questionnaire on smoking urges (QSU)

Data signed: (hfarmer1) 26 Mar 2015 13:38:57

Generated On: 20 Jul 2016 10:56:43

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

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

Date of assessment	2014 JAN 19
--------------------	-------------

DD/MMM/YYYY

Time of assessment	20:05
--------------------	-------

hour:min 24-hour clock

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

1. I have a desire for a cigarette right now	Somewhat disagree <input type="radio"/>
--	---

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

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

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

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

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 3

Form: Questionnaire on smoking urges (QSU)

Data signed: (hfarmer1) 26 Mar 2015 13:38:57

Generated On: 20 Jul 2016 10:56:43

7. A cigarette would taste good now Somewhat disagree ☐

8. I would do almost anything for a cigarette now Disagree ☐

9. Smoking would make me less depressed Strongly disagree ☐

10. I am going to smoke as soon as possible Somewhat disagree ☐

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 3

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

Data signed: (hfarmer1) 26 Mar 2015 13:38:58

Generated On: 20 Jul 2016 10:56:43

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 3

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

Data signed: (hfarmer1) 26 Mar 2015 13:38:58

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05112450000017
----------------	----------------

Analyte	HPMA
---------	------

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

Result	850
--------	-----

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-JAN-19
--------------------	-------------

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

Urine Start Day	3
-----------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 3

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

Data signed: (hfarmer1) 26 Mar 2015 13:38:58

Generated On: 20 Jul 2016 10:56:43

Urine End Day

4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 3

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (2)

Data signed: (hfarmer1) 26 Mar 2015 13:38:58

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05112450000017
----------------	----------------

Analyte	CEMA
---------	------

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

Result	197
--------	-----

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-JAN-19
--------------------	-------------

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

Urine Start Day	3
-----------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 3

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (2)

Data signed: (hfarmer1) 26 Mar 2015 13:38:58

Generated On: 20 Jul 2016 10:56:43

Urine End Day

4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 3

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (3)

Data signed: (hfarmer1) 26 Mar 2015 13:38:58

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05112450000017
Analyte	HBMA
Sample type	URINE
Result	533
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-JAN-19
Timepoint-minutes	
Urine Start Day	3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 3

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (3)

Data signed: (hfarmer1) 26 Mar 2015 13:38:58

Generated On: 20 Jul 2016 10:56:43

Urine End Day

4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 3

Form: Biomarker-Urine (NNN, NNAL)

Data signed: (hfarmer1) 26 Mar 2015 13:38:58

Generated On: 20 Jul 2016 10:56:43

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 3

Form: Biomarker-Urine (NNN, NNAL) (1)

Data signed: (hfarmer1) 26 Mar 2015 13:38:58

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05112460000017
Analyte	NNAL
Sample type	URINE
Result	803
Result Unit	PG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	3
Celerion Study Number	AA99128-04
Date of Collection	2014-JAN-19
Timepoint-minutes	
Urine Start Day	3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 3

Form: Biomarker-Urine (NNN, NNAL) (1)

Data signed: (hfarmer1) 26 Mar 2015 13:38:58

Generated On: 20 Jul 2016 10:56:43

Urine End Day

4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 3

Form: Biomarker-Urine (NNN, NNAL) (2)

Data signed: (hfarmer1) 26 Mar 2015 13:38:58

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05112460000017
Analyte	NNN
Sample type	URINE
Result	22.9
Result Unit	PG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	3
Celerion Study Number	AA99128-04
Date of Collection	2014-JAN-19
Timepoint-minutes	
Urine Start Day	3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 3

Form: Biomarker-Urine (NNN, NNAL) (2)

Data signed: (hfarmer1) 26 Mar 2015 13:38:58

Generated On: 20 Jul 2016 10:56:43

Urine End Day

4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 3

Form: Biomarker-Urine (HEMA)

Data signed: (hfarmer1) 26 Mar 2015 13:38:58

Generated On: 20 Jul 2016 10:56:43

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 3

Form: Biomarker-Urine (HEMA) (1)

Data signed: (hfarmer1) 26 Mar 2015 13:38:58

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05112470000017
Analyte	HEMA
Sample type	URINE
Result	11.7
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	3
Celerion Study Number	AA99128-05
Date of Collection	2014-JAN-19
Timepoint-minutes	
Urine Start Day	3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 3

Form: Biomarker-Urine (HEMA) (1)

Data signed: (hfarmer1) 26 Mar 2015 13:38:58

Generated On: 20 Jul 2016 10:56:43

Urine End Day

4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 3

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

Data signed: (hfarmer1) 26 Mar 2015 13:38:58

Generated On: 20 Jul 2016 10:56:43

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 3

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

Data signed: (hfarmer1) 26 Mar 2015 13:38:58

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05112480000017
Analyte	COT
Sample type	URINE
Result	1360
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-JAN-20
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 3

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

Data signed: (hfarmer1) 26 Mar 2015 13:38:58

Generated On: 20 Jul 2016 10:56:43

Urine Start Day	3
-----------------	---

Urine End Day	4
---------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 3

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

Data signed: (hfarmer1) 26 Mar 2015 13:38:58

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05112480000017
----------------	----------------

Analyte	COT-GLUC
---------	----------

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

Result	9180
--------	------

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-JAN-20
--------------------	-------------

Timepoint-minutes	
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 3

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

Data signed: (hfarmer1) 26 Mar 2015 13:38:58

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Day 3

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(3)**

Data signed: (hfarmer1) 26 Mar 2015 13:38:58

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05112480000017
Analyte	NIC
Sample type	URINE
Result	1120
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-JAN-20
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 3

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(3)**

Data signed: (hfarmer1) 26 Mar 2015 13:38:58

Generated On: 20 Jul 2016 10:56:43

Urine Start Day	3
-----------------	---

Urine End Day	4
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 3

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

Data signed: (hfarmer1) 26 Mar 2015 13:38:58

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05112480000017
Analyte	NIC-GLUC
Sample type	URINE
Result	1530
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-JAN-20
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 3

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

Data signed: (hfarmer1) 26 Mar 2015 13:38:58

Generated On: 20 Jul 2016 10:56:43

Urine Start Day	3
-----------------	---

Urine End Day	4
---------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 3

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

Data signed: (hfarmer1) 26 Mar 2015 13:38:58

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05112480000017
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Analyte	THCOT
---------	-------

Sample type	URINE
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Result	3360
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Result Unit	NG/ML
-------------	-------

Lab Status	OK
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Sample comment	
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Detection method	LC-MS/MS
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Planned time point (Hour)	0
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Day of Visit	3
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Celerion Study Number	AA99128-06
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Date of Collection	2014-JAN-20
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Timepoint-minutes	
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 3

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

Data signed: (hfarmer1) 26 Mar 2015 13:38:58

Generated On: 20 Jul 2016 10:56:43

Urine Start Day	3
-----------------	---

Urine End Day	4
---------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 3

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

Data signed: (hfarmer1) 26 Mar 2015 13:38:58

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05112480000017
Analyte	THCOT-GLUC
Sample type	URINE
Result	2950
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-JAN-20
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 3

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

Data signed: (hfarmer1) 26 Mar 2015 13:38:58

Generated On: 20 Jul 2016 10:56:43

Urine Start Day	3
-----------------	---

Urine End Day	4
---------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 3

Form: Biomarker-Urine (3-OH BaP)

Data signed: (hfarmer1) 26 Mar 2015 13:38:59

Generated On: 20 Jul 2016 10:56:43

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 3

Form: Biomarker-Urine (3-OH BaP) (1)

Data signed: (hfarmer1) 26 Mar 2015 13:38:59

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05112490000017
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Analyte	3-OH BAP
---------	----------

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

Result	159
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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	3
--------------	---

Celerion Study Number	AA99128-07
-----------------------	------------

Date of Collection	2014-JAN-19
--------------------	-------------

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

Urine Start Day	3
-----------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 3

Form: Biomarker-Urine (3-OH BaP) (1)

Data signed: (hfarmer1) 26 Mar 2015 13:38:59

Generated On: 20 Jul 2016 10:56:43

Urine End Day

4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 3

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP)

Data signed: (hfarmer1) 26 Mar 2015 13:38:59

Generated On: 20 Jul 2016 10:56:43

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 3

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (1)

Data signed: (hfarmer1) 26 Mar 2015 13:38:59

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05112510000017
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Analyte	1-NA
---------	------

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

Result	120
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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	3
--------------	---

Celerion Study Number	AA99128-09
-----------------------	------------

Date of Collection	2014-JAN-19
--------------------	-------------

Timepoint-minutes	
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Urine Start Day	3
-----------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 3

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (1)

Data signed: (hfarmer1) 26 Mar 2015 13:38:59

Generated On: 20 Jul 2016 10:56:43

Urine End Day

4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 3

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (2)

Data signed: (hfarmer1) 26 Mar 2015 13:38:59

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05112510000017
Analyte	2-NA
Sample type	URINE
Result	37.4
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-JAN-19
Timepoint-minutes	
Urine Start Day	3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 3

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (2)

Data signed: (hfarmer1) 26 Mar 2015 13:38:59

Generated On: 20 Jul 2016 10:56:43

Urine End Day

4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 3

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (3)

Data signed: (hfarmer1) 26 Mar 2015 13:38:59

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05112510000017
Analyte	4-ABP
Sample type	URINE
Result	22.4
Result Unit	PG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	3
Celerion Study Number	AA99128-09
Date of Collection	2014-JAN-19
Timepoint-minutes	
Urine Start Day	3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 3

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (3)

Data signed: (hfarmer1) 26 Mar 2015 13:38:59

Generated On: 20 Jul 2016 10:56:43

Urine End Day

4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 3

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (4)

Data signed: (hfarmer1) 26 Mar 2015 13:38:59

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05112510000017
Analyte	O-TOL
Sample type	URINE
Result	187
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-JAN-19
Timepoint-minutes	
Urine Start Day	3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 3

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (4)

Data signed: (hfarmer1) 26 Mar 2015 13:38:59

Generated On: 20 Jul 2016 10:56:43

Urine End Day

4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 3

Form: Biomarker-Urine (1-OHP)

Data signed: (hfarmer1) 26 Mar 2015 13:38:59

Generated On: 20 Jul 2016 10:56:43

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 3

Form: Biomarker-Urine (1-OHP) (1)

Data signed: (hfarmer1) 26 Mar 2015 13:38:59

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05115190001106
Analyte	1-OHP
Sample type	URINE
Result	157
Result Unit	PG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	3
Celerion Study Number	AA99598-03
Date of Collection	2014-JAN-19
Timepoint-minutes	
Urine Start Day	3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 3

Form: Biomarker-Urine (1-OHP) (1)

Data signed: (hfarmer1) 26 Mar 2015 13:38:59

Generated On: 20 Jul 2016 10:56:43

Urine End Day

4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 3

Form: Biomarker-Urine (SPMA, SBMA)

Data signed: (hfarmer1) 26 Mar 2015 13:38:58

Generated On: 20 Jul 2016 10:56:43

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 3

Form: Biomarker-Urine (SPMA, SBMA) (1)

Data signed: (hfarmer1) 26 Mar 2015 13:38:58

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05115170001773
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Analyte	SBMA
---------	------

Sample type	URINE
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Result	8.38
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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	3
--------------	---

Celerion Study Number	AA99598-01
-----------------------	------------

Date of Collection	2014-JAN-19
--------------------	-------------

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

Urine Start Day	3
-----------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 3

Form: Biomarker-Urine (SPMA, SBMA) (1)

Data signed: (hfarmer1) 26 Mar 2015 13:38:58

Generated On: 20 Jul 2016 10:56:43

Urine End Day

4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 3

Form: Biomarker-Urine (SPMA, SBMA) (2)

Data signed: (hfarmer1) 26 Mar 2015 13:38:58

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05115170001773
----------------	----------------

Analyte	SPMA
---------	------

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

Result	5.02
--------	------

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-JAN-19
--------------------	-------------

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

Urine Start Day	3
-----------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 3

Form: Biomarker-Urine (SPMA, SBMA) (2)

Data signed: (hfarmer1) 26 Mar 2015 13:38:58

Generated On: 20 Jul 2016 10:56:43

Urine End Day

4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 3

Form: Biomarker-Urine (MHBMA)

Data signed: (hfarmer1) 26 Mar 2015 13:38:58

Generated On: 20 Jul 2016 10:56:43

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 3

Form: Biomarker-Urine (MHBMA) (1)

Data signed: (hfarmer1) 26 Mar 2015 13:38:58

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05115180000017
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Analyte	MHBMA
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Sample type	URINE
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Result	1.93
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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	AA99598-02
-----------------------	------------

Date of Collection	2014-JAN-19
--------------------	-------------

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

Urine Start Day	3
-----------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 3

Form: Biomarker-Urine (MHBMA) (1)

Data signed: (hfarmer1) 26 Mar 2015 13:38:58

Generated On: 20 Jul 2016 10:56:43

Urine End Day

4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 3

Form: Biomarker-Urine (Creatinine)

Data signed: (hfarmer1) 26 Mar 2015 13:38:59

Generated On: 20 Jul 2016 10:56:43

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 3

Form: Biomarker-Urine (Creatinine) (1)

Data signed: (hfarmer1) 26 Mar 2015 13:38:59

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05115160000017
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	3
Celerion Study Number	AA99128-14
Date of Collection	2014-JAN-19
Timepoint-minutes	
Urine Start Day	3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 3

Form: Biomarker-Urine (Creatinine) (1)

Data signed: (hfarmer1) 26 Mar 2015 13:38:59

Generated On: 20 Jul 2016 10:56:43

Urine End Day

4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 3

Form: Biomarker-Plasma (Nic, Cot, tHCot)

Data signed: (hfarmer1) 26 Mar 2015 13:38:58

Generated On: 20 Jul 2016 10:56:43

Sample type

PLASMA

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 3

Form: Biomarker-Plasma (Nic, Cot, tHCot) (1)

Data signed: (hfarmer1) 26 Mar 2015 13:38:58

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05112430000023
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Analyte	COT
---------	-----

Sample type	PLASMA
-------------	--------

Result	252
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Result Unit	NG/ML
-------------	-------

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	AA99128-01
-----------------------	------------

Date of Collection	2014-JAN-19
--------------------	-------------

Timepoint-minutes	0
-------------------	---

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 3

Form: Biomarker-Plasma (Nic, Cot, tHCot) (1)

Data signed: (hfarmer1) 26 Mar 2015 13:38:58

Generated On: 20 Jul 2016 10:56:43

Urine End Day

3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 3

Form: Biomarker-Plasma (Nic, Cot, tHCot) (2)

Data signed: (hfarmer1) 26 Mar 2015 13:38:58

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05112430000023
----------------	----------------

Analyte	NIC
---------	-----

Sample type	PLASMA
-------------	--------

Result	29.2
--------	------

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

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

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

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	3
--------------	---

Celerion Study Number	AA99128-01
-----------------------	------------

Date of Collection	2014-JAN-19
--------------------	-------------

Timepoint-minutes	0
-------------------	---

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 3

Form: Biomarker-Plasma (Nic, Cot, tHCot) (2)

Data signed: (hfarmer1) 26 Mar 2015 13:38:58

Generated On: 20 Jul 2016 10:56:43

Urine End Day

3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 4

Form: Date of Visit

Data signed: (hfarmer1) 26 Mar 2015 13:39:01

Generated On: 20 Jul 2016 10:56:43

Date of Visit

20 JAN 2014
DD/MMM/YYYY

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 4

Form: Vital Signs

Data signed: (hfarmer1) 26 Mar 2015 13:39:01

Generated On: 20 Jul 2016 10:56:43

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

09:39
hour:min 24-hour clock

Pulse rate

73
beats per minute

Respiratory rate

14
breaths per minute

Blood Pressure (systolic)

112
mmHg

Blood Pressure (diastolic)

61
mmHg

Vital Signs Position of Subject

Supine ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 4

Form: Socio-Economic Status

Data signed: (hfarmer1) 26 Mar 2015 13:39:01

Generated On: 20 Jul 2016 10:56:43

Was paper questionnaire used? Yes ☒

Reason not done _____

Date 20 JAN 2014
DD/MMM/YYYY

Time 06:33
hour:min 24-hour clock

Q1. What is the highest level of education you have completed? Less than High School ☒

Q2. What is your current occupational status? Keeping house ☒

SPECIFY _____

Q3. How many people are currently living in your household, including yourself? 6

Q4. Of these people, how many are children? 3

Q5. Of these people, how many are adults? 3

Q6. Of the adults, how many bring income into the household? 1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 4

Form: Socio-Economic Status

Data signed: (hfarmer1) 26 Mar 2015 13:39:01

Generated On: 20 Jul 2016 10:56:43

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.

\$10,000 to \$29,999 ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 4

Form: Plasma Nicotine Sample

Data signed: (hfarmer1) 26 Mar 2015 13:39:00

Generated On: 20 Jul 2016 10:56:43

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	20 JAN 2014
---------------------	-------------

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 4

Form: Plasma Cotinine Sample

Data signed: (hfarmer1) 26 Mar 2015 13:39:00

Generated On: 20 Jul 2016 10:56:43

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	20 JAN 2014
---------------------	-------------

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 4

Form: CoHb Blood Sample

Data signed: (hfarmer1) 26 Mar 2015 13:39:00

Generated On: 20 Jul 2016 10:56:43

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	20 JAN 2014
---------------------	-------------

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

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 4

Form: CO Breath Test (1)

Data signed: (hfarmer1) 26 Mar 2015 13:39:01

Generated On: 20 Jul 2016 10:56:43

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

If Not Done, please specify the reason: _____

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

Actual Time of Assessment hour:min 24-hour clock	06:35
---	-------

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 4

Form: CO Breath Test (2)

Data signed: (hfarmer1) 26 Mar 2015 13:39:01

Generated On: 20 Jul 2016 10:56:43

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

If Not Done, please specify the reason: _____

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

Actual Time of Assessment hour:min 24-hour clock	12:05
---	-------

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 4

Form: CO Breath Test (3)

Data signed: (hfarmer1) 26 Mar 2015 13:39:01

Generated On: 20 Jul 2016 10:56:43

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	16:43
---	-------

Result(ppm)	25
-------------	----

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 4

Form: CO Breath Test (4)

Data signed: (hfarmer1) 26 Mar 2015 13:39:01

Generated On: 20 Jul 2016 10:56:43

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	21:13
---	-------

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 4

Form: 24 hour urine collections

Data signed: (hfarmer1) 26 Mar 2015 13:39:01

Generated On: 20 Jul 2016 10:56:43

Start Time	05:58
	hour:min 24-hour clock

End Date	21 JAN 2014
	DD/MMM/YYYY

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

Volume	1394
	mL

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 4

Form: Sample Urine Collection

Data signed: (hfarmer1) 26 Mar 2015 13:39:01

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Day 4

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Data signed: (hfarmer1) 26 Mar 2015 13:39:02

Generated On: 20 Jul 2016 10:56:43

Date of Birth

(b) (6)

Date of assessment
DD/MMM/YYYY

2014 JAN 20
DD/MMM/YYYY

Time of assessment

06:23
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?

Moderate ☒

4. Desire or craving to smoke

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 4

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Data signed: (hfarmer1) 26 Mar 2015 13:39:02

Generated On: 20 Jul 2016 10:56:43

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

5. Difficulty concentrating

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

6. Increased appetite, hungry, weight gain

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

7. Insomnia, sleep problems, awakening at night

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

8. Restless

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

12. Coughing

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 4

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Data signed: (hfarmer1) 26 Mar 2015 13:39:02

Generated On: 20 Jul 2016 10:56:43

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: 1002

Folder: Day 4

Form: Cough Assessment

Data signed: (hfarmer1) 26 Mar 2015 13:39:02

Generated On: 20 Jul 2016 10:56:43

Date of Birth

(b) (6)

Date of assessment
DD/MMM/YYYY

2014 JAN 20
DD/MMM/YYYY

Time of assessment

06:22
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?

26

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

Mild ☒

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

Sometimes ☒

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: 1002**

Folder: Day 4

Form: Lab_BU_COHB (1)

Data signed: (hfarmer1) 26 Mar 2015 13:39:02

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05115150000023
----------------	----------------

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

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

Result	7.90
--------	------

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

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

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

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

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

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

Day of Visit	4
--------------	---

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

Date of Collection	2014-JAN-20
--------------------	-------------

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 4

Form: Lab_BU_COHB (1)

Data signed: (hfarmer1) 26 Mar 2015 13:39:02

Generated On: 20 Jul 2016 10:56:43

Start Day (24 hour urine only)

End Day (24 hour Urine Only)

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 4

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)

Data signed: (hfarmer1) 26 Mar 2015 13:39:02

Generated On: 20 Jul 2016 10:56:43

Date of Birth

(b) (6)

Date of assessment

2014 JAN 20

DD/MMM/YYYY

DD/MMM/YYYY

Time of assessment

20:05

hour:min 24-hour clock

Assessment Status

Completed ☒

1. Was smoking satisfying?

A lot ☒

2. Did cigarettes taste good?

Moderately ☒

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

Little ☒

4. Did smoking calm you down?

Little ☒

5. Did smoking make you feel more awake?

Little ☒

6. Did smoking make you feel less irritable?

Little ☒

7. Did smoking help you concentrate?

Little ☒

8. Did smoking reduce your hunger for food?

Not at all ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 4

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)

Data signed: (hfarmer1) 26 Mar 2015 13:39:02

Generated On: 20 Jul 2016 10:56:43

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

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

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

12. Did you enjoy smoking? A lot ☐

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 4

Form: Human Smoking Topography Questionnaire

Data signed: (hfarmer1) 26 Mar 2015 13:39:01

Generated On: 20 Jul 2016 10:56:43

Type	HUMAN SMOKING TOPOGRAPHY QUESTIONNAIRE
------	--

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

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

Date of assessment	20 JAN 2014 DD/MMM/YYYY
--------------------	----------------------------

Time of assessment	20:06 hour:min 24-hour clock
--------------------	---------------------------------

How do you agree with the following sentences/affirmations :

1. The smoking of the conventional cigarettes/products is different with the device.	Neither agree nor disagree <input type="radio"/>
--	--

If you agree or strongly agree, please describe :	<hr/>
---	-------

2. You enjoy smoking with the device as much as without it.	Neither agree nor disagree <input type="radio"/>
---	--

If you disagree or strongly disagree, please describe :	<hr/>
---	-------

3. The taste of the conventional cigarettes/products is different with the device.	Neither agree nor disagree <input type="radio"/>
--	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 4

Form: Human Smoking Topography Questionnaire

Data signed: (hfarmer1) 26 Mar 2015 13:39:01

Generated On: 20 Jul 2016 10:56:43

If you agree or strongly agree, please describe : _____

4. The device is easy to use.

Neither agree nor disagree ☒

If you disagree or strongly disagree, please describe : _____

5. Your smoking is disturbed by the device.

Neither agree nor disagree ☒

If you agree or strongly agree, please describe : _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 4

Form: Questionnaire on smoking urges (QSU)

Data signed: (hfarmer1) 26 Mar 2015 13:39:01

Generated On: 20 Jul 2016 10:56:43

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

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

Date of assessment	2014 JAN 20
--------------------	-------------

DD/MMM/YYYY

Time of assessment	20:04
--------------------	-------

hour:min 24-hour clock

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

1. I have a desire for a cigarette right now	Disagree <input type="radio"/>
--	--------------------------------

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

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

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

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

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 4

Form: Questionnaire on smoking urges (QSU)

Data signed: (hfarmer1) 26 Mar 2015 13:39:01

Generated On: 20 Jul 2016 10:56:43

7. A cigarette would taste good now Somewhat disagree ☐

8. I would do almost anything for a cigarette now Disagree ☐

9. Smoking would make me less depressed Disagree ☐

10. I am going to smoke as soon as possible Somewhat disagree ☐

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 4

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

Data signed: (hfarmer1) 26 Mar 2015 13:39:02

Generated On: 20 Jul 2016 10:56:43

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 4

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

Data signed: (hfarmer1) 26 Mar 2015 13:39:02

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05112450000018
----------------	----------------

Analyte	HPMA
---------	------

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

Result	939
--------	-----

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-JAN-20
--------------------	-------------

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

Urine Start Day	4
-----------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 4

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

Data signed: (hfarmer1) 26 Mar 2015 13:39:02

Generated On: 20 Jul 2016 10:56:43

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 4

Form: Biomarker-Urine (CEMA, HPMa, HBMA) (2)

Data signed: (hfarmer1) 26 Mar 2015 13:39:02

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05112450000018
----------------	----------------

Analyte	CEMA
---------	------

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

Result	203
--------	-----

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	AA99128-03
-----------------------	------------

Date of Collection	2014-JAN-20
--------------------	-------------

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

Urine Start Day	4
-----------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 4

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (2)

Data signed: (hfarmer1) 26 Mar 2015 13:39:02

Generated On: 20 Jul 2016 10:56:43

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 4

Form: Biomarker-Urine (CEMA, HPMa, HBMA) (3)

Data signed: (hfarmer1) 26 Mar 2015 13:39:02

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05112450000018
----------------	----------------

Analyte	HBMA
---------	------

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

Result	405
--------	-----

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-JAN-20
--------------------	-------------

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

Urine Start Day	4
-----------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 4

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (3)

Data signed: (hfarmer1) 26 Mar 2015 13:39:02

Generated On: 20 Jul 2016 10:56:43

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 4

Form: Biomarker-Urine (NNN, NNAL)

Data signed: (hfarmer1) 26 Mar 2015 13:39:02

Generated On: 20 Jul 2016 10:56:43

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 4

Form: Biomarker-Urine (NNN, NNAL) (1)

Data signed: (hfarmer1) 26 Mar 2015 13:39:02

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05112460000018
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Analyte	NNAL
---------	------

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

Result	731
--------	-----

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-JAN-20
--------------------	-------------

Timepoint-minutes	
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Urine Start Day	4
-----------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 4

Form: Biomarker-Urine (NNN, NNAL) (1)

Data signed: (hfarmer1) 26 Mar 2015 13:39:02

Generated On: 20 Jul 2016 10:56:43

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 4

Form: Biomarker-Urine (NNN, NNAL) (2)

Data signed: (hfarmer1) 26 Mar 2015 13:39:02

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05112460000018
Analyte	NNN
Sample type	URINE
Result	19.5
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-JAN-20
Timepoint-minutes	
Urine Start Day	4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 4

Form: Biomarker-Urine (NNN, NNAL) (2)

Data signed: (hfarmer1) 26 Mar 2015 13:39:02

Generated On: 20 Jul 2016 10:56:43

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 4

Form: Biomarker-Urine (HEMA)

Data signed: (hfarmer1) 26 Mar 2015 13:39:02

Generated On: 20 Jul 2016 10:56:43

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 4

Form: Biomarker-Urine (HEMA) (1)

Data signed: (hfarmer1) 26 Mar 2015 13:39:02

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05112470000018
----------------	----------------

Analyte	HEMA
---------	------

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

Result	9.76
--------	------

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-JAN-20
--------------------	-------------

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

Urine Start Day	4
-----------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 4

Form: Biomarker-Urine (HEMA) (1)

Data signed: (hfarmer1) 26 Mar 2015 13:39:02

Generated On: 20 Jul 2016 10:56:43

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 4

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

Data signed: (hfarmer1) 26 Mar 2015 13:39:02

Generated On: 20 Jul 2016 10:56:43

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 4

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

Data signed: (hfarmer1) 26 Mar 2015 13:39:02

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05112480000018
Analyte	COT
Sample type	URINE
Result	1280
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-JAN-22
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 4

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

Data signed: (hfarmer1) 26 Mar 2015 13:39:02

Generated On: 20 Jul 2016 10:56:43

Urine Start Day	4
<hr/>	
Urine End Day	5
<hr/>	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 4

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

Data signed: (hfarmer1) 26 Mar 2015 13:39:02

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05112480000018
----------------	----------------

Analyte	COT-GLUC
---------	----------

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

Result	8340
--------	------

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-JAN-22
--------------------	-------------

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 4

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

Data signed: (hfarmer1) 26 Mar 2015 13:39:02

Generated On: 20 Jul 2016 10:56:43

Urine Start Day	4
-----------------	---

Urine End Day	5
---------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 4

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(3)**

Data signed: (hfarmer1) 26 Mar 2015 13:39:02

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05112480000018
----------------	----------------

Analyte	NIC
---------	-----

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-JAN-22
--------------------	-------------

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 4

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(3)**

Data signed: (hfarmer1) 26 Mar 2015 13:39:02

Generated On: 20 Jul 2016 10:56:43

Urine Start Day	4
-----------------	---

Urine End Day	5
---------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 4

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

Data signed: (hfarmer1) 26 Mar 2015 13:39:02

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05112480000018
Analyte	NIC-GLUC
Sample type	URINE
Result	1250
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-JAN-22
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 4

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

Data signed: (hfarmer1) 26 Mar 2015 13:39:02

Generated On: 20 Jul 2016 10:56:43

Urine Start Day	4
-----------------	---

Urine End Day	5
---------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 4

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

Data signed: (hfarmer1) 26 Mar 2015 13:39:02

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05112480000018
Analyte	THCOT
Sample type	URINE
Result	3220
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-JAN-22
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 4

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

Data signed: (hfarmer1) 26 Mar 2015 13:39:02

Generated On: 20 Jul 2016 10:56:43

Urine Start Day	4
-----------------	---

Urine End Day	5
---------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 4

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

Data signed: (hfarmer1) 26 Mar 2015 13:39:02

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05112480000018
----------------	----------------

Analyte	THCOT-GLUC
---------	------------

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

Result	3000
--------	------

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-JAN-22
--------------------	-------------

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 4

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

Data signed: (hfarmer1) 26 Mar 2015 13:39:02

Generated On: 20 Jul 2016 10:56:43

Urine Start Day	4
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Urine End Day	5
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 4

Form: Biomarker-Urine (3-OH BaP)

Data signed: (hfarmer1) 26 Mar 2015 13:39:03

Generated On: 20 Jul 2016 10:56:43

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 4

Form: Biomarker-Urine (3-OH BaP) (1)

Data signed: (hfarmer1) 26 Mar 2015 13:39:03

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05112490000018
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Analyte	3-OH BAP
---------	----------

Sample type	URINE
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Result	145
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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	4
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Celerion Study Number	AA99128-07
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Date of Collection	2014-JAN-20
--------------------	-------------

Timepoint-minutes	
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Urine Start Day	4
-----------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 4

Form: Biomarker-Urine (3-OH BaP) (1)

Data signed: (hfarmer1) 26 Mar 2015 13:39:03

Generated On: 20 Jul 2016 10:56:43

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 4

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP)

Data signed: (hfarmer1) 26 Mar 2015 13:39:03

Generated On: 20 Jul 2016 10:56:43

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 4

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (1)

Data signed: (hfarmer1) 26 Mar 2015 13:39:03

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05112510000018
Analyte	1-NA
Sample type	URINE
Result	92.3
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-JAN-20
Timepoint-minutes	
Urine Start Day	4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 4

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (1)

Data signed: (hfarmer1) 26 Mar 2015 13:39:03

Generated On: 20 Jul 2016 10:56:43

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 4

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (2)

Data signed: (hfarmer1) 26 Mar 2015 13:39:03

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05112510000018
Analyte	2-NA
Sample type	URINE
Result	32.6
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-JAN-20
Timepoint-minutes	
Urine Start Day	4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 4

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (2)

Data signed: (hfarmer1) 26 Mar 2015 13:39:03

Generated On: 20 Jul 2016 10:56:43

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 4

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (3)

Data signed: (hfarmer1) 26 Mar 2015 13:39:03

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05112510000018
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Analyte	4-ABP
---------	-------

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

Result	15.6
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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	4
--------------	---

Celerion Study Number	AA99128-09
-----------------------	------------

Date of Collection	2014-JAN-20
--------------------	-------------

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

Urine Start Day	4
-----------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 4

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (3)

Data signed: (hfarmer1) 26 Mar 2015 13:39:03

Generated On: 20 Jul 2016 10:56:43

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 4

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (4)

Data signed: (hfarmer1) 26 Mar 2015 13:39:03

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05112510000018
Analyte	O-TOL
Sample type	URINE
Result	156
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-JAN-20
Timepoint-minutes	
Urine Start Day	4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 4

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (4)

Data signed: (hfarmer1) 26 Mar 2015 13:39:03

Generated On: 20 Jul 2016 10:56:43

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 4

Form: Biomarker-Urine (1-OHP)

Data signed: (hfarmer1) 26 Mar 2015 13:39:03

Generated On: 20 Jul 2016 10:56:43

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 4

Form: Biomarker-Urine (1-OHP) (1)

Data signed: (hfarmer1) 26 Mar 2015 13:39:03

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05115190001107
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Analyte	1-OHP
---------	-------

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

Result	148
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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	4
--------------	---

Celerion Study Number	AA99598-03
-----------------------	------------

Date of Collection	2014-JAN-20
--------------------	-------------

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

Urine Start Day	4
-----------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 4

Form: Biomarker-Urine (1-OHP) (1)

Data signed: (hfarmer1) 26 Mar 2015 13:39:03

Generated On: 20 Jul 2016 10:56:43

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 4

Form: Biomarker-Urine (SPMA, SBMA)

Data signed: (hfarmer1) 26 Mar 2015 13:39:02

Generated On: 20 Jul 2016 10:56:43

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 4

Form: Biomarker-Urine (SPMA, SBMA) (1)

Data signed: (hfarmer1) 26 Mar 2015 13:39:02

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05115170001774
----------------	----------------

Analyte	SBMA
---------	------

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

Result	5.72
--------	------

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-JAN-20
--------------------	-------------

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

Urine Start Day	4
-----------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 4

Form: Biomarker-Urine (SPMA, SBMA) (1)

Data signed: (hfarmer1) 26 Mar 2015 13:39:02

Generated On: 20 Jul 2016 10:56:43

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 4

Form: Biomarker-Urine (SPMA, SBMA) (2)

Data signed: (hfarmer1) 26 Mar 2015 13:39:02

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05115170001774
----------------	----------------

Analyte	SPMA
---------	------

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

Result	2.36
--------	------

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-JAN-20
--------------------	-------------

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

Urine Start Day	4
-----------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 4

Form: Biomarker-Urine (SPMA, SBMA) (2)

Data signed: (hfarmer1) 26 Mar 2015 13:39:02

Generated On: 20 Jul 2016 10:56:43

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 4

Form: Biomarker-Urine (MHBMA)

Data signed: (hfarmer1) 26 Mar 2015 13:39:02

Generated On: 20 Jul 2016 10:56:43

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 4

Form: Biomarker-Urine (MHBMA) (1)

Data signed: (hfarmer1) 26 Mar 2015 13:39:02

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05115180000018
----------------	----------------

Analyte	MHBMA
---------	-------

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

Result	1.58
--------	------

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-JAN-20
--------------------	-------------

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

Urine Start Day	4
-----------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 4

Form: Biomarker-Urine (MHBMA) (1)

Data signed: (hfarmer1) 26 Mar 2015 13:39:02

Generated On: 20 Jul 2016 10:56:43

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 4

Form: Biomarker-Urine (Creatinine)

Data signed: (hfarmer1) 26 Mar 2015 13:39:03

Generated On: 20 Jul 2016 10:56:43

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 4

Form: Biomarker-Urine (Creatinine) (1)

Data signed: (hfarmer1) 26 Mar 2015 13:39:03

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05115160000018
----------------	----------------

Analyte	CREATININE
---------	------------

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

Result	81.9
--------	------

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-JAN-20
--------------------	-------------

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

Urine Start Day	4
-----------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 4

Form: Biomarker-Urine (Creatinine) (1)

Data signed: (hfarmer1) 26 Mar 2015 13:39:03

Generated On: 20 Jul 2016 10:56:43

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 4

Form: Biomarker-Plasma (Nic, Cot, tHCot)

Data signed: (hfarmer1) 26 Mar 2015 13:39:02

Generated On: 20 Jul 2016 10:56:43

Sample type

PLASMA

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 4

Form: Biomarker-Plasma (Nic, Cot, tHCot) (1)

Data signed: (hfarmer1) 26 Mar 2015 13:39:02

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05112430000024
----------------	----------------

Analyte	COT
---------	-----

Sample type	PLASMA
-------------	--------

Result	193
--------	-----

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-JAN-20
--------------------	-------------

Timepoint-minutes	0
-------------------	---

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 4

Form: Biomarker-Plasma (Nic, Cot, tHCot) (1)

Data signed: (hfarmer1) 26 Mar 2015 13:39:02

Generated On: 20 Jul 2016 10:56:43

Urine End Day

4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 4

Form: Biomarker-Plasma (Nic, Cot, tHCot) (2)

Data signed: (hfarmer1) 26 Mar 2015 13:39:02

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05112430000024
----------------	----------------

Analyte	NIC
---------	-----

Sample type	PLASMA
-------------	--------

Result	12.6
--------	------

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-JAN-20
--------------------	-------------

Timepoint-minutes	0
-------------------	---

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 4

Form: Biomarker-Plasma (Nic, Cot, tHCot) (2)

Data signed: (hfarmer1) 26 Mar 2015 13:39:02

Generated On: 20 Jul 2016 10:56:43

Urine End Day

4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 5

Form: Date of Visit

Data signed: (hfarmer1) 26 Mar 2015 13:39:06

Generated On: 20 Jul 2016 10:56:43

Date of Visit

21 JAN 2014
DD/MMM/YYYY

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 5

Form: Vital Signs

Data signed: (hfarmer1) 26 Mar 2015 13:39:06

Generated On: 20 Jul 2016 10:56:43

Were Vitals Signs assessed?

Yes ☒

If No, please specify the reason: _____

Has the subject smoked within 15 minutes prior to
assessment

No ☒

Time of assessment

10:14
hour:min 24-hour clock

Pulse rate

73
beats per minute

Respiratory rate

24
breaths per minute

Blood Pressure (systolic)

109
mmHg

Blood Pressure (diastolic)

68
mmHg

Vital Signs Position of Subject

Supine ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 5

Form: Plasma Nicotine Samples <Day 5> (1)

Data signed: (hfarmer1) 26 Mar 2015 13:39:09

Generated On: 20 Jul 2016 10:56:43

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

If Not Done, please specify the reason: _____

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

Scheduled Time	T0 -15 min <input checked="" type="radio"/>
----------------	---

Time hour:min 24-hour clock	06:34
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 5

Form: Plasma Nicotine Samples <Day 5> (2)

Data signed: (hfarmer1) 26 Mar 2015 13:39:09

Generated On: 20 Jul 2016 10:56:43

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

If Not Done, please specify the reason: _____

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

Scheduled Time	T1 <input checked="" type="radio"/>
----------------	-------------------------------------

Time hour:min 24-hour clock	08:34
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 5

Form: Plasma Nicotine Samples <Day 5> (3)

Data signed: (hfarmer1) 26 Mar 2015 13:39:09

Generated On: 20 Jul 2016 10:56:43

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	21 JAN 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: 1002**

Folder: Day 5

Form: Plasma Nicotine Samples <Day 5> (4)

Data signed: (hfarmer1) 26 Mar 2015 13:39:09

Generated On: 20 Jul 2016 10:56:43

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

If Not Done, please specify the reason: _____

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

Scheduled Time	T3 <input checked="" type="radio"/>
----------------	-------------------------------------

Time hour:min 24-hour clock	12:34
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 5

Form: Plasma Nicotine Samples <Day 5> (5)

Data signed: (hfarmer1) 26 Mar 2015 13:39:09

Generated On: 20 Jul 2016 10:56:43

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	21 JAN 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: 1002**

Folder: Day 5

Form: Plasma Nicotine Samples <Day 5> (6)

Data signed: (hfarmer1) 26 Mar 2015 13:39:09

Generated On: 20 Jul 2016 10:56:43

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	21 JAN 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: 1002**

Folder: Day 5

Form: Plasma Nicotine Samples <Day 5> (7)

Data signed: (hfarmer1) 26 Mar 2015 13:39:09

Generated On: 20 Jul 2016 10:56:43

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	21 JAN 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: 1002**

Folder: Day 5

Form: Plasma Nicotine Samples <Day 5> (8)

Data signed: (hfarmer1) 26 Mar 2015 13:39:09

Generated On: 20 Jul 2016 10:56:43

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	21 JAN 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: 1002**

Folder: Day 5

Form: Plasma Nicotine Samples <Day 5> (9)

Data signed: (hfarmer1) 26 Mar 2015 13:39:09

Generated On: 20 Jul 2016 10:56:43

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	21 JAN 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: 1002**

Folder: Day 5

Form: Plasma Cotinine Samples <Day 5> (1)

Data signed: (hfarmer1) 26 Mar 2015 13:39:08

Generated On: 20 Jul 2016 10:56:43

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

If Not Done, please specify the reason: _____

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

Scheduled Time	T0 -15 min <input checked="" type="radio"/>
----------------	---

Time hour:min 24-hour clock	06:34
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 5

Form: Plasma Cotinine Samples <Day 5> (2)

Data signed: (hfarmer1) 26 Mar 2015 13:39:08

Generated On: 20 Jul 2016 10:56:43

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

If Not Done, please specify the reason: _____

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

Scheduled Time	T1 <input checked="" type="radio"/>
----------------	-------------------------------------

Time hour:min 24-hour clock	08:34
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 5

Form: Plasma Cotinine Samples <Day 5> (3)

Data signed: (hfarmer1) 26 Mar 2015 13:39:08

Generated On: 20 Jul 2016 10:56:43

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	21 JAN 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: 1002**

Folder: Day 5

Form: Plasma Cotinine Samples <Day 5> (4)

Data signed: (hfarmer1) 26 Mar 2015 13:39:08

Generated On: 20 Jul 2016 10:56:43

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

If Not Done, please specify the reason: _____

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

Scheduled Time	T3 <input checked="" type="radio"/>
----------------	-------------------------------------

Time hour:min 24-hour clock	12:34
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 5

Form: Plasma Cotinine Samples <Day 5> (5)

Data signed: (hfarmer1) 26 Mar 2015 13:39:08

Generated On: 20 Jul 2016 10:56:43

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	21 JAN 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: 1002**

Folder: Day 5

Form: Plasma Cotinine Samples <Day 5> (6)

Data signed: (hfarmer1) 26 Mar 2015 13:39:08

Generated On: 20 Jul 2016 10:56:43

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	21 JAN 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: 1002**

Folder: Day 5

Form: Plasma Cotinine Samples <Day 5> (7)

Data signed: (hfarmer1) 26 Mar 2015 13:39:08

Generated On: 20 Jul 2016 10:56:43

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	21 JAN 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: 1002**

Folder: Day 5

Form: Plasma Cotinine Samples <Day 5> (8)

Data signed: (hfarmer1) 26 Mar 2015 13:39:08

Generated On: 20 Jul 2016 10:56:43

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	21 JAN 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: 1002**

Folder: Day 5

Form: Plasma Cotinine Samples <Day 5> (9)

Data signed: (hfarmer1) 26 Mar 2015 13:39:08

Generated On: 20 Jul 2016 10:56:43

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	21 JAN 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: 1002**

Folder: Day 5

Form: CoHb Blood Sample(CC/THS) (1)

Data signed: (hfarmer1) 26 Mar 2015 13:39:07

Generated On: 20 Jul 2016 10:56:43

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

If Not Done, please specify the reason: _____

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

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

Time hour:min 24-hour clock	06:34
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 5

Form: CoHb Blood Sample(CC/THS) (2)

Data signed: (hfarmer1) 26 Mar 2015 13:39:07

Generated On: 20 Jul 2016 10:56:43

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

If Not Done, please specify the reason: _____

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

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

Time hour:min 24-hour clock	12:34
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 5

Form: CoHb Blood Sample(CC/THS) (3)

Data signed: (hfarmer1) 26 Mar 2015 13:39:07

Generated On: 20 Jul 2016 10:56:43

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	21 JAN 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: 1002**

Folder: Day 5

Form: CoHb Blood Sample(CC/THS) (4)

Data signed: (hfarmer1) 26 Mar 2015 13:39:07

Generated On: 20 Jul 2016 10:56:43

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	21 JAN 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: 1002**

Folder: Day 5

Form: CO Breath Test (1)

Data signed: (hfarmer1) 26 Mar 2015 13:39:07

Generated On: 20 Jul 2016 10:56:43

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	06:25
---	-------

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 5

Form: CO Breath Test (2)

Data signed: (hfarmer1) 26 Mar 2015 13:39:07

Generated On: 20 Jul 2016 10:56:43

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

If Not Done, please specify the reason: _____

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

Actual Time of Assessment hour:min 24-hour clock	12:02
---	-------

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 5

Form: CO Breath Test (3)

Data signed: (hfarmer1) 26 Mar 2015 13:39:07

Generated On: 20 Jul 2016 10:56:43

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	16:59
---	-------

Result(ppm)	33
-------------	----

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 5

Form: CO Breath Test (4)

Data signed: (hfarmer1) 26 Mar 2015 13:39:07

Generated On: 20 Jul 2016 10:56:43

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	20:21
---	-------

Result(ppm)	35
-------------	----

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1002

Folder: Day 5

Form: CYP1A2 activity Sample

Data signed: (hfarmer1) 26 Mar 2015 13:39:03

Generated On: 20 Jul 2016 10:56:43

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
21 JAN 2014	16:04	Caffeine
21 JAN 2014	16:04	Paraxanthine

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 5

Form: 24 hour urine collections

Data signed: (hfarmer1) 26 Mar 2015 13:39:06

Generated On: 20 Jul 2016 10:56:43

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

End Date	22 JAN 2014
	DD/MMM/YYYY

End Time	06:13
	hour:min 24-hour clock

Volume	2327
	mL

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 5

Form: Sample Urine Collection

Data signed: (hfarmer1) 26 Mar 2015 13:39:06

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Day 5

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Data signed: (hfarmer1) 26 Mar 2015 13:39:09

Generated On: 20 Jul 2016 10:56:43

Date of Birth

(b) (6)

Date of assessment
DD/MMM/YYYY

2014 JAN 21
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?

Moderate ☐

4. Desire or craving to smoke

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 5

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Data signed: (hfarmer1) 26 Mar 2015 13:39:09

Generated On: 20 Jul 2016 10:56:43

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? Slight ☐

8. Restless

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

9. Impatient

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

10. Constipation

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

11. Dizziness

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

12. Coughing

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 5

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Data signed: (hfarmer1) 26 Mar 2015 13:39:09

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Day 5

Form: Cough Assessment

Data signed: (hfarmer1) 26 Mar 2015 13:39:10

Generated On: 20 Jul 2016 10:56:43

Date of Birth

(b) (6)

Date of assessment
DD/MMM/YYYY

2014 JAN 21
DD/MMM/YYYY

Time of assessment

06:02
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?

22

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

Mild ☒

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

Sometimes ☒

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: 1002**

Folder: Day 5

Form: Lab_BU_COHB (1)

Data signed: (hfarmer1) 26 Mar 2015 13:39:10

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05115150000024
Analyte	CARBOXYHEMOGLOBIN
Sample type	BLOOD
Result	4.10
Result Unit	%
Lab Status	OK
Sample comment	
Detection method	SPECTROPHOTOMETRIC
Lower limit of quantification	0.500
Planned time point (Hour)	6
Day of Visit	5
Celerion Study Number	AA99128-16
Date of Collection	2014-JAN-21
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 5

Form: Lab_BU_COHB (1)

Data signed: (hfarmer1) 26 Mar 2015 13:39:10

Generated On: 20 Jul 2016 10:56:43

Start Day (24 hour urine only) _____

End Day (24 hour Urine Only) _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 5

Form: Lab_BU_COHB (2)

Data signed: (hfarmer1) 26 Mar 2015 13:39:10

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05115150000025
----------------	----------------

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

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

Result	8.30
--------	------

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-JAN-21
--------------------	-------------

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 5

Form: Lab_BU_COHB (2)

Data signed: (hfarmer1) 26 Mar 2015 13:39:10

Generated On: 20 Jul 2016 10:56:43

Start Day (24 hour urine only) _____

End Day (24 hour Urine Only) _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 5

Form: Lab_BU_COHB (3)

Data signed: (hfarmer1) 26 Mar 2015 13:39:10

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05115150000026
Analyte	CARBOXYHEMOGLOBIN
Sample type	BLOOD
Result	9.20
Result Unit	%
Lab Status	OK
Sample comment	
Detection method	SPECTROPHOTOMETRIC
Lower limit of quantification	0.500
Planned time point (Hour)	16
Day of Visit	5
Celerion Study Number	AA99128-16
Date of Collection	2014-JAN-21
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 5

Form: Lab_BU_COHB (3)

Data signed: (hfarmer1) 26 Mar 2015 13:39:10

Generated On: 20 Jul 2016 10:56:43

Start Day (24 hour urine only) _____

End Day (24 hour Urine Only) _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 5

Form: Lab_BU_COHB (4)

Data signed: (hfarmer1) 26 Mar 2015 13:39:10

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05115150000027
Analyte	CARBOXYHEMOGLOBIN
Sample type	BLOOD
Result	8.50
Result Unit	%
Lab Status	OK
Sample comment	
Detection method	SPECTROPHOTOMETRIC
Lower limit of quantification	0.500
Planned time point (Hour)	20
Day of Visit	5
Celerion Study Number	AA99128-16
Date of Collection	2014-JAN-21
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 5

Form: Lab_BU_COHB (4)

Data signed: (hfarmer1) 26 Mar 2015 13:39:10

Generated On: 20 Jul 2016 10:56:43

Start Day (24 hour urine only) _____

End Day (24 hour Urine Only) _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 5

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)

Data signed: (hfarmer1) 26 Mar 2015 13:39:10

Generated On: 20 Jul 2016 10:56:43

Date of Birth

(b) (6)

Date of assessment

2014 JAN 21
DD/MMM/YYYY

DD/MMM/YYYY

Time of assessment

20:06
hour:min 24-hour clock

Assessment Status

Completed ☒

1. Was smoking satisfying?

Quite a lot ☒

2. Did cigarettes taste good?

Quite a lot ☒

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

Moderately ☒

4. Did smoking calm you down?

Moderately ☒

5. Did smoking make you feel more awake?

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: 1002**

Folder: Day 5

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)

Data signed: (hfarmer1) 26 Mar 2015 13:39:10

Generated On: 20 Jul 2016 10:56:43

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

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

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

12. Did you enjoy smoking? Quite a lot ☐

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 5

Form: Behavioral Risk Factor Surveillance System Questionnaire

Data signed: (hfarmer1) 26 Mar 2015 13:39:03

Generated On: 20 Jul 2016 10:56:43

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

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

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

Date of assessment	21 JAN 2014 DD/MMM/YYYY
--------------------	----------------------------

Time of assessment	20:32 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: 1002**

Folder: Day 5

Form: Behavioral Risk Factor Surveillance System Questionnaire

Data signed: (hfarmer1) 26 Mar 2015 13:39:03

Generated On: 20 Jul 2016 10:56:43

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: 1002

Folder: Day 5

Form: Smoking Questionnaire (SQ)

Data signed: (hfarmer1) 26 Mar 2015 13:39:03

Generated On: 20 Jul 2016 10:56:43

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

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

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

Date of assessment	21 JAN 2014 DD/MMM/YYYY
--------------------	----------------------------

Time of assessment	20:32 hour:min 24-hour clock
--------------------	---------------------------------

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

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

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

4. If you ever smoked cigarettes regularly: At what age did you start to smoke regularly?	20 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: 1002**

Folder: Day 5

Form: Smoking Questionnaire (SQ)

Data signed: (hfarmer1) 26 Mar 2015 13:39:03

Generated On: 20 Jul 2016 10:56:43

Months

Days

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

Years

Months

Days

7. What brand of cigarettes/hand-rolled tobacco did you predominantly smoke in the last 12 months of smoking? 305 MENTHOL 100'S

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1002

Folder: Day 5

Form: Smoking Questionnaire (SQ) (1)

Data signed: (hfarmer1) 26 Mar 2015 13:39:03

Generated On: 20 Jul 2016 10:56:43

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

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

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

Date of assessment	21 JAN 2014 DD/MMM/YYYY
--------------------	----------------------------

Time of assessment	20:32 hour:min 24-hour clock
--------------------	---------------------------------

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

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

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

4. If you ever smoked cigarettes regularly: At what age did you start to smoke regularly?	20 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: 1002**

Folder: Day 5

Form: Smoking Questionnaire (SQ) (1)

Data signed: (hfarmer1) 26 Mar 2015 13:39:03

Generated On: 20 Jul 2016 10:56:43

Months

Days

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

Years

Months

Days

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

Time

Currently (last 3 months) ☒

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?

Hand-rolled Cigarettes
per day

10

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 5

Form: Smoking Questionnaire (SQ) (1)

Data signed: (hfarmer1) 26 Mar 2015 13:39:03

Generated On: 20 Jul 2016 10:56:43

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: 1002

Folder: Day 5

Form: Smoking Questionnaire (SQ) (2)

Data signed: (hfarmer1) 26 Mar 2015 13:39:03

Generated On: 20 Jul 2016 10:56:43

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

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

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

Date of assessment	21 JAN 2014 DD/MMM/YYYY
--------------------	----------------------------

Time of assessment	20:32 hour:min 24-hour clock
--------------------	---------------------------------

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

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

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

4. If you ever smoked cigarettes regularly: At what age did you start to smoke regularly?	20 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: 1002**

Folder: Day 5

Form: Smoking Questionnaire (SQ) (2)

Data signed: (hfarmer1) 26 Mar 2015 13:39:03

Generated On: 20 Jul 2016 10:56:43

Months

Days

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

Years

Months

Days

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

Time

1 year ago ☒

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

Manufactured Cigarettes
per day

15

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: 1002**

Folder: Day 5

Form: Smoking Questionnaire (SQ) (2)

Data signed: (hfarmer1) 26 Mar 2015 13:39:03

Generated On: 20 Jul 2016 10:56:43

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: 1002

Folder: Day 5

Form: Smoking Questionnaire (SQ) (3)

Data signed: (hfarmer1) 26 Mar 2015 13:39:03

Generated On: 20 Jul 2016 10:56:43

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

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

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

Date of assessment	21 JAN 2014 DD/MMM/YYYY
--------------------	----------------------------

Time of assessment	20:32 hour:min 24-hour clock
--------------------	---------------------------------

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

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

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

4. If you ever smoked cigarettes regularly: At what age did you start to smoke regularly?	20 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: 1002**

Folder: Day 5

Form: Smoking Questionnaire (SQ) (3)

Data signed: (hfarmer1) 26 Mar 2015 13:39:03

Generated On: 20 Jul 2016 10:56:43

Months _____

Days _____

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

Years _____

Months _____

Days _____

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

Time

5 years ago ☒

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

None ☒

Manufactured Cigarettes
per day _____

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

None ☒

Hand-rolled Cigarettes
per day _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 5

Form: Smoking Questionnaire (SQ) (3)

Data signed: (hfarmer1) 26 Mar 2015 13:39:03

Generated On: 20 Jul 2016 10:56:43

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: 1002

Folder: Day 5

Form: Smoking Questionnaire (SQ) (4)

Data signed: (hfarmer1) 26 Mar 2015 13:39:03

Generated On: 20 Jul 2016 10:56:43

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

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

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

Date of assessment	21 JAN 2014 DD/MMM/YYYY
--------------------	----------------------------

Time of assessment	20:32 hour:min 24-hour clock
--------------------	---------------------------------

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

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

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

4. If you ever smoked cigarettes regularly: At what age did you start to smoke regularly?	20 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: 1002**

Folder: Day 5

Form: Smoking Questionnaire (SQ) (4)

Data signed: (hfarmer1) 26 Mar 2015 13:39:03

Generated On: 20 Jul 2016 10:56:43

Months

Days

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

Years

Months

Days

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

Time

10 years ago ☒

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

None ☒

Manufactured Cigarettes
per day

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

None ☒

Hand-rolled Cigarettes
per day

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 5

Form: Smoking Questionnaire (SQ) (4)

Data signed: (hfarmer1) 26 Mar 2015 13:39:03

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Day 5

Form: Smoking Questionnaire (SQ) (5)

Data signed: (hfarmer1) 26 Mar 2015 13:39:03

Generated On: 20 Jul 2016 10:56:43

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

Was paper questionnaire used?	Yes <input type="radio"/>
-------------------------------	---------------------------

Reason not done	<hr/>
-----------------	-------

Date of assessment	21 JAN 2014 DD/MMM/YYYY
--------------------	----------------------------

Time of assessment	20:32 hour:min 24-hour clock
--------------------	---------------------------------

1. What is your current cigarette smoking behavior (including hand-rolled cigarettes)?	Daily smoker (at least one cigarette per day, disregarding religious fasting) <input type="radio"/>
---	--

2. Have you ever smoked 100 cigarettes or more in your life?	Yes <input type="radio"/>
---	---------------------------

3. Did you ever smoke cigarettes regularly, i.e. at least 1 cigarette per day?	Yes <input type="radio"/>
---	---------------------------

4. If you ever smoked cigarettes regularly: At what age did you start to smoke regularly?	20 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: 1002**

Folder: Day 5

Form: Smoking Questionnaire (SQ) (5)

Data signed: (hfarmer1) 26 Mar 2015 13:39:03

Generated On: 20 Jul 2016 10:56:43

Months _____

Days _____

6. If you ever quit regular cigarette smoking: For how long did you quit altogether?
(Please add together any separate periods of quitting)

Years _____

Months _____

Days _____

7. What brand of cigarettes/hand-rolled tobacco did you predominantly smoke in the last 12 months of smoking?

Time 15 years ago ☒

8. On average, how many Manufactured cigarettes do/did you smoke per day? None ☒

Manufactured Cigarettes
per day _____

8. On average, how many Hand-rolled Cigarettes do/did you smoke per day? None ☒

Hand-rolled Cigarettes
per day _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 5

Form: Smoking Questionnaire (SQ) (5)

Data signed: (hfarmer1) 26 Mar 2015 13:39:03

Generated On: 20 Jul 2016 10:56:43

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: 1002

Folder: Day 5

Form: Smoking Questionnaire (SQ) (6)

Data signed: (hfarmer1) 26 Mar 2015 13:39:03

Generated On: 20 Jul 2016 10:56:43

Type	SMOKING QUESTIONNAIRE
------	-----------------------

Was paper questionnaire used?	Yes <input type="radio"/>
-------------------------------	---------------------------

Reason not done	<hr/>
-----------------	-------

Date of assessment	21 JAN 2014 DD/MMM/YYYY
--------------------	----------------------------

Time of assessment	20:32 hour:min 24-hour clock
--------------------	---------------------------------

1. What is your current cigarette smoking behavior (including hand-rolled cigarettes)?	Daily smoker (at least one cigarette per day, disregarding religious fasting) <input type="radio"/>
--	---

2. Have you ever smoked 100 cigarettes or more in your life?	Yes <input type="radio"/>
--	---------------------------

3. Did you ever smoke cigarettes regularly, i.e. at least 1 cigarette per day?	Yes <input type="radio"/>
--	---------------------------

4. If you ever smoked cigarettes regularly: At what age did you start to smoke regularly?	20 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: 1002**

Folder: Day 5

Form: Smoking Questionnaire (SQ) (6)

Data signed: (hfarmer1) 26 Mar 2015 13:39:03

Generated On: 20 Jul 2016 10:56:43

Months _____

Days _____

6. If you ever quit regular cigarette smoking: For how long did you quit altogether?
(Please add together any separate periods of quitting)

Years _____

Months _____

Days _____

7. What brand of cigarettes/hand-rolled tobacco did you predominantly smoke in the last 12 months of smoking? 305 MENTHOL 100'S

Time _____ 20 years ago ☒

8. On average, how many Manufactured cigarettes do/did you smoke per day? None ☒

Manufactured Cigarettes
per day _____

8. On average, how many Hand-rolled Cigarettes do/did you smoke per day? None ☒

Hand-rolled Cigarettes
per day _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 5

Form: Smoking Questionnaire (SQ) (6)

Data signed: (hfarmer1) 26 Mar 2015 13:39:03

Generated On: 20 Jul 2016 10:56:43

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: 1002

Folder: Day 5

Form: Smoking Questionnaire (SQ) (7)

Data signed: (hfarmer1) 26 Mar 2015 13:39:03

Generated On: 20 Jul 2016 10:56:43

Type	SMOKING QUESTIONNAIRE
------	-----------------------

Was paper questionnaire used?	Yes <input type="radio"/>
-------------------------------	---------------------------

Reason not done	<hr/>
-----------------	-------

Date of assessment	21 JAN 2014 DD/MMM/YYYY
--------------------	----------------------------

Time of assessment	20:32 hour:min 24-hour clock
--------------------	---------------------------------

1. What is your current cigarette smoking behavior (including hand-rolled cigarettes)?	Daily smoker (at least one cigarette per day, disregarding religious fasting) <input type="radio"/>
--	---

2. Have you ever smoked 100 cigarettes or more in your life?	Yes <input type="radio"/>
--	---------------------------

3. Did you ever smoke cigarettes regularly, i.e. at least 1 cigarette per day?	Yes <input type="radio"/>
--	---------------------------

4. If you ever smoked cigarettes regularly: At what age did you start to smoke regularly?	20 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: 1002**

Folder: Day 5

Form: Smoking Questionnaire (SQ) (7)

Data signed: (hfarmer1) 26 Mar 2015 13:39:03

Generated On: 20 Jul 2016 10:56:43

Months _____

Days _____

6. If you ever quit regular cigarette smoking: For how long did you quit altogether?
(Please add together any separate periods of quitting)

Years _____

Months _____

Days _____

7. What brand of cigarettes/hand-rolled tobacco did you predominantly smoke in the last 12 months of smoking? 305 MENTHOL 100'S

Time

More than 20 years ago ☒

8. On average, how many Manufactured cigarettes
do/did you smoke per day?

None ☐

Manufactured Cigarettes
per day _____

8. On average, how many Hand-rolled Cigarettes do/did
you smoke per day?

None ☐

Hand-rolled Cigarettes
per day _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 5

Form: Smoking Questionnaire (SQ) (7)

Data signed: (hfarmer1) 26 Mar 2015 13:39:03

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Day 5

Form: Supplemental Questions

Data signed: (hfarmer1) 26 Mar 2015 13:39:06

Generated On: 20 Jul 2016 10:56:43

Was paper questionnaire used?

Yes ☒

Reason not done

Date of Assessment

21 JAN 2014
DD/MMM/YYYY

Time of assessment

20:36

1. How long it takes for the subject to complete the SQ

3 minutes

Comments (open-end)

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 5

Form: Supplemental Questions (1)

Data signed: (hfarmer1) 26 Mar 2015 13:39:06

Generated On: 20 Jul 2016 10:56:43

Was paper questionnaire used? Yes ☐

Reason not done _____

Date of Assessment 21 JAN 2014
DD/MMM/YYYY

Time of assessment 20:36

1. How long it takes for the subject to complete the SQ 3 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: 1002**

Folder: Day 5

Form: Supplemental Questions (2)

Data signed: (hfarmer1) 26 Mar 2015 13:39:06

Generated On: 20 Jul 2016 10:56:43

Was paper questionnaire used? Yes ☐

Reason not done _____

Date of Assessment 21 JAN 2014
DD/MMM/YYYY

Time of assessment 20:36

1. How long it takes for the subject to complete the SQ 3 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: 1002**

Folder: Day 5

Form: Supplemental Questions (3)

Data signed: (hfarmer1) 26 Mar 2015 13:39:06

Generated On: 20 Jul 2016 10:56:43

Was paper questionnaire used? Yes ☐

Reason not done _____

Date of Assessment 21 JAN 2014
DD/MMM/YYYY

Time of assessment 20:36

1. How long it takes for the subject to complete the SQ 3 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: 1002**

Folder: Day 5

Form: Supplemental Questions (4)

Data signed: (hfarmer1) 26 Mar 2015 13:39:06

Generated On: 20 Jul 2016 10:56:43

Was paper questionnaire used? Yes ☐

Reason not done _____

Date of Assessment 21 JAN 2014
DD/MMM/YYYY

Time of assessment 20:36

1. How long it takes for the subject to complete the SQ 3 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: 1002**

Folder: Day 5

Form: Supplemental Questions (5)

Data signed: (hfarmer1) 26 Mar 2015 13:39:06

Generated On: 20 Jul 2016 10:56:43

Was paper questionnaire used? Yes ☐

Reason not done _____

Date of Assessment 21 JAN 2014
DD/MMM/YYYY

Time of assessment 20:36

1. How long it takes for the subject to complete the SQ 3 minutes

Question 6. Was the SQ ☐
self-explaining?

Answer Yes ☐

Comments (open-end) _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 5

Form: Supplemental Questions (6)

Data signed: (hfarmer1) 26 Mar 2015 13:39:06

Generated On: 20 Jul 2016 10:56:43

Was paper questionnaire used? Yes ☐

Reason not done _____

Date of Assessment 21 JAN 2014
DD/MMM/YYYY

Time of assessment 20:36

1. How long it takes for the subject to complete the SQ 3 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: 1002**

Folder: Day 5

Form: Questionnaire on smoking urges (QSU)

Data signed: (hfarmer1) 26 Mar 2015 13:39:09

Generated On: 20 Jul 2016 10:56:43

Type	QSU
Date of Birth	(b) (6)
Date of assessment DD/MMM/YYYY	2014 JAN 21
Time of assessment hour:min 24-hour clock	20:05
Assessment Status	Completed <input type="radio"/>
1. I have a desire for a cigarette right now	Strongly 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	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: 1002**

Folder: Day 5

Form: Questionnaire on smoking urges (QSU)

Data signed: (hfarmer1) 26 Mar 2015 13:39:09

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Day 5

Form: Biomarker-Urine (CEMA, HPMa, HBMA)

Data signed: (hfarmer1) 26 Mar 2015 13:39:13

Generated On: 20 Jul 2016 10:56:43

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 5

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (1)

Data signed: (hfarmer1) 26 Mar 2015 13:39:13

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05112450000019
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Analyte	HPMA
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Sample type	URINE
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Result	625
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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	5
--------------	---

Celerion Study Number	AA99128-03
-----------------------	------------

Date of Collection	2014-JAN-22
--------------------	-------------

Timepoint-minutes	
-------------------	--

Urine Start Day	5
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 5

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (1)

Data signed: (hfarmer1) 26 Mar 2015 13:39:13

Generated On: 20 Jul 2016 10:56:43

Urine End Day

6

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 5

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (2)

Data signed: (hfarmer1) 26 Mar 2015 13:39:13

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05112450000019
Analyte	CEMA
Sample type	URINE
Result	134
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-JAN-22
Timepoint-minutes	
Urine Start Day	5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 5

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (2)

Data signed: (hfarmer1) 26 Mar 2015 13:39:13

Generated On: 20 Jul 2016 10:56:43

Urine End Day

6

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 5

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (3)

Data signed: (hfarmer1) 26 Mar 2015 13:39:13

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05112450000019
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Analyte	HBMA
---------	------

Sample type	URINE
-------------	-------

Result	308
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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	5
--------------	---

Celerion Study Number	AA99128-03
-----------------------	------------

Date of Collection	2014-JAN-22
--------------------	-------------

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: 1002**

Folder: Day 5

Form: Biomarker-Urine (CEMA, HPMa, HBMA) (3)

Data signed: (hfarmer1) 26 Mar 2015 13:39:13

Generated On: 20 Jul 2016 10:56:43

Urine End Day

6

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 5

Form: Biomarker-Urine (NNN, NNAL)

Data signed: (hfarmer1) 26 Mar 2015 13:39:10

Generated On: 20 Jul 2016 10:56:43

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 5

Form: Biomarker-Urine (NNN, NNAL) (1)

Data signed: (hfarmer1) 26 Mar 2015 13:39:10

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05112460000019
Analyte	NNAL
Sample type	URINE
Result	472
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-JAN-22
Timepoint-minutes	
Urine Start Day	5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 5

Form: Biomarker-Urine (NNN, NNAL) (1)

Data signed: (hfarmer1) 26 Mar 2015 13:39:10

Generated On: 20 Jul 2016 10:56:43

Urine End Day

6

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 5

Form: Biomarker-Urine (NNN, NNAL) (2)

Data signed: (hfarmer1) 26 Mar 2015 13:39:10

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05112460000019
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Analyte	NNN
---------	-----

Sample type	URINE
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Result	14.5
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Result Unit	PG/ML
-------------	-------

Lab Status	OK
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Sample comment	
----------------	--

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	5
--------------	---

Celerion Study Number	AA99128-04
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Date of Collection	2014-JAN-22
--------------------	-------------

Timepoint-minutes	
-------------------	--

Urine Start Day	5
-----------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 5

Form: Biomarker-Urine (NNN, NNAL) (2)

Data signed: (hfarmer1) 26 Mar 2015 13:39:10

Generated On: 20 Jul 2016 10:56:43

Urine End Day

6

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 5

Form: Biomarker-Urine (HEMA)

Data signed: (hfarmer1) 26 Mar 2015 13:39:10

Generated On: 20 Jul 2016 10:56:43

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 5

Form: Biomarker-Urine (HEMA) (1)

Data signed: (hfarmer1) 26 Mar 2015 13:39:10

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05112470000019
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Analyte	HEMA
---------	------

Sample type	URINE
-------------	-------

Result	7.64
--------	------

Result Unit	NG/ML
-------------	-------

Lab Status	OK
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Sample comment	
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Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	5
--------------	---

Celerion Study Number	AA99128-05
-----------------------	------------

Date of Collection	2014-JAN-22
--------------------	-------------

Timepoint-minutes	
-------------------	--

Urine Start Day	5
-----------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 5

Form: Biomarker-Urine (HEMA) (1)

Data signed: (hfarmer1) 26 Mar 2015 13:39:10

Generated On: 20 Jul 2016 10:56:43

Urine End Day

6

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 5

Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)

Data signed: (hfarmer1) 26 Mar 2015 13:39:13

Generated On: 20 Jul 2016 10:56:43

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 5

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(1)**

Data signed: (hfarmer1) 26 Mar 2015 13:39:13

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05112480000019
Analyte	COT
Sample type	URINE
Result	837
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-JAN-22
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 5

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(1)**

Data signed: (hfarmer1) 26 Mar 2015 13:39:13

Generated On: 20 Jul 2016 10:56:43

Urine Start Day	5
<hr/>	
Urine End Day	6
<hr/>	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 5

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(2)**

Data signed: (hfarmer1) 26 Mar 2015 13:39:13

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05112480000019
Analyte	COT-GLUC
Sample type	URINE
Result	4060
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-JAN-22
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 5

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(2)**

Data signed: (hfarmer1) 26 Mar 2015 13:39:13

Generated On: 20 Jul 2016 10:56:43

Urine Start Day	5
<hr/>	
Urine End Day	6
<hr/>	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 5

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(3)**

Data signed: (hfarmer1) 26 Mar 2015 13:39:13

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05112480000019
Analyte	NIC
Sample type	URINE
Result	935
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-JAN-22
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 5

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(3)**

Data signed: (hfarmer1) 26 Mar 2015 13:39:13

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Day 5

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(4)**

Data signed: (hfarmer1) 26 Mar 2015 13:39:13

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05112480000019
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Analyte	NIC-GLUC
---------	----------

Sample type	URINE
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Result	638
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Result Unit	NG/ML
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Lab Status	OK
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Sample comment	
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Detection method	LC-MS/MS
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Planned time point (Hour)	0
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Day of Visit	5
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Celerion Study Number	AA99128-06
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Date of Collection	2014-JAN-22
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Timepoint-minutes	
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 5

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(4)**

Data signed: (hfarmer1) 26 Mar 2015 13:39:13

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Day 5

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(5)**

Data signed: (hfarmer1) 26 Mar 2015 13:39:13

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05112480000019
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Analyte	THCOT
---------	-------

Sample type	URINE
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Result	1770
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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
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Day of Visit	5
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Celerion Study Number	AA99128-06
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Date of Collection	2014-JAN-22
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Timepoint-minutes	
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 5

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(5)**

Data signed: (hfarmer1) 26 Mar 2015 13:39:13

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Day 5

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(6)**

Data signed: (hfarmer1) 26 Mar 2015 13:39:13

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05112480000019
Analyte	THCOT-GLUC
Sample type	URINE
Result	1540
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-JAN-22
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 5

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(6)**

Data signed: (hfarmer1) 26 Mar 2015 13:39:13

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Day 5

Form: Biomarker-Urine (3-OH BaP)

Data signed: (hfarmer1) 26 Mar 2015 13:39:13

Generated On: 20 Jul 2016 10:56:43

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 5

Form: Biomarker-Urine (3-OH BaP) (1)

Data signed: (hfarmer1) 26 Mar 2015 13:39:13

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05112490000019
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Analyte	3-OH BAP
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Sample type	URINE
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Result	99.6
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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
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Day of Visit	5
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Celerion Study Number	AA99128-07
-----------------------	------------

Date of Collection	2014-JAN-22
--------------------	-------------

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: 1002**

Folder: Day 5

Form: Biomarker-Urine (3-OH BaP) (1)

Data signed: (hfarmer1) 26 Mar 2015 13:39:13

Generated On: 20 Jul 2016 10:56:43

Urine End Day

6

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 5

Form: Biomarker-Plasma (Caffeine, Paraxanthine)

Generated On: 20 Jul 2016 10:56:43

Sample type

PLASMA

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 5

Form: Biomarker-Plasma (Caffeine, Paraxanthine) (1)

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05112500000005
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Analyte	CAFFEINE
---------	----------

Sample type	PLASMA
-------------	--------

Result	708
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Result Unit	NG/ML
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Lab Status	OK
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Sample comment	
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Detection method	LC-MS/MS
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Planned time point (Hour)	6
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Day of Visit	5
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Celerion Study Number	AA99128-08
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Date of Collection	2014-JAN-21
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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: 1002**

Folder: Day 5

Form: Biomarker-Plasma (Caffeine, Paraxanthine) (1)

Generated On: 20 Jul 2016 10:56:43

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 5

Form: Biomarker-Plasma (Caffeine, Paraxanthine) (2)

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05112500000005
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Analyte	PARAXANTHINE
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Sample type	PLASMA
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Result	1170
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Result Unit	NG/ML
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Lab Status	OK
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Sample comment	
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Detection method	LC-MS/MS
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Planned time point (Hour)	6
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Day of Visit	5
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Celerion Study Number	AA99128-08
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Date of Collection	2014-JAN-21
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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: 1002**

Folder: Day 5

Form: Biomarker-Plasma (Caffeine, Paraxanthine) (2)

Generated On: 20 Jul 2016 10:56:43

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 5

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP)

Data signed: (hfarmer1) 26 Mar 2015 13:39:14

Generated On: 20 Jul 2016 10:56:43

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 5

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (1)

Data signed: (hfarmer1) 26 Mar 2015 13:39:14

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05112510000019
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Analyte	1-NA
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Sample type	URINE
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Result	73.2
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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	AA99128-09
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Date of Collection	2014-JAN-22
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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: 1002**

Folder: Day 5

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (1)

Data signed: (hfarmer1) 26 Mar 2015 13:39:14

Generated On: 20 Jul 2016 10:56:43

Urine End Day

6

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 5

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (2)

Data signed: (hfarmer1) 26 Mar 2015 13:39:14

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05112510000019
Analyte	2-NA
Sample type	URINE
Result	24.5
Result Unit	PG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	5
Celerion Study Number	AA99128-09
Date of Collection	2014-JAN-22
Timepoint-minutes	
Urine Start Day	5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 5

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (2)

Data signed: (hfarmer1) 26 Mar 2015 13:39:14

Generated On: 20 Jul 2016 10:56:43

Urine End Day

6

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 5

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (3)

Data signed: (hfarmer1) 26 Mar 2015 13:39:14

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05112510000019
Analyte	4-ABP
Sample type	URINE
Result	14.8
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	AA99128-09
Date of Collection	2014-JAN-22
Timepoint-minutes	
Urine Start Day	5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 5

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (3)

Data signed: (hfarmer1) 26 Mar 2015 13:39:14

Generated On: 20 Jul 2016 10:56:43

Urine End Day

6

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 5

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (4)

Data signed: (hfarmer1) 26 Mar 2015 13:39:14

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05112510000019
Analyte	O-TOL
Sample type	URINE
Result	122
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-JAN-22
Timepoint-minutes	
Urine Start Day	5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 5

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (4)

Data signed: (hfarmer1) 26 Mar 2015 13:39:14

Generated On: 20 Jul 2016 10:56:43

Urine End Day

6

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 5

Form: Biomarker-Urine (11-dTXb2)

Data signed: (hfarmer1) 26 Mar 2015 13:39:11

Generated On: 20 Jul 2016 10:56:43

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 5

Form: Biomarker-Urine (11-dTXb2) (1)

Data signed: (hfarmer1) 26 Mar 2015 13:39:11

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05112530000011
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Analyte	11-DTXB2
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Sample type	URINE
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Result	560
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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	AA99128-11
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Date of Collection	2014-JAN-22
--------------------	-------------

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: 1002**

Folder: Day 5

Form: Biomarker-Urine (11-dTXb2) (1)

Data signed: (hfarmer1) 26 Mar 2015 13:39:11

Generated On: 20 Jul 2016 10:56:43

Urine End Day

6

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 5

Form: Biomarker-Urine (iPF2a-III)

Data signed: (hfarmer1) 26 Mar 2015 13:39:11

Generated On: 20 Jul 2016 10:56:43

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 5

Form: Biomarker-Urine (iPF2a-III) (1)

Data signed: (hfarmer1) 26 Mar 2015 13:39:11

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05112540000011
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Analyte	IPF2A-III
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Sample type	URINE
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Result	126
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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	AA99128-12
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Date of Collection	2014-JAN-22
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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: 1002**

Folder: Day 5

Form: Biomarker-Urine (iPF2a-III) (1)

Data signed: (hfarmer1) 26 Mar 2015 13:39:11

Generated On: 20 Jul 2016 10:56:43

Urine End Day

6

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 5

Form: Biomarker-Urine (Ames)

Data signed: (hfarmer1) 26 Mar 2015 13:39:14

Generated On: 20 Jul 2016 10:56:43

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 5

Form: Biomarker-Urine (Ames) (1)

Data signed: (hfarmer1) 26 Mar 2015 13:39:14

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05113320000005
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Analyte	AMES
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Sample type	URINE
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Result	19.9
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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
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Day of Visit	5
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Celerion Study Number	AA99128-15
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Date of Collection	2014-JAN-22
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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: 1002**

Folder: Day 5

Form: Biomarker-Urine (Ames) (1)

Data signed: (hfarmer1) 26 Mar 2015 13:39:14

Generated On: 20 Jul 2016 10:56:43

Urine End Day

6

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 5

Form: Biomarker-Urine (1-OHP)

Data signed: (hfarmer1) 26 Mar 2015 13:39:14

Generated On: 20 Jul 2016 10:56:43

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 5

Form: Biomarker-Urine (1-OHP) (1)

Data signed: (hfarmer1) 26 Mar 2015 13:39:14

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05115190001108
Analyte	1-OHP
Sample type	URINE
Result	83.1
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	AA99598-03
Date of Collection	2014-JAN-22
Timepoint-minutes	
Urine Start Day	5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 5

Form: Biomarker-Urine (1-OHP) (1)

Data signed: (hfarmer1) 26 Mar 2015 13:39:14

Generated On: 20 Jul 2016 10:56:43

Urine End Day

6

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 5

Form: Biomarker-Urine (SPMA, SBMA)

Data signed: (hfarmer1) 26 Mar 2015 13:39:11

Generated On: 20 Jul 2016 10:56:43

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 5

Form: Biomarker-Urine (SPMA, SBMA) (1)

Data signed: (hfarmer1) 26 Mar 2015 13:39:11

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05115170001775
Analyte	SBMA
Sample type	URINE
Result	3.20
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-JAN-22
Timepoint-minutes	
Urine Start Day	5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 5

Form: Biomarker-Urine (SPMA, SBMA) (1)

Data signed: (hfarmer1) 26 Mar 2015 13:39:11

Generated On: 20 Jul 2016 10:56:43

Urine End Day

6

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 5

Form: Biomarker-Urine (SPMA, SBMA) (2)

Data signed: (hfarmer1) 26 Mar 2015 13:39:11

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05115170001775
Analyte	SPMA
Sample type	URINE
Result	2.31
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-JAN-22
Timepoint-minutes	
Urine Start Day	5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 5

Form: Biomarker-Urine (SPMA, SBMA) (2)

Data signed: (hfarmer1) 26 Mar 2015 13:39:11

Generated On: 20 Jul 2016 10:56:43

Urine End Day

6

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 5

Form: Biomarker-Urine (MHBMA)

Data signed: (hfarmer1) 26 Mar 2015 13:39:11

Generated On: 20 Jul 2016 10:56:43

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 5

Form: Biomarker-Urine (MHBMA) (1)

Data signed: (hfarmer1) 26 Mar 2015 13:39:11

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05115180000019
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Analyte	MHBMA
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Sample type	URINE
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Result	0.807
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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	AA99598-02
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Date of Collection	2014-JAN-22
--------------------	-------------

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: 1002**

Folder: Day 5

Form: Biomarker-Urine (MHBMA) (1)

Data signed: (hfarmer1) 26 Mar 2015 13:39:11

Generated On: 20 Jul 2016 10:56:43

Urine End Day

6

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 5

Form: Biomarker-Urine (Creatinine)

Data signed: (hfarmer1) 26 Mar 2015 13:39:14

Generated On: 20 Jul 2016 10:56:43

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 5

Form: Biomarker-Urine (Creatinine) (1)

Data signed: (hfarmer1) 26 Mar 2015 13:39:14

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05115160000019
Analyte	CREATININE
Sample type	URINE
Result	47.6
Result Unit	MG/DL
Lab Status	OK
Sample comment	
Detection method	SPECTROPHOTOMETRIC
Planned time point (Hour)	0
Day of Visit	5
Celerion Study Number	AA99128-14
Date of Collection	2014-JAN-22
Timepoint-minutes	
Urine Start Day	5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 5

Form: Biomarker-Urine (Creatinine) (1)

Data signed: (hfarmer1) 26 Mar 2015 13:39:14

Generated On: 20 Jul 2016 10:56:43

Urine End Day

6

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot)

Data signed: (hfarmer1) 26 Mar 2015 13:39:11

Generated On: 20 Jul 2016 10:56:43

Sample type

PLASMA

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (1)

Data signed: (hfarmer1) 26 Mar 2015 13:39:11

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05112430000025
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Analyte	COT
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Sample type	PLASMA
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Result	160
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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	AA99128-01
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Date of Collection	2014-JAN-21
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Timepoint-minutes	-15
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Urine Start Day	
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (1)

Data signed: (hfarmer1) 26 Mar 2015 13:39:11

Generated On: 20 Jul 2016 10:56:43

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (2)

Data signed: (hfarmer1) 26 Mar 2015 13:39:11

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05112430000025
----------------	----------------

Analyte	NIC
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Sample type	PLASMA
-------------	--------

Result	1.14
--------	------

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-JAN-21
--------------------	-------------

Timepoint-minutes	-15
-------------------	-----

Urine Start Day	
-----------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (2)

Data signed: (hfarmer1) 26 Mar 2015 13:39:11

Generated On: 20 Jul 2016 10:56:43

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (3)

Data signed: (hfarmer1) 26 Mar 2015 13:39:11

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05112430000026
----------------	----------------

Analyte	COT
---------	-----

Sample type	PLASMA
-------------	--------

Result	174
--------	-----

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-JAN-21
--------------------	-------------

Timepoint-minutes	0
-------------------	---

Urine Start Day	
-----------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (3)

Data signed: (hfarmer1) 26 Mar 2015 13:39:11

Generated On: 20 Jul 2016 10:56:43

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (4)

Data signed: (hfarmer1) 26 Mar 2015 13:39:11

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05112430000026
----------------	----------------

Analyte	NIC
---------	-----

Sample type	PLASMA
-------------	--------

Result	11.8
--------	------

Result Unit	NG/ML
-------------	-------

Lab Status	OK
------------	----

Sample comment	
----------------	--

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	2
---------------------------	---

Day of Visit	5
--------------	---

Celerion Study Number	AA99128-01
-----------------------	------------

Date of Collection	2014-JAN-21
--------------------	-------------

Timepoint-minutes	0
-------------------	---

Urine Start Day	
-----------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (4)

Data signed: (hfarmer1) 26 Mar 2015 13:39:11

Generated On: 20 Jul 2016 10:56:43

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (5)

Data signed: (hfarmer1) 26 Mar 2015 13:39:11

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05112430000027
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Analyte	COT
---------	-----

Sample type	PLASMA
-------------	--------

Result	161
--------	-----

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-JAN-21
--------------------	-------------

Timepoint-minutes	0
-------------------	---

Urine Start Day	
-----------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (5)

Data signed: (hfarmer1) 26 Mar 2015 13:39:11

Generated On: 20 Jul 2016 10:56:43

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (6)

Data signed: (hfarmer1) 26 Mar 2015 13:39:11

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05112430000027
----------------	----------------

Analyte	NIC
---------	-----

Sample type	PLASMA
-------------	--------

Result	7.93
--------	------

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-JAN-21
--------------------	-------------

Timepoint-minutes	0
-------------------	---

Urine Start Day	
-----------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (6)

Data signed: (hfarmer1) 26 Mar 2015 13:39:11

Generated On: 20 Jul 2016 10:56:43

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (7)

Data signed: (hfarmer1) 26 Mar 2015 13:39:11

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05112430000028
----------------	----------------

Analyte	COT
---------	-----

Sample type	PLASMA
-------------	--------

Result	185
--------	-----

Result Unit	NG/ML
-------------	-------

Lab Status	OK
------------	----

Sample comment	
----------------	--

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	6
---------------------------	---

Day of Visit	5
--------------	---

Celerion Study Number	AA99128-01
-----------------------	------------

Date of Collection	2014-JAN-21
--------------------	-------------

Timepoint-minutes	0
-------------------	---

Urine Start Day	
-----------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (7)

Data signed: (hfarmer1) 26 Mar 2015 13:39:11

Generated On: 20 Jul 2016 10:56:43

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (8)

Data signed: (hfarmer1) 26 Mar 2015 13:39:11

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05112430000028
----------------	----------------

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)	6
---------------------------	---

Day of Visit	5
--------------	---

Celerion Study Number	AA99128-01
-----------------------	------------

Date of Collection	2014-JAN-21
--------------------	-------------

Timepoint-minutes	0
-------------------	---

Urine Start Day	
-----------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (8)

Data signed: (hfarmer1) 26 Mar 2015 13:39:11

Generated On: 20 Jul 2016 10:56:43

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (9)

Data signed: (hfarmer1) 26 Mar 2015 13:39:11

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05112430000029
----------------	----------------

Analyte	COT
---------	-----

Sample type	PLASMA
-------------	--------

Result	173
--------	-----

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-JAN-21
--------------------	-------------

Timepoint-minutes	0
-------------------	---

Urine Start Day	
-----------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (9)

Data signed: (hfarmer1) 26 Mar 2015 13:39:11

Generated On: 20 Jul 2016 10:56:43

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (10)

Data signed: (hfarmer1) 26 Mar 2015 13:39:11

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05112430000029
----------------	----------------

Analyte	NIC
---------	-----

Sample type	PLASMA
-------------	--------

Result	13.3
--------	------

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-JAN-21
--------------------	-------------

Timepoint-minutes	0
-------------------	---

Urine Start Day	
-----------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (10)

Data signed: (hfarmer1) 26 Mar 2015 13:39:11

Generated On: 20 Jul 2016 10:56:43

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (11)

Data signed: (hfarmer1) 26 Mar 2015 13:39:11

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05112430000030
----------------	----------------

Analyte	COT
---------	-----

Sample type	PLASMA
-------------	--------

Result	186
--------	-----

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-JAN-21
--------------------	-------------

Timepoint-minutes	0
-------------------	---

Urine Start Day	
-----------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (11)

Data signed: (hfarmer1) 26 Mar 2015 13:39:11

Generated On: 20 Jul 2016 10:56:43

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (12)

Data signed: (hfarmer1) 26 Mar 2015 13:39:11

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05112430000030
----------------	----------------

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)	10
---------------------------	----

Day of Visit	5
--------------	---

Celerion Study Number	AA99128-01
-----------------------	------------

Date of Collection	2014-JAN-21
--------------------	-------------

Timepoint-minutes	0
-------------------	---

Urine Start Day	
-----------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (12)

Data signed: (hfarmer1) 26 Mar 2015 13:39:11

Generated On: 20 Jul 2016 10:56:43

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (13)

Data signed: (hfarmer1) 26 Mar 2015 13:39:11

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05112430000031
----------------	----------------

Analyte	COT
---------	-----

Sample type	PLASMA
-------------	--------

Result	195
--------	-----

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-JAN-21
--------------------	-------------

Timepoint-minutes	0
-------------------	---

Urine Start Day	
-----------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (13)

Data signed: (hfarmer1) 26 Mar 2015 13:39:11

Generated On: 20 Jul 2016 10:56:43

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (14)

Data signed: (hfarmer1) 26 Mar 2015 13:39:11

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05112430000031
----------------	----------------

Analyte	NIC
---------	-----

Sample type	PLASMA
-------------	--------

Result	21.2
--------	------

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-JAN-21
--------------------	-------------

Timepoint-minutes	0
-------------------	---

Urine Start Day	
-----------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (14)

Data signed: (hfarmer1) 26 Mar 2015 13:39:11

Generated On: 20 Jul 2016 10:56:43

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (15)

Data signed: (hfarmer1) 26 Mar 2015 13:39:11

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05112430000032
----------------	----------------

Analyte	COT
---------	-----

Sample type	PLASMA
-------------	--------

Result	197
--------	-----

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-JAN-21
--------------------	-------------

Timepoint-minutes	0
-------------------	---

Urine Start Day	
-----------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (15)

Data signed: (hfarmer1) 26 Mar 2015 13:39:11

Generated On: 20 Jul 2016 10:56:43

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (16)

Data signed: (hfarmer1) 26 Mar 2015 13:39:11

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05112430000032
----------------	----------------

Analyte	NIC
---------	-----

Sample type	PLASMA
-------------	--------

Result	18.8
--------	------

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-JAN-21
--------------------	-------------

Timepoint-minutes	0
-------------------	---

Urine Start Day	
-----------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (16)

Data signed: (hfarmer1) 26 Mar 2015 13:39:11

Generated On: 20 Jul 2016 10:56:43

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (17)

Data signed: (hfarmer1) 26 Mar 2015 13:39:11

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05112430000033
----------------	----------------

Analyte	COT
---------	-----

Sample type	PLASMA
-------------	--------

Result	215
--------	-----

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-JAN-21
--------------------	-------------

Timepoint-minutes	0
-------------------	---

Urine Start Day	
-----------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (17)

Data signed: (hfarmer1) 26 Mar 2015 13:39:11

Generated On: 20 Jul 2016 10:56:43

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (18)

Data signed: (hfarmer1) 26 Mar 2015 13:39:11

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05112430000033
----------------	----------------

Analyte	NIC
---------	-----

Sample type	PLASMA
-------------	--------

Result	13.4
--------	------

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-JAN-21
--------------------	-------------

Timepoint-minutes	0
-------------------	---

Urine Start Day	
-----------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (18)

Data signed: (hfarmer1) 26 Mar 2015 13:39:11

Generated On: 20 Jul 2016 10:56:43

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 6

Form: Date of Visit

Data signed: (hfarmer1) 26 Mar 2015 13:39:14

Generated On: 20 Jul 2016 10:56:43

Date of Visit

22 JAN 2014
DD/MMM/YYYY

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 6

Form: Plasma Nicotine Samples <Day 6> (1)

Data signed: (hfarmer1) 26 Mar 2015 13:39:14

Generated On: 20 Jul 2016 10:56:43

Not Done	False
----------	-------

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	22 JAN 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: 1002**

Folder: Day 6

Form: Plasma Nicotine Samples <Day 6> (2)

Data signed: (hfarmer1) 26 Mar 2015 13:39:14

Generated On: 20 Jul 2016 10:56:43

Not Done	False
----------	-------

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	22 JAN 2014
---------------------	-------------

Scheduled Time	T0 + 24H <input checked="" type="radio"/>
----------------	---

Time hour:min 24-hour clock	06:35
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 6

Form: Plasma Cotinine Samples <Day 6> (1)

Data signed: (hfarmer1) 26 Mar 2015 13:39:14

Generated On: 20 Jul 2016 10:56:43

Not Done	False
----------	-------

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	22 JAN 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: 1002**

Folder: Day 6

Form: Plasma Cotinine Samples <Day 6> (2)

Data signed: (hfarmer1) 26 Mar 2015 13:39:14

Generated On: 20 Jul 2016 10:56:43

Not Done	False
----------	-------

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	22 JAN 2014
---------------------	-------------

Scheduled Time	T0 + 24H <input checked="" type="radio"/>
----------------	---

Time hour:min 24-hour clock	06:35
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 6

Form: CoHb Blood Sample <prior to gas transfer and product>

Data signed: (hfarmer1) 26 Mar 2015 13:39:14

Generated On: 20 Jul 2016 10:56:43

Not Done	False
----------	-------

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	22 JAN 2014
---------------------	-------------

Timepoint	Prior to gas transfer assessment and prior to product use <input checked="" type="radio"/>
-----------	--

Time hour:min 24-hour clock	06:35
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 6

Form: Oxysterols

Data signed: (hfarmer1) 26 Mar 2015 13:39:14

Generated On: 20 Jul 2016 10:56:43

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	22 JAN 2014
---------------------	-------------

Time hour:min 24-hour clock	06:35
--------------------------------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1002

Folder: Day 6

Form: CYP2A6 activity Sample

Data signed: (hfarmer1) 26 Mar 2015 13:39:14

Generated On: 20 Jul 2016 10:56:43

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

22 JAN 2014

06:35

trans-3'-hydroxyc
otinine

22 JAN 2014

06:35

cotinine

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 6

Form: Risk Marker: sICAM-1

Data signed: (hfarmer1) 26 Mar 2015 13:39:14

Generated On: 20 Jul 2016 10:56:43

Not Done	False
----------	-------

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	22 JAN 2014
---------------------	-------------

Time hour:min 24-hour clock	06:35
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 6

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Data signed: (hfarmer1) 26 Mar 2015 13:39:14

Generated On: 20 Jul 2016 10:56:43

Date of Birth

(b) (6)

Date of assessment
DD/MMM/YYYY

2014 JAN 22
DD/MMM/YYYY

Time of assessment

06:20
hour:min 24-hour clock

Assessment Status

Completed ☒

Please indicate for each of the items below, how you have been feeling over the past 24 hours

How have you been feeling over the past 24 hours?

None ☐

1. Angry, irritable, frustrated

How have you been feeling over the past 24 hours?

None ☐

2. Anxious, nervous

How have you been feeling over the past 24 hours?

None ☐

3. Depressed Mood, sad

How have you been feeling over the past 24 hours?

Severe ☐

4. Desire or craving to smoke

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 6

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Data signed: (hfarmer1) 26 Mar 2015 13:39:14

Generated On: 20 Jul 2016 10:56:43

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? Slight ☐

8. Restless

How have you been feeling over the past 24 hours? Slight ☐

9. Impatient

How have you been feeling over the past 24 hours? None ☐

10. Constipation

How have you been feeling over the past 24 hours? None ☐

11. Dizziness

How have you been feeling over the past 24 hours? Slight ☐

12. Coughing

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 6

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Data signed: (hfarmer1) 26 Mar 2015 13:39:14

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Day 6

Form: Cough Assessment

Data signed: (hfarmer1) 26 Mar 2015 13:39:14

Generated On: 20 Jul 2016 10:56:43

Date of Birth

(b) (6)

Date of assessment
DD/MMM/YYYY

2014 JAN 22
DD/MMM/YYYY

Time of assessment

06:18
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?

14

Second Question: Cough Intensity Scale:
How intense is your cough?

Mild ☒

Third Question: Cough Frequency Scale:
How frequently do you normally have to cough each
day?

Sometimes ☒

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: 1002**

Folder: Day 6

Form: Bio-banking (Transcriptomics)

Data signed: (hfarmer1) 26 Mar 2015 13:39:14

Generated On: 20 Jul 2016 10:56:43

Was a Bio-banking sample for transcriptomics taken?

Yes ☒

Time of Sample Collection

06:35
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: 1002**

Folder: Day 6

Form: Bio-banking (Biomarkers of exposure and risk markers)

Data signed: (hfarmer1) 26 Mar 2015 13:39:14

Generated On: 20 Jul 2016 10:56:43

Was a Bio-banking sample for biomarkers of exposure
and risk markers taken?

Yes ☒

Time of Sample Collection

06:35
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: 1002**

Folder: Day 6

Form: Bio-banking (nasal epithelial collection/buccal collection)

Data signed: (hfarmer1) 26 Mar 2015 13:39:14

Generated On: 20 Jul 2016 10:56:43

Was a Bio-banking sample for nasal epithelial
collection/buccal collection taken?

Yes ☒

Time of Buccal Collection

11:26
hour:min 24-hour clock

Time of Nasal Epithelial Collection

11:24
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: 1002**

Folder: Day 6

Form: Oxysterol results (1)

Generated On: 20 Jul 2016 10:56:43

Sample Accession number	3122582115
-------------------------	------------

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: 1002**

Folder: Day 6

Form: Oxysterol results (2)

Generated On: 20 Jul 2016 10:56:43

Sample Accession number	3122582115
-------------------------	------------

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: 1002**

Folder: Day 6

Form: Oxysterol results (3)

Generated On: 20 Jul 2016 10:56:43

Sample Accession number	3122582115
-------------------------	------------

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: 1002**

Folder: Day 6

Form: Oxysterol results (4)

Generated On: 20 Jul 2016 10:56:43

Sample Accession number	3122582115
-------------------------	------------

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: 1002**

Folder: Day 6

Form: Oxysterol results (5)

Generated On: 20 Jul 2016 10:56:43

Sample Accession number	3122582115
-------------------------	------------

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: 1002**

Folder: Day 6

Form: Oxysterol results (6)

Generated On: 20 Jul 2016 10:56:43

Sample Accession number	3122582115
-------------------------	------------

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: 1002**

Folder: Day 6

Form: Oxysterol results (7)

Generated On: 20 Jul 2016 10:56:43

Sample Accession number	3122582115
-------------------------	------------

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: 1002**

Folder: Day 6

Form: Oxysterol results (8)

Generated On: 20 Jul 2016 10:56:43

Sample Accession number	3122582115
-------------------------	------------

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: 1002**

Folder: Day 6

Form: Oxysterol results (9)

Generated On: 20 Jul 2016 10:56:43

Sample Accession number	3122582115
-------------------------	------------

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: 1002**

Folder: Day 6

Form: Oxysterol results (10)

Generated On: 20 Jul 2016 10:56:43

Sample Accession number	3122582115
-------------------------	------------

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: 1002**

Folder: Day 6

Form: Oxysterol results (11)

Generated On: 20 Jul 2016 10:56:43

Sample Accession number	3122582115
-------------------------	------------

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: 1002**

Folder: Day 6

Form: Oxysterol results (12)

Generated On: 20 Jul 2016 10:56:43

Sample Accession number	3122582115
-------------------------	------------

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: 1002**

Folder: Day 6

Form: Lab_BU_COHB (1)

Data signed: (hfarmer1) 26 Mar 2015 13:39:15

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05115150000028
----------------	----------------

Analyte	CARBOXYHEMOGLOBIN
---------	-------------------

Sample type	BLOOD
-------------	-------

Result	4.50
--------	------

Result Unit	%
-------------	---

Lab Status	OK
------------	----

Sample comment	
----------------	--

Detection method	SPECTROPHOTOMETRIC
------------------	--------------------

Lower limit of quantification	0.500
-------------------------------	-------

Planned time point (Hour)	6
---------------------------	---

Day of Visit	6
--------------	---

Celerion Study Number	AA99128-16
-----------------------	------------

Date of Collection	2014-JAN-22
--------------------	-------------

Timepoint-minutes	
-------------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 6

Form: Lab_BU_COHB (1)

Data signed: (hfarmer1) 26 Mar 2015 13:39:15

Generated On: 20 Jul 2016 10:56:43

Start Day (24 hour urine only) _____

End Day (24 hour Urine Only) _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 6

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)

Data signed: (hfarmer1) 26 Mar 2015 13:39:14

Generated On: 20 Jul 2016 10:56:43

Date of Birth

(b) (6)

Date of assessment

2014 JAN 22

DD/MMM/YYYY

DD/MMM/YYYY

Time of assessment

06:21

hour:min 24-hour clock

Assessment Status

Completed ☒

1. Was smoking satisfying?

Quite a lot ☒

2. Did cigarettes taste good?

Moderately ☒

3. Did you enjoy the sensation in your throat and chest?

Little ☒

4. Did smoking calm you down?

Moderately ☒

5. Did smoking make you feel more awake?

Little ☒

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: 1002**

Folder: Day 6

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)

Data signed: (hfarmer1) 26 Mar 2015 13:39:14

Generated On: 20 Jul 2016 10:56:43

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? Extremely ☐

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 6

Form: Questionnaire on smoking urges (QSU)

Data signed: (hfarmer1) 26 Mar 2015 13:39:14

Generated On: 20 Jul 2016 10:56:43

Type	QSU
Date of Birth	(b) (6)
Date of assessment DD/MMM/YYYY	2014 JAN 22
Time of assessment hour:min 24-hour clock	06:22
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	Somewhat 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: 1002**

Folder: Day 6

Form: Questionnaire on smoking urges (QSU)

Data signed: (hfarmer1) 26 Mar 2015 13:39:14

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Day 6

Form: Risk Markers(CCLS) (1)

Data signed: (hfarmer1) 26 Mar 2015 13:39:14

Generated On: 20 Jul 2016 10:56:43

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	1002
----------------------	------

Subject Sex	F
-------------	---

Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	DAY6
------------	------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	V225821
--------------	---------

Actual Collection Date	2014 01 22
------------------------	------------

Actual Collection Time	06:35
------------------------	-------

Specimen Condition	
--------------------	--

Battery ID	IM2293
------------	--------

Battery Name	SICAM-1
--------------	---------

Lab Test ID	IMT1768
-------------	---------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 6

Form: Risk Markers(CCLS) (1)

Data signed: (hfarmer1) 26 Mar 2015 13:39:14

Generated On: 20 Jul 2016 10:56:43

Lab Test Name	SICAM-1-RUO
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	270.2
Reported Numeric Result	270.2
Reference Range low	98.8
Reference Range high	320.0
Range Units	NG/ML
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 6

Form: Risk Markers(CCLS) (1)

Data signed: (hfarmer1) 26 Mar 2015 13:39:14

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Day 6

Form: Biomarker-Plasma (Nic, Cot, tHCot)

Data signed: (hfarmer1) 26 Mar 2015 13:39:15

Generated On: 20 Jul 2016 10:56:43

Sample type

PLASMA

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 6

Form: Biomarker-Plasma (Nic, Cot, tHCot) (1)

Data signed: (hfarmer1) 26 Mar 2015 13:39:15

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05112430000034
----------------	----------------

Analyte	COT
---------	-----

Sample type	PLASMA
-------------	--------

Result	198
--------	-----

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-JAN-22
--------------------	-------------

Timepoint-minutes	0
-------------------	---

Urine Start Day	
-----------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 6

Form: Biomarker-Plasma (Nic, Cot, tHCot) (1)

Data signed: (hfarmer1) 26 Mar 2015 13:39:15

Generated On: 20 Jul 2016 10:56:43

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 6

Form: Biomarker-Plasma (Nic, Cot, tHCot) (2)

Data signed: (hfarmer1) 26 Mar 2015 13:39:15

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05112430000034
----------------	----------------

Analyte	NIC
---------	-----

Sample type	PLASMA
-------------	--------

Result	6.17
--------	------

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-JAN-22
--------------------	-------------

Timepoint-minutes	0
-------------------	---

Urine Start Day	
-----------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 6

Form: Biomarker-Plasma (Nic, Cot, tHCot) (2)

Data signed: (hfarmer1) 26 Mar 2015 13:39:15

Generated On: 20 Jul 2016 10:56:43

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 6

Form: Biomarker-Plasma (Nic, Cot, tHCot) (3)

Data signed: (hfarmer1) 26 Mar 2015 13:39:15

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05112430000035
Analyte	COT
Sample type	PLASMA
Result	189
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-JAN-22
Timepoint-minutes	0
Urine Start Day	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 6

Form: Biomarker-Plasma (Nic, Cot, tHCot) (3)

Data signed: (hfarmer1) 26 Mar 2015 13:39:15

Generated On: 20 Jul 2016 10:56:43

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 6

Form: Biomarker-Plasma (Nic, Cot, tHCot) (4)

Data signed: (hfarmer1) 26 Mar 2015 13:39:15

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05112430000035
----------------	----------------

Analyte	NIC
---------	-----

Sample type	PLASMA
-------------	--------

Result	2.07
--------	------

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-JAN-22
--------------------	-------------

Timepoint-minutes	0
-------------------	---

Urine Start Day	
-----------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 6

Form: Biomarker-Plasma (Nic, Cot, tHCot) (4)

Data signed: (hfarmer1) 26 Mar 2015 13:39:15

Generated On: 20 Jul 2016 10:56:43

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 6

Form: Biomarker-Plasma (Nic, Cot, tHCot) (5)

Data signed: (hfarmer1) 26 Mar 2015 13:39:15

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05112520000005
----------------	----------------

Analyte	COT
---------	-----

Sample type	PLASMA
-------------	--------

Result	190
--------	-----

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-JAN-22
--------------------	-------------

Timepoint-minutes	0
-------------------	---

Urine Start Day	
-----------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 6

Form: Biomarker-Plasma (Nic, Cot, tHCot) (5)

Data signed: (hfarmer1) 26 Mar 2015 13:39:15

Generated On: 20 Jul 2016 10:56:43

Urine End Day

6

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 6

Form: Biomarker-Plasma (Nic, Cot, tHCot) (6)

Data signed: (hfarmer1) 26 Mar 2015 13:39:15

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05112520000005
----------------	----------------

Analyte	THCOT
---------	-------

Sample type	PLASMA
-------------	--------

Result	74.6
--------	------

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-JAN-22
--------------------	-------------

Timepoint-minutes	0
-------------------	---

Urine Start Day	
-----------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 6

Form: Biomarker-Plasma (Nic, Cot, tHCot) (6)

Data signed: (hfarmer1) 26 Mar 2015 13:39:15

Generated On: 20 Jul 2016 10:56:43

Urine End Day

6

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Discharge (Confinement)

Form: Date of Discharge

Data signed: (hfarmer1) 26 Mar 2015 13:39:17

Generated On: 20 Jul 2016 10:56:43

Date of Visit

22 JAN 2014
DD/MMM/YYYY

Discharge Time

12:06
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: 1002**

Folder: Discharge (Confinement)

Form: Vital Signs

Data signed: (hfarmer1) 26 Mar 2015 13:39:17

Generated On: 20 Jul 2016 10:56:43

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 10:13
hour:min 24-hour clock

Pulse rate 73
beats per minute

Respiratory rate 18
breaths per minute

Blood Pressure (systolic) 106
mmHg

Blood Pressure (diastolic) 64
mmHg

Vital Signs Position of Subject Supine ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Discharge (Confinement)

Form: Advice on the risk of smoking and debriefing

Data signed: (hfarmer1) 26 Mar 2015 13:39:17

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Discharge (Confinement)

Form: Physical Examination

Data signed: (hfarmer1) 26 Mar 2015 13:39:15

Generated On: 20 Jul 2016 10:56:43

Was the physical examination performed?

Yes ☒

If No, please specify the reason:

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Discharge (Confinement)

Form: Physical Examination (1)

Data signed: (hfarmer1) 26 Mar 2015 13:39:15

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Discharge (Confinement)

Form: Physical Examination (2)

Data signed: (hfarmer1) 26 Mar 2015 13:39:15

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Discharge (Confinement)

Form: Physical Examination (3)

Data signed: (hfarmer1) 26 Mar 2015 13:39:15

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Discharge (Confinement)

Form: Physical Examination (4)

Data signed: (hfarmer1) 26 Mar 2015 13:39:15

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Discharge (Confinement)

Form: Physical Examination (5)

Data signed: (hfarmer1) 26 Mar 2015 13:39:15

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Discharge (Confinement)

Form: Physical Examination (6)

Data signed: (hfarmer1) 26 Mar 2015 13:39:15

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Discharge (Confinement)

Form: Physical Examination (7)

Data signed: (hfarmer1) 26 Mar 2015 13:39:15

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Discharge (Confinement)

Form: Physical Examination (8)

Data signed: (hfarmer1) 26 Mar 2015 13:39:15

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Discharge (Confinement)

Form: Physical Examination (9)

Data signed: (hfarmer1) 26 Mar 2015 13:39:15

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Discharge (Confinement)

Form: Physical Examination (10)

Data signed: (hfarmer1) 26 Mar 2015 13:39:15

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Discharge (Confinement)

Form: Physical Examination (11)

Data signed: (hfarmer1) 26 Mar 2015 13:39:15

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Discharge (Confinement)

Form: Physical Examination (12)

Data signed: (hfarmer1) 26 Mar 2015 13:39:15

Generated On: 20 Jul 2016 10:56:43

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

System Musculoskeletal ☒

Outcome Abnormal ☒

Abnormal, please specify RIGHT ELBOW DEFORMITY

Clinically significant No ☒

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Discharge (Confinement)

Form: Physical Examination (13)

Data signed: (hfarmer1) 26 Mar 2015 13:39:15

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Discharge (Confinement)

Form: Physical Examination (14)

Data signed: (hfarmer1) 26 Mar 2015 13:39:15

Generated On: 20 Jul 2016 10:56:43

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

System Dentition ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Discharge (Confinement)

Form: Physical Examination (15)

Data signed: (hfarmer1) 26 Mar 2015 13:39:15

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Discharge (Confinement)

Form: Physical Examination (16)

Data signed: (hfarmer1) 26 Mar 2015 13:39:15

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Discharge (Confinement)

Form: Physical Examination (17)

Data signed: (hfarmer1) 26 Mar 2015 13:39:15

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Discharge (Confinement)

Form: Physical Examination (18)

Data signed: (hfarmer1) 26 Mar 2015 13:39:15

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Discharge (Confinement)

Form: Physical Examination (19)

Data signed: (hfarmer1) 26 Mar 2015 13:39:15

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Discharge (Confinement)

Form: Weight

Data signed: (hfarmer1) 26 Mar 2015 13:39:17

Generated On: 20 Jul 2016 10:56:43

Measurement(s) assessed?

Yes ☒

If No, please specify the reason: _____

Date of Assessment

22 JAN 2014
DD/MMM/YYYY

Time of assessment

11:32
hour:min 24-hour clock

Weight

64.2
kg

BMI

24.6

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Discharge (Confinement)

Form: ECG (12-Lead Standard)

Data signed: (hfarmer1) 26 Mar 2015 13:39:15

Generated On: 20 Jul 2016 10:56:43

Was the ECG performed? Yes ☒

If No, please specify the reason: _____

Position Supine ☒

Heart Rate 60
beats per minute

QRS Interval 89
msec

QT Interval 387
msec

QTcB Interval 389
msec

PR Interval 193
msec

QTcF Interval 388
msec

Interpretation Normal ☒

If Abnormal, Clinical Significance _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Discharge (Confinement)

Form: ECG (12-Lead Standard)

Data signed: (hfarmer1) 26 Mar 2015 13:39:15

Generated On: 20 Jul 2016 10:56:43

If Not Clinically significant or clinically Significant, Please
specify the finding(s) _____

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1002

Folder: Discharge (Confinement)

Form: Gas Transfer

Data signed: (hfarmer1) 26 Mar 2015 13:39:16

Generated On: 20 Jul 2016 10:56:43

Was the Gas Transfer performed? Yes ☒

If No, please specify the reason: _____

Category _____

Position SITTING

Date of assessment 22 JAN 2014
DD/MMM/YYYY

Time of assessment 06:57

DLCO value 18.35
ml/min/mmHg

KCO value 1.27
mmol/min/kPa/L

DLCO/VA value 3.63
mL/min/mmHg/L

Interpretation Abnormal ☒

If Abnormal, Clinical Significance Not clinically significant ☒

If Not Clinically Significant or Clinically Significant, Please MILD DECREASED ON DLCO specify the finding(s)

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Discharge (Confinement)

Form: Lung Volume Measurements

Data signed: (hfarmer1) 26 Mar 2015 13:39:16

Generated On: 20 Jul 2016 10:56:43

Were the Lung Volume Measurements performed? Yes ☒

If No, please specify the reason: _____

Category _____

Position SITTING

Date of assessment 22 JAN 2014
DD/MMM/YYYY

Time of assessment 07:12

VC value 4.04
L

TLC value 4.98
L

IC value 2.20
L

FRC value 2.78
L

Interpretation Abnormal ☒

If Abnormal, Clinical Significance Not clinically significant ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Discharge (Confinement)

Form: Lung Volume Measurements

Data signed: (hfarmer1) 26 Mar 2015 13:39:16

Generated On: 20 Jul 2016 10:56:43

If Not Clinically Significant or Clinically Significant, Please MILD DECREASE IN SRSIDUAL
specify the finding(s) VOLUME (RV)

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1002

Folder: Discharge (Confinement)

Form: Spirometry with a short-acting bronchodilator

Data signed: (hcoleman1) 18 Jun 2015 19:27:30

Generated On: 20 Jul 2016 10:56:43

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

22 JAN 2014

Time of assessment

07:46

Name of bronchodilator

ALUTEROL SULFATE

Dose

180 MCG

Predicted FVC value

3.76
L

Best measured FVC value

4.04
L

Percent of predicted FVC value

107
%

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Discharge (Confinement)

Form: Spirometry with a short-acting bronchodilator

Data signed: (hcoleman1) 18 Jun 2015 19:27:30

Generated On: 20 Jul 2016 10:56:43

Best measured FEV1 value	2.55 L
--------------------------	-----------

Predicted FEV1 value	3.26 L
----------------------	-----------

Percent of predicted FEV1 value	78 %
---------------------------------	---------

Calculated ratio between FEV1/FVC	_____
-----------------------------------	-------

MEF 25/75 value	1.60 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: 1002**

Folder: Discharge (Confinement)

Form: Haematology

Data signed: (hfarmer1) 26 Mar 2015 13:39:15

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Discharge (Confinement)

Form: Clinical Chemistry

Data signed: (hfarmer1) 26 Mar 2015 13:39:15

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Discharge (Confinement)

Form: Urine analysis

Data signed: (hfarmer1) 26 Mar 2015 13:39:15

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Discharge (Confinement)

Form: Urine Pregnancy Test

Data signed: (hfarmer1) 26 Mar 2015 13:39:17

Generated On: 20 Jul 2016 10:56:43

Not Done	False
----------	-------

If Not Done, specify reason	<hr/>
-----------------------------	-------

Date of Test	22 JAN 2014 DD/MMM/YYYY
--------------	----------------------------

Time of Test	09:04 hour:min 24-hour clock
--------------	---------------------------------

Specify result	Negative <input checked="" type="radio"/>
----------------	---

If unclear, please confirm with FSH test

Specify result of FSH test	<hr/>
----------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Discharge (Confinement)

Form: CO Breath Test

Data signed: (hfarmer1) 26 Mar 2015 13:39:15

Generated On: 20 Jul 2016 10:56:43

Assessment not done	False
---------------------	-------

If Not Done, please specify the reason: _____

Actual Time of Assessment	10:17
	hour:min 24-hour clock

Result	22
	ppm

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (1)

Data signed: (hfarmer1) 26 Mar 2015 13:39:17

Generated On: 20 Jul 2016 10:56:43

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	V225821
--------------	---------

Actual Collection Date	2014 01 22
------------------------	------------

Actual Collection Time	06:35
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	RC1029
------------	--------

Battery Name	TRIGLYCERIDES
--------------	---------------

Lab Test ID	RCT19
-------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (1)

Data signed: (hfarmer1) 26 Mar 2015 13:39:17

Generated On: 20 Jul 2016 10:56:43

Lab Test Name	TRIGLYCERIDES (GPO)
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	188
Reported Numeric Result	188
Reference Range low	36
Reference Range high	144
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: 1002**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (1)

Data signed: (hfarmer1) 26 Mar 2015 13:39:17

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (2)

Data signed: (hfarmer1) 26 Mar 2015 13:39:17

Generated On: 20 Jul 2016 10:56:43

Transmission Type Cumulative ☒

Subject ID or Number

Subject Sex F

Subject Date of Birth (b) (6) 

Visit Name

Visit Type Scheduled ☒

Accession ID V225821

Actual Collection Date 2014 01 22

Actual Collection Time 06:35

Specimen Condition

Battery ID RC1092

Battery Name FASTING GLUCOSE

Lab Test ID RCT142

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1002

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (2)

Data signed: (hfarmer1) 26 Mar 2015 13:39:17

Generated On: 20 Jul 2016 10:56:43

Lab Test Name	FASTING GLUCOSE
Test ID	
Test Status	Done <input type="checkbox"/>
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: 1002**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (2)

Data signed: (hfarmer1) 26 Mar 2015 13:39:17

Generated On: 20 Jul 2016 10:56:43

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (3)

Data signed: (hfarmer1) 26 Mar 2015 13:39:17

Generated On: 20 Jul 2016 10:56:43

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex F

Subject Date of Birth (b) (6)

Visit Name _____

Visit Type Scheduled ☒

Accession ID V225821

Actual Collection Date 2014 01 22

Actual Collection Time 06:35

Specimen Condition _____

Battery ID RC272

Battery Name TOTAL CHOLESTEROL

Lab Test ID RCT20

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (3)

Data signed: (hfarmer1) 26 Mar 2015 13:39:17

Generated On: 20 Jul 2016 10:56:43

Lab Test Name	CHOLESTEROL (HIGH PERFORMANCE)
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	168
Reported Numeric Result	168
Reference Range low	128
Reference Range high	218
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: 1002**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (3)

Data signed: (hfarmer1) 26 Mar 2015 13:39:17

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (4)

Data signed: (hfarmer1) 26 Mar 2015 13:39:17

Generated On: 20 Jul 2016 10:56:43

Transmission Type Cumulative ☐

Subject ID or Number

Subject Sex F

Subject Date of Birth (b) (6) 

Visit Name

Visit Type Scheduled ☐

Accession ID V225821

Actual Collection Date 2014 01 22

Actual Collection Time 06:35

Specimen Condition

Battery ID RC9255

Battery Name CHEMISTRY PANEL

Lab Test ID RCT1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (4)

Data signed: (hfarmer1) 26 Mar 2015 13:39:17

Generated On: 20 Jul 2016 10:56:43

Lab Test Name	TOTAL BILIRUBIN
Test ID	
Test Status	Done <input checked="" type="checkbox"/>
Reported Text Result	0.5
Reported Numeric Result	0.5
Reference Range low	0.2
Reference Range high	1.2
Range Units	MG/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (4)

Data signed: (hfarmer1) 26 Mar 2015 13:39:17

Generated On: 20 Jul 2016 10:56:43

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (5)

Data signed: (hfarmer1) 26 Mar 2015 13:39:17

Generated On: 20 Jul 2016 10:56:43

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex F

Subject Date of Birth (b) (6) ☒

Visit Name _____

Visit Type Scheduled ☒

Accession ID V225821

Actual Collection Date 2014 01 22

Actual Collection Time 06:35

Specimen Condition _____

Battery ID RC9255

Battery Name CHEMISTRY PANEL

Lab Test ID RCT12

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (5)

Data signed: (hfarmer1) 26 Mar 2015 13:39:17

Generated On: 20 Jul 2016 10:56:43

Lab Test Name	TOTAL PROTEIN
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	7.2
Reported Numeric Result	7.2
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: 1002**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (5)

Data signed: (hfarmer1) 26 Mar 2015 13:39:17

Generated On: 20 Jul 2016 10:56:43

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (6)

Data signed: (hfarmer1) 26 Mar 2015 13:39:17

Generated On: 20 Jul 2016 10:56:43

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex F

Subject Date of Birth (b) (6) 

Visit Name _____

Visit Type Scheduled ☒

Accession ID V225821

Actual Collection Date 2014 01 22

Actual Collection Time 06:35

Specimen Condition _____

Battery ID RC9255

Battery Name CHEMISTRY PANEL

Lab Test ID RCT13

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (6)

Data signed: (hfarmer1) 26 Mar 2015 13:39:17

Generated On: 20 Jul 2016 10:56:43

Lab Test Name	ALBUMIN
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	4.2
Reported Numeric Result	4.2
Reference Range low	3.3
Reference Range high	4.9
Range Units	G/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (6)

Data signed: (hfarmer1) 26 Mar 2015 13:39:17

Generated On: 20 Jul 2016 10:56:43

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (7)

Data signed: (hfarmer1) 26 Mar 2015 13:39:17

Generated On: 20 Jul 2016 10:56:43

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex F

Subject Date of Birth (b) (6) ☒

Visit Name _____

Visit Type Scheduled ☒

Accession ID V225821

Actual Collection Date 2014 01 22

Actual Collection Time 06:35

Specimen Condition _____

Battery ID RC9255

Battery Name CHEMISTRY PANEL

Lab Test ID RCT1407

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1002

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (7)

Data signed: (hfarmer1) 26 Mar 2015 13:39:17

Generated On: 20 Jul 2016 10:56:43

Lab Test Name	ALKALINE PHOSPHATASE
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	69
Reported Numeric Result	69
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: 1002**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (7)

Data signed: (hfarmer1) 26 Mar 2015 13:39:17

Generated On: 20 Jul 2016 10:56:43

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (8)


Data signed: (hfarmer1) 26 Mar 2015 13:39:17

Generated On: 20 Jul 2016 10:56:43

Transmission Type Cumulative ☐

Subject ID or Number _____

Subject Sex F

Subject Date of Birth (b) (6) 

Visit Name _____

Visit Type Scheduled ☐

Accession ID V225821

Actual Collection Date 2014 01 22

Actual Collection Time 06:35

Specimen Condition _____

Battery ID RC9255

Battery Name CHEMISTRY PANEL

Lab Test ID RCT1408

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (8)

Data signed: (hfarmer1) 26 Mar 2015 13:39:17

Generated On: 20 Jul 2016 10:56:43

Lab Test Name	LDH
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	113
Reported Numeric Result	113
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: 1002**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (8)

Data signed: (hfarmer1) 26 Mar 2015 13:39:17

Generated On: 20 Jul 2016 10:56:43

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (9)


Data signed: (hfarmer1) 26 Mar 2015 13:39:17

Generated On: 20 Jul 2016 10:56:43

Transmission Type Cumulative ☐

Subject ID or Number _____

Subject Sex F

Subject Date of Birth (b) (6) 

Visit Name _____

Visit Type Scheduled ☐

Accession ID V225821

Actual Collection Date 2014 01 22

Actual Collection Time 06:35

Specimen Condition _____

Battery ID RC9255

Battery Name CHEMISTRY PANEL

Lab Test ID RCT15

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (9)

Data signed: (hfarmer1) 26 Mar 2015 13:39:17

Generated On: 20 Jul 2016 10:56:43

Lab Test Name	SERUM SODIUM
Test ID	
Test Status	Done <input type="checkbox"/>
Reported Text Result	142
Reported Numeric Result	142
Reference Range low	132
Reference Range high	147
Range Units	MEQ/L
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (9)

Data signed: (hfarmer1) 26 Mar 2015 13:39:17

Generated On: 20 Jul 2016 10:56:43

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (10)

Data signed: (hfarmer1) 26 Mar 2015 13:39:17

Generated On: 20 Jul 2016 10:56:43

Transmission Type Cumulative ☐

Subject ID or Number _____

Subject Sex F

Subject Date of Birth (b) (6) 

Visit Name _____

Visit Type Scheduled ☐

Accession ID V225821

Actual Collection Date 2014 01 22

Actual Collection Time 06:35

Specimen Condition _____

Battery ID RC9255

Battery Name CHEMISTRY PANEL

Lab Test ID RCT16

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (10)

Data signed: (hfarmer1) 26 Mar 2015 13:39:17

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (10)

Data signed: (hfarmer1) 26 Mar 2015 13:39:17

Generated On: 20 Jul 2016 10:56:43

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (11)

Data signed: (hfarmer1) 26 Mar 2015 13:39:17

Generated On: 20 Jul 2016 10:56:43

Transmission Type Cumulative ☐

Subject ID or Number _____

Subject Sex F

Subject Date of Birth (b) (6) 

Visit Name _____

Visit Type Scheduled ☐

Accession ID V225821

Actual Collection Date 2014 01 22

Actual Collection Time 06:35

Specimen Condition _____

Battery ID RC9255

Battery Name CHEMISTRY PANEL

Lab Test ID RCT29

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (11)

Data signed: (hfarmer1) 26 Mar 2015 13:39:17

Generated On: 20 Jul 2016 10:56:43

Lab Test Name	DIRECT BILIRUBIN
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	0.1
Reported Numeric Result	0.1
Reference Range low	0.0
Reference Range high	0.4
Range Units	MG/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (11)

Data signed: (hfarmer1) 26 Mar 2015 13:39:17

Generated On: 20 Jul 2016 10:56:43

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (12)

Data signed: (hfarmer1) 26 Mar 2015 13:39:17

Generated On: 20 Jul 2016 10:56:43

Transmission Type Cumulative ☐

Subject ID or Number _____

Subject Sex F

Subject Date of Birth (b) (6)

Visit Name _____

Visit Type Scheduled ☐

Accession ID V225821

Actual Collection Date 2014 01 22

Actual Collection Time 06:35

Specimen Condition _____

Battery ID RC9255

Battery Name CHEMISTRY PANEL

Lab Test ID RCT3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (12)

Data signed: (hfarmer1) 26 Mar 2015 13:39:17

Generated On: 20 Jul 2016 10:56:43

Lab Test Name	GGT
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	7
Reported Numeric Result	7
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: 1002**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (12)

Data signed: (hfarmer1) 26 Mar 2015 13:39:17

Generated On: 20 Jul 2016 10:56:43

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (13)

Data signed: (hfarmer1) 26 Mar 2015 13:39:17

Generated On: 20 Jul 2016 10:56:43

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex F

Subject Date of Birth (b) (6) 

Visit Name _____

Visit Type Scheduled ☒

Accession ID V225821

Actual Collection Date 2014 01 22

Actual Collection Time 06:35

Specimen Condition _____

Battery ID RC9255

Battery Name CHEMISTRY PANEL

Lab Test ID RCT392

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1002

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (13)

Data signed: (hfarmer1) 26 Mar 2015 13:39:17

Generated On: 20 Jul 2016 10:56:43

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	0.8
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Reported Numeric Result	0.8
-------------------------	-----

Reference Range low	0.4
---------------------	-----

Reference Range high	1.1
----------------------	-----

Range Units	MG/DL
-------------	-------

Conventional Text Result	<hr/>
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Conventional Numeric Result	<hr/>
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Conventional Reference Range Low	<hr/>
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Conventional Reference Range High	<hr/>
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Conventional Units	<hr/>
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SI Text Result	<hr/>
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (13)

Data signed: (hfarmer1) 26 Mar 2015 13:39:17

Generated On: 20 Jul 2016 10:56:43

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (14)

Data signed: (hfarmer1) 26 Mar 2015 13:39:17

Generated On: 20 Jul 2016 10:56:43

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex F

Subject Date of Birth (b) (6) ☒

Visit Name _____

Visit Type Scheduled ☒

Accession ID V225821

Actual Collection Date 2014 01 22

Actual Collection Time 06:35

Specimen Condition _____

Battery ID RC9255

Battery Name CHEMISTRY PANEL

Lab Test ID RCT4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (14)

Data signed: (hfarmer1) 26 Mar 2015 13:39:17

Generated On: 20 Jul 2016 10:56:43

Lab Test Name	ALT (SGPT)
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	32
Reported Numeric Result	32
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: 1002**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (14)

Data signed: (hfarmer1) 26 Mar 2015 13:39:17

Generated On: 20 Jul 2016 10:56:43

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (15)

Data signed: (hfarmer1) 26 Mar 2015 13:39:17

Generated On: 20 Jul 2016 10:56:43

Transmission Type Cumulative ☒

Subject ID or Number

Subject Sex F

Subject Date of Birth (b) (6) 

Visit Name

Visit Type Scheduled ☒

Accession ID V225821

Actual Collection Date 2014 01 22

Actual Collection Time 06:35

Specimen Condition

Battery ID RC9255

Battery Name CHEMISTRY PANEL

Lab Test ID RCT5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (15)

Data signed: (hfarmer1) 26 Mar 2015 13:39:17

Generated On: 20 Jul 2016 10:56:43

Lab Test Name	AST (SGOT)
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	27
Reported Numeric Result	27
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: 1002**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (15)

Data signed: (hfarmer1) 26 Mar 2015 13:39:17

Generated On: 20 Jul 2016 10:56:43

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (16)

Data signed: (hfarmer1) 26 Mar 2015 13:39:17

Generated On: 20 Jul 2016 10:56:43

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	V225821
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Actual Collection Date	2014 01 22
------------------------	------------

Actual Collection Time	06:35
------------------------	-------

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: 1002**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (16)

Data signed: (hfarmer1) 26 Mar 2015 13:39:17

Generated On: 20 Jul 2016 10:56:43

Lab Test Name	UREA NITROGEN
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	12
Reported Numeric Result	12
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: 1002**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (16)

Data signed: (hfarmer1) 26 Mar 2015 13:39:17

Generated On: 20 Jul 2016 10:56:43

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (17)

Data signed: (hfarmer1) 26 Mar 2015 13:39:17

Generated On: 20 Jul 2016 10:56:43

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"/>
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Accession ID	V225821
--------------	---------

Actual Collection Date	2014 01 22
------------------------	------------

Actual Collection Time	06:35
------------------------	-------

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: 1002**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (17)

Data signed: (hfarmer1) 26 Mar 2015 13:39:17

Generated On: 20 Jul 2016 10:56:43

Lab Test Name	MONOCYTES
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	0.32
Reported Numeric Result	0.32
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: 1002**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (17)

Data signed: (hfarmer1) 26 Mar 2015 13:39:17

Generated On: 20 Jul 2016 10:56:43

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (18)

Data signed: (hfarmer1) 26 Mar 2015 13:39:17

Generated On: 20 Jul 2016 10:56:43

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	V225821
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Actual Collection Date	2014 01 22
------------------------	------------

Actual Collection Time	06:35
------------------------	-------

Specimen Condition	<hr/>
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Battery ID	HM1604
------------	--------

Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
--------------	-----------------------------------

Lab Test ID	HMT100
-------------	--------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (18)

Data signed: (hfarmer1) 26 Mar 2015 13:39:17

Generated On: 20 Jul 2016 10:56:43

Lab Test Name	MCH
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	29
Reported Numeric Result	29
Reference Range low	26
Reference Range high	34
Range Units	PG
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (18)

Data signed: (hfarmer1) 26 Mar 2015 13:39:17

Generated On: 20 Jul 2016 10:56:43

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (19)

Data signed: (hfarmer1) 26 Mar 2015 13:39:17

Generated On: 20 Jul 2016 10:56:43

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	V225821
--------------	---------

Actual Collection Date	2014 01 22
------------------------	------------

Actual Collection Time	06:35
------------------------	-------

Specimen Condition	<hr/>
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Battery ID	HM1604
------------	--------

Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
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Lab Test ID	HMT102
-------------	--------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (19)

Data signed: (hfarmer1) 26 Mar 2015 13:39:17

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (19)

Data signed: (hfarmer1) 26 Mar 2015 13:39:17

Generated On: 20 Jul 2016 10:56:43

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (20)

Data signed: (hfarmer1) 26 Mar 2015 13:39:17

Generated On: 20 Jul 2016 10:56:43

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	V225821
--------------	---------

Actual Collection Date	2014 01 22
------------------------	------------

Actual Collection Time	06:35
------------------------	-------

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: 1002**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (20)

Data signed: (hfarmer1) 26 Mar 2015 13:39:17

Generated On: 20 Jul 2016 10:56:43

Lab Test Name	EOSINOPHILS
Test ID	
Test Status	Done <input type="checkbox"/>
Reported Text Result	0.29
Reported Numeric Result	0.29
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: 1002**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (20)

Data signed: (hfarmer1) 26 Mar 2015 13:39:17

Generated On: 20 Jul 2016 10:56:43

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (21)

Data signed: (hfarmer1) 26 Mar 2015 13:39:17

Generated On: 20 Jul 2016 10:56:43

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	V225821
--------------	---------

Actual Collection Date	2014 01 22
------------------------	------------

Actual Collection Time	06:35
------------------------	-------

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: 1002**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (21)

Data signed: (hfarmer1) 26 Mar 2015 13:39:17

Generated On: 20 Jul 2016 10:56:43

Lab Test Name	BASOPHILS
Test ID	
Test Status	Done <input checked="" type="checkbox"/>
Reported Text Result	0.04
Reported Numeric Result	0.04
Reference Range low	0.00
Reference Range high	0.20
Range Units	X10^3/UL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (21)

Data signed: (hfarmer1) 26 Mar 2015 13:39:17

Generated On: 20 Jul 2016 10:56:43

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (22)

Data signed: (hfarmer1) 26 Mar 2015 13:39:17

Generated On: 20 Jul 2016 10:56:43

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	V225821
--------------	---------

Actual Collection Date	2014 01 22
------------------------	------------

Actual Collection Time	06:35
------------------------	-------

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: 1002**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (22)

Data signed: (hfarmer1) 26 Mar 2015 13:39:17

Generated On: 20 Jul 2016 10:56:43

Lab Test Name	PLATELETS
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	294
Reported Numeric Result	294
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: 1002**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (22)

Data signed: (hfarmer1) 26 Mar 2015 13:39:17

Generated On: 20 Jul 2016 10:56:43

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (23)

Data signed: (hfarmer1) 26 Mar 2015 13:39:17

Generated On: 20 Jul 2016 10:56:43

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	V225821
--------------	---------

Actual Collection Date	2014 01 22
------------------------	------------

Actual Collection Time	06:35
------------------------	-------

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: 1002**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (23)

Data signed: (hfarmer1) 26 Mar 2015 13:39:17

Generated On: 20 Jul 2016 10:56:43

Lab Test Name	NEUTROPHILS (%)
Test ID	
Test Status	Done <input checked="" type="checkbox"/>
Reported Text Result	40.0
Reported Numeric Result	40.0
Reference Range low	40.5
Reference Range high	75.0
Range Units	%
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (23)

Data signed: (hfarmer1) 26 Mar 2015 13:39:17

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (24)

Data signed: (hfarmer1) 26 Mar 2015 13:39:17

Generated On: 20 Jul 2016 10:56:43

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	V225821
--------------	---------

Actual Collection Date	2014 01 22
------------------------	------------

Actual Collection Time	06:35
------------------------	-------

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: 1002**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (24)

Data signed: (hfarmer1) 26 Mar 2015 13:39:17

Generated On: 20 Jul 2016 10:56:43

Lab Test Name	LYMPHOCYTES (%)
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	50.2
Reported Numeric Result	50.2
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: 1002**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (24)

Data signed: (hfarmer1) 26 Mar 2015 13:39:17

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (25)

Data signed: (hfarmer1) 26 Mar 2015 13:39:17

Generated On: 20 Jul 2016 10:56:43

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"/>
------------	--

Accession ID	V225821
--------------	---------

Actual Collection Date	2014 01 22
------------------------	------------

Actual Collection Time	06:35
------------------------	-------

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: 1002**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (25)

Data signed: (hfarmer1) 26 Mar 2015 13:39:17

Generated On: 20 Jul 2016 10:56:43

Lab Test Name	MONOCYTES (%)
Test ID	
Test Status	Done <input type="checkbox"/>
Reported Text Result	4.8
Reported Numeric Result	4.8
Reference Range low	2.6
Reference Range high	10.1
Range Units	%
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (25)

Data signed: (hfarmer1) 26 Mar 2015 13:39:17

Generated On: 20 Jul 2016 10:56:43

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (26)

Data signed: (hfarmer1) 26 Mar 2015 13:39:17

Generated On: 20 Jul 2016 10:56:43

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"/>
------------	--

Accession ID	V225821
--------------	---------

Actual Collection Date	2014 01 22
------------------------	------------

Actual Collection Time	06:35
------------------------	-------

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: 1002**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (26)

Data signed: (hfarmer1) 26 Mar 2015 13:39:17

Generated On: 20 Jul 2016 10:56:43

Lab Test Name	EOSINOPHILS (%)
Test ID	
Test Status	Done <input type="checkbox"/>
Reported Text Result	4.4
Reported Numeric Result	4.4
Reference Range low	0.0
Reference Range high	6.8
Range Units	%
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (26)

Data signed: (hfarmer1) 26 Mar 2015 13:39:17

Generated On: 20 Jul 2016 10:56:43

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (27)

Data signed: (hfarmer1) 26 Mar 2015 13:39:17

Generated On: 20 Jul 2016 10:56:43

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	V225821
--------------	---------

Actual Collection Date	2014 01 22
------------------------	------------

Actual Collection Time	06:35
------------------------	-------

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: 1002**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (27)

Data signed: (hfarmer1) 26 Mar 2015 13:39:17

Generated On: 20 Jul 2016 10:56:43

Lab Test Name	BASOPHILS (%)
Test ID	
Test Status	Done <input checked="" type="radio"/>
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: 1002**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (27)

Data signed: (hfarmer1) 26 Mar 2015 13:39:17

Generated On: 20 Jul 2016 10:56:43

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (28)

Data signed: (hfarmer1) 26 Mar 2015 13:39:17

Generated On: 20 Jul 2016 10:56:43

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	V225821
--------------	---------

Actual Collection Date	2014 01 22
------------------------	------------

Actual Collection Time	06:35
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	HM1604
------------	--------

Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
--------------	-----------------------------------

Lab Test ID	HMT2
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (28)

Data signed: (hfarmer1) 26 Mar 2015 13:39:17

Generated On: 20 Jul 2016 10:56:43

Lab Test Name	HEMATOCRIT
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	44
Reported Numeric Result	44
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: 1002**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (28)

Data signed: (hfarmer1) 26 Mar 2015 13:39:17

Generated On: 20 Jul 2016 10:56:43

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (29)

Data signed: (hfarmer1) 26 Mar 2015 13:39:17

Generated On: 20 Jul 2016 10:56:43

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	V225821
--------------	---------

Actual Collection Date	2014 01 22
------------------------	------------

Actual Collection Time	06:35
------------------------	-------

Specimen Condition	<hr/>
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Battery ID	HM1604
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Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
--------------	-----------------------------------

Lab Test ID	HMT3
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (29)

Data signed: (hfarmer1) 26 Mar 2015 13:39:17

Generated On: 20 Jul 2016 10:56:43

Lab Test Name	RBC
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	5.2
Reported Numeric Result	5.2
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: 1002**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (29)

Data signed: (hfarmer1) 26 Mar 2015 13:39:17

Generated On: 20 Jul 2016 10:56:43

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (30)

Data signed: (hfarmer1) 26 Mar 2015 13:39:17

Generated On: 20 Jul 2016 10:56:43

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"/>
------------	--

Accession ID	V225821
--------------	---------

Actual Collection Date	2014 01 22
------------------------	------------

Actual Collection Time	06:35
------------------------	-------

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: 1002

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (30)

Data signed: (hfarmer1) 26 Mar 2015 13:39:17

Generated On: 20 Jul 2016 10:56:43

Lab Test Name	MCV
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	84
Reported Numeric Result	84
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: 1002**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (30)

Data signed: (hfarmer1) 26 Mar 2015 13:39:17

Generated On: 20 Jul 2016 10:56:43

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (31)

Data signed: (hfarmer1) 26 Mar 2015 13:39:17

Generated On: 20 Jul 2016 10:56:43

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	V225821
--------------	---------

Actual Collection Date	2014 01 22
------------------------	------------

Actual Collection Time	06:35
------------------------	-------

Specimen Condition	<hr/>
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Battery ID	HM1604
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Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
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Lab Test ID	HMT40
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1002

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (31)

Data signed: (hfarmer1) 26 Mar 2015 13:39:17

Generated On: 20 Jul 2016 10:56:43

Lab Test Name	HEMOGLOBIN
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	14.8
Reported Numeric Result	14.8
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: 1002**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (31)

Data signed: (hfarmer1) 26 Mar 2015 13:39:17

Generated On: 20 Jul 2016 10:56:43

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (32)

Data signed: (hfarmer1) 26 Mar 2015 13:39:17

Generated On: 20 Jul 2016 10:56:43

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/>
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	V225821
--------------	---------

Actual Collection Date	2014 01 22
------------------------	------------

Actual Collection Time	06:35
------------------------	-------

Specimen Condition	<hr/>
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Battery ID	HM1604
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Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
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Lab Test ID	HMT7
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (32)

Data signed: (hfarmer1) 26 Mar 2015 13:39:17

Generated On: 20 Jul 2016 10:56:43

Lab Test Name	WBC
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	6.63
Reported Numeric Result	6.63
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: 1002**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (32)

Data signed: (hfarmer1) 26 Mar 2015 13:39:17

Generated On: 20 Jul 2016 10:56:43

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (33)

Data signed: (hfarmer1) 26 Mar 2015 13:39:17

Generated On: 20 Jul 2016 10:56:43

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	V225821
--------------	---------

Actual Collection Date	2014 01 22
------------------------	------------

Actual Collection Time	06:35
------------------------	-------

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: 1002**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (33)

Data signed: (hfarmer1) 26 Mar 2015 13:39:17


Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (33)

Data signed: (hfarmer1) 26 Mar 2015 13:39:17

Generated On: 20 Jul 2016 10:56:43

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (34)

Data signed: (hfarmer1) 26 Mar 2015 13:39:17

Generated On: 20 Jul 2016 10:56:43

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	V225821
--------------	---------

Actual Collection Date	2014 01 22
------------------------	------------

Actual Collection Time	06:35
------------------------	-------

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: 1002**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (34)

Data signed: (hfarmer1) 26 Mar 2015 13:39:17

Generated On: 20 Jul 2016 10:56:43

Lab Test Name	NEUTROPHILS
Test ID	
Test Status	Done <input type="checkbox"/>
Reported Text Result	2.65
Reported Numeric Result	2.65
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: 1002**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (34)

Data signed: (hfarmer1) 26 Mar 2015 13:39:17

Generated On: 20 Jul 2016 10:56:43

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (35)

Data signed: (hfarmer1) 26 Mar 2015 13:39:17

Generated On: 20 Jul 2016 10:56:43

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	V225821
--------------	---------

Actual Collection Date	2014 01 22
------------------------	------------

Actual Collection Time	06:35
------------------------	-------

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: 1002**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (35)

Data signed: (hfarmer1) 26 Mar 2015 13:39:17

Generated On: 20 Jul 2016 10:56:43

Lab Test Name	LYMPHOCYTES
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	3.32
Reported Numeric Result	3.32
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: 1002**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (35)

Data signed: (hfarmer1) 26 Mar 2015 13:39:17

Generated On: 20 Jul 2016 10:56:43

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (36)

Data signed: (hfarmer1) 26 Mar 2015 13:39:17

Generated On: 20 Jul 2016 10:56:43

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	V225821
--------------	---------

Actual Collection Date	2014 01 22
------------------------	------------

Actual Collection Time	06:35
------------------------	-------

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: 1002**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (36)

Data signed: (hfarmer1) 26 Mar 2015 13:39:17


Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (36)

Data signed: (hfarmer1) 26 Mar 2015 13:39:17

Generated On: 20 Jul 2016 10:56:43

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (37)

Data signed: (hfarmer1) 26 Mar 2015 13:39:17

Generated On: 20 Jul 2016 10:56:43

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	V225821
--------------	---------

Actual Collection Date	2014 01 22
------------------------	------------

Actual Collection Time	06:35
------------------------	-------

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: 1002**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (37)

Data signed: (hfarmer1) 26 Mar 2015 13:39:17

Generated On: 20 Jul 2016 10:56:43

Lab Test Name	UR SPECIFIC GRAVITY
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	1.019
Reported Numeric Result	1.019
Reference Range low	1.003
Reference Range high	1.035
Range Units	
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (37)

Data signed: (hfarmer1) 26 Mar 2015 13:39:17

Generated On: 20 Jul 2016 10:56:43

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (38)

Data signed: (hfarmer1) 26 Mar 2015 13:39:17

Generated On: 20 Jul 2016 10:56:43

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	V225821
--------------	---------

Actual Collection Date	2014 01 22
------------------------	------------

Actual Collection Time	06:35
------------------------	-------

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: 1002**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (38)

Data signed: (hfarmer1) 26 Mar 2015 13:39:17

Generated On: 20 Jul 2016 10:56:43

Lab Test Name	UR PH
Test ID	
Test Status	Done <input type="checkbox"/>
Reported Text Result	5.0
Reported Numeric Result	5.0
Reference Range low	5.0
Reference Range high	8.0
Range Units	
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (38)

Data signed: (hfarmer1) 26 Mar 2015 13:39:17

Generated On: 20 Jul 2016 10:56:43

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (39)

Data signed: (hfarmer1) 26 Mar 2015 13:39:17

Generated On: 20 Jul 2016 10:56:43

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	V225821
--------------	---------

Actual Collection Date	2014 01 22
------------------------	------------

Actual Collection Time	06:35
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	UA1538
------------	--------

Battery Name	URINE MACRO PANEL
--------------	-------------------

Lab Test ID	UAT43
-------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (39)

Data signed: (hfarmer1) 26 Mar 2015 13:39:17


Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (39)

Data signed: (hfarmer1) 26 Mar 2015 13:39:17

Generated On: 20 Jul 2016 10:56:43

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (40)

Data signed: (hfarmer1) 26 Mar 2015 13:39:17

Generated On: 20 Jul 2016 10:56:43

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	V225821
--------------	---------

Actual Collection Date	2014 01 22
------------------------	------------

Actual Collection Time	06:35
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	UA1538
------------	--------

Battery Name	URINE MACRO PANEL
--------------	-------------------

Lab Test ID	UAT49
-------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (40)

Data signed: (hfarmer1) 26 Mar 2015 13:39:17

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (40)

Data signed: (hfarmer1) 26 Mar 2015 13:39:17

Generated On: 20 Jul 2016 10:56:43

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (41)

Data signed: (hfarmer1) 26 Mar 2015 13:39:17

Generated On: 20 Jul 2016 10:56:43

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	V225821
--------------	---------

Actual Collection Date	2014 01 22
------------------------	------------

Actual Collection Time	06:35
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	UA1538
------------	--------

Battery Name	URINE MACRO PANEL
--------------	-------------------

Lab Test ID	UAT5
-------------	------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (41)

Data signed: (hfarmer1) 26 Mar 2015 13:39:17


Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (41)

Data signed: (hfarmer1) 26 Mar 2015 13:39:17

Generated On: 20 Jul 2016 10:56:43

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (42)

Data signed: (hfarmer1) 26 Mar 2015 13:39:17

Generated On: 20 Jul 2016 10:56:43

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	V225821
--------------	---------

Actual Collection Date	2014 01 22
------------------------	------------

Actual Collection Time	06:35
------------------------	-------

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: 1002**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (42)

Data signed: (hfarmer1) 26 Mar 2015 13:39:17


Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (42)

Data signed: (hfarmer1) 26 Mar 2015 13:39:17

Generated On: 20 Jul 2016 10:56:43

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 30

Form: Date of Visit

Data signed: (hfarmer1) 26 Mar 2015 13:39:46

Generated On: 20 Jul 2016 10:56:43

Visit Not Done	False
----------------	-------

If Not Done, Specify Reason	<hr/>
-----------------------------	-------

Date of Visit	15 FEB 2014 DD/MMM/YYYY
---------------	----------------------------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 30

Form: Vital Signs

Data signed: (hfarmer1) 26 Mar 2015 13:39:46

Generated On: 20 Jul 2016 10:56:43

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

15 FEB 2014
DD/MMM/YYYY

Time of assessment

14:48
hour:min 24-hour clock

Pulse rate

64
beats per minute

Respiratory rate

12
breaths per minute

Blood Pressure (systolic)

107
mmHg

Blood Pressure (diastolic)

65
mmHg

Vital Signs Position of Subject

Supine ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 30

Form: Advice on the risk of smoking and debriefing

Data signed: (hfarmer1) 26 Mar 2015 13:39:46

Generated On: 20 Jul 2016 10:56:43

Date	16 FEB 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: 1002**

Folder: Day 30

Form: Physical Examination

Data signed: (hfarmer1) 26 Mar 2015 13:39:43

Generated On: 20 Jul 2016 10:56:43

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of Assessment

15 FEB 2014
DD/MMM/YYYY

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 30

Form: Physical Examination (1)

Data signed: (hfarmer1) 26 Mar 2015 13:39:43

Generated On: 20 Jul 2016 10:56:43

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of Assessment 15 FEB 2014
DD/MMM/YYYY

System General Appearance ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 30

Form: Physical Examination (2)

Data signed: (hfarmer1) 26 Mar 2015 13:39:43

Generated On: 20 Jul 2016 10:56:43

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of Assessment

15 FEB 2014
DD/MMM/YYYY

System

HEENT ☒
(head, eyes, ears, nose,
throat)

Outcome

Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done

False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 30

Form: Physical Examination (3)

Data signed: (hfarmer1) 26 Mar 2015 13:39:43

Generated On: 20 Jul 2016 10:56:43

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of Assessment 15 FEB 2014
DD/MMM/YYYY

System Thyroid Gland ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 30

Form: Physical Examination (4)

Data signed: (hfarmer1) 26 Mar 2015 13:39:43

Generated On: 20 Jul 2016 10:56:43

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of Assessment 15 FEB 2014
DD/MMM/YYYY

System Heart ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 30

Form: Physical Examination (5)

Data signed: (hfarmer1) 26 Mar 2015 13:39:43

Generated On: 20 Jul 2016 10:56:43

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of Assessment 15 FEB 2014
DD/MMM/YYYY

System Chest ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 30

Form: Physical Examination (6)

Data signed: (hfarmer1) 26 Mar 2015 13:39:43

Generated On: 20 Jul 2016 10:56:43

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of Assessment 15 FEB 2014
DD/MMM/YYYY

System Lungs ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 30

Form: Physical Examination (7)

Data signed: (hfarmer1) 26 Mar 2015 13:39:43

Generated On: 20 Jul 2016 10:56:43

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of Assessment 15 FEB 2014
DD/MMM/YYYY

System Gastrointestinal ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 30

Form: Physical Examination (8)

Data signed: (hfarmer1) 26 Mar 2015 13:39:43

Generated On: 20 Jul 2016 10:56:43

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of Assessment 15 FEB 2014
DD/MMM/YYYY

System Cardiovascular System ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 30

Form: Physical Examination (9)

Data signed: (hfarmer1) 26 Mar 2015 13:39:43

Generated On: 20 Jul 2016 10:56:43

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of Assessment

15 FEB 2014
DD/MMM/YYYY

System

Neurologic ☒

Outcome

Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done

False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 30

Form: Physical Examination (10)

Data signed: (hfarmer1) 26 Mar 2015 13:39:43

Generated On: 20 Jul 2016 10:56:43

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of Assessment

15 FEB 2014
DD/MMM/YYYY

System

Skin ☒

Outcome

Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done

False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 30

Form: Physical Examination (11)

Data signed: (hfarmer1) 26 Mar 2015 13:39:43

Generated On: 20 Jul 2016 10:56:43

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of Assessment

15 FEB 2014
DD/MMM/YYYY

System

Back ☒

Outcome

Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done

False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 30

Form: Physical Examination (12)

Data signed: (hfarmer1) 26 Mar 2015 13:39:43

Generated On: 20 Jul 2016 10:56:43

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of Assessment 15 FEB 2014
DD/MMM/YYYY

System Musculoskeletal ☒

Outcome Abnormal ☒

Abnormal, please specify RIGHT ELBOW DEFORMITY

Clinically significant No ☒

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 30

Form: Physical Examination (13)

Data signed: (hfarmer1) 26 Mar 2015 13:39:43

Generated On: 20 Jul 2016 10:56:43

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of Assessment 15 FEB 2014
DD/MMM/YYYY

System Abdomen ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 30

Form: Physical Examination (14)

Data signed: (hfarmer1) 26 Mar 2015 13:39:43

Generated On: 20 Jul 2016 10:56:43

Was the physical examination performed? Yes ☐

If No, please specify the reason: _____

Date of Assessment 15 FEB 2014
DD/MMM/YYYY

System Dentition ☐

Outcome Normal ☐

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 30

Form: Physical Examination (15)

Data signed: (hfarmer1) 26 Mar 2015 13:39:43

Generated On: 20 Jul 2016 10:56:43

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of Assessment

15 FEB 2014
DD/MMM/YYYY

System

Other ☒

Other, Specify _____

Outcome _____

Abnormal, please specify _____

Clinically significant _____

Not Done

True

Not Done; please specify the reason: _____

NOT EXAMINED

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 30

Form: Physical Examination (16)

Data signed: (hfarmer1) 26 Mar 2015 13:39:43

Generated On: 20 Jul 2016 10:56:43

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of Assessment

15 FEB 2014
DD/MMM/YYYY

System

Other ☒

Other, Specify _____

Outcome _____

Abnormal, please specify _____

Clinically significant _____

Not Done

True

Not Done; please specify the reason: _____

NOT EXAMINED

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 30

Form: Physical Examination (17)

Data signed: (hfarmer1) 26 Mar 2015 13:39:43

Generated On: 20 Jul 2016 10:56:43

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of Assessment

15 FEB 2014
DD/MMM/YYYY

System

Other ☒

Other, Specify _____

Outcome _____

Abnormal, please specify _____

Clinically significant _____

Not Done

True

Not Done; please specify the reason: _____

NOT EXAMINED

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 30

Form: Physical Examination (18)

Data signed: (hfarmer1) 26 Mar 2015 13:39:43

Generated On: 20 Jul 2016 10:56:43

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of Assessment

15 FEB 2014
DD/MMM/YYYY

System

Other ☒

Other, Specify _____

Outcome _____

Abnormal, please specify _____

Clinically significant _____

Not Done

True

Not Done; please specify the reason: _____

NOT EXAMINED

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 30

Form: Physical Examination (19)

Data signed: (hfarmer1) 26 Mar 2015 13:39:43

Generated On: 20 Jul 2016 10:56:43

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of Assessment

15 FEB 2014
DD/MMM/YYYY

System

Other ☒

Other, Specify _____

Outcome _____

Abnormal, please specify _____

Clinically significant _____

Not Done

True

Not Done; please specify the reason: _____

NOT EXAMINED

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 30

Form: Weight

Data signed: (hfarmer1) 26 Mar 2015 13:39:46

Generated On: 20 Jul 2016 10:56:43

Measurement(s) assessed?

Yes ☒

If No, please specify the reason: _____

Date of Assessment

15 FEB 2014
DD/MMM/YYYY

Time of assessment

15:40
hour:min 24-hour clock

Weight

63.9
kg

BMI

24.4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 30

Form: ECG (12-Lead Standard)

Data signed: (hfarmer1) 26 Mar 2015 13:39:42

Generated On: 20 Jul 2016 10:56:43

Was the ECG performed? Yes ☒

If No, please specify the reason: _____

Date of Assessment 15 FEB 2014
DD/MMM/YYYY

Position Supine ☒

Heart Rate 61
beats per minute

QRS Interval 89
msec

QT Interval 397
msec

QTcB Interval 403
msec

PR Interval 209
msec

QTcF Interval 401
msec

Interpretation Normal ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 30

Form: ECG (12-Lead Standard)

Data signed: (hfarmer1) 26 Mar 2015 13:39:42

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Day 30

Form: Haematology

Data signed: (hfarmer1) 26 Mar 2015 13:39:42

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Day 30

Form: Clinical Chemistry

Data signed: (hfarmer1) 26 Mar 2015 13:39:42

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Day 30

Form: Urine analysis

Data signed: (hfarmer1) 26 Mar 2015 13:39:42

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Day 30

Form: Urine Pregnancy Test

Data signed: (hfarmer1) 26 Mar 2015 13:39:46

Generated On: 20 Jul 2016 10:56:43

Not Done	False
----------	-------

If Not Done, specify reason	<hr/>
-----------------------------	-------

Date of Test	15 FEB 2014 DD/MMM/YYYY
--------------	----------------------------

Time of Test	17:21 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: 1002**

Folder: Day 30

Form: Plasma Nicotine Sample

Data signed: (hfarmer1) 26 Mar 2015 13:39:43

Generated On: 20 Jul 2016 10:56:43

Not Done	False
----------	-------

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	15 FEB 2014
---------------------	-------------

Time hour:min 24-hour clock	10:05
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 30

Form: Plasma Cotinine Sample

Data signed: (hfarmer1) 26 Mar 2015 13:39:42

Generated On: 20 Jul 2016 10:56:43

Not Done	False
----------	-------

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	15 FEB 2014
---------------------	-------------

Time hour:min 24-hour clock	10:05
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 30

Form: CoHb Blood Sample <D30_D60>

Data signed: (hfarmer1) 26 Mar 2015 13:39:42

Generated On: 20 Jul 2016 10:56:43

Not Done	False
----------	-------

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	15 FEB 2014
---------------------	-------------

Timepoint	10:00 - 11:30 <input checked="" type="radio"/>
-----------	--

Time hour:min 24-hour clock	10:05
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 30

Form: CO Breath Test

Data signed: (hfarmer1) 26 Mar 2015 13:39:42

Generated On: 20 Jul 2016 10:56:43

Assessment not done	False
---------------------	-------

If Not Done, please specify the reason: _____

Actual Date of Assessment	15 FEB 2014 DD/MMM/YYYY
---------------------------	----------------------------

Actual Time of Assessment	10:08 hour:min 24-hour clock
---------------------------	---------------------------------

Result	32 ppm
--------	-----------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 30

Form: Risk markers: hs-CRP, fibrinogen, homocysteine, LDL, HDL, sICAM-1

Data signed: (hfarmer1) 26 Mar 2015 13:39:43

Generated On: 20 Jul 2016 10:56:43

Not Done	False
----------	-------

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	16 FEB 2014
---------------------	-------------

Time hour:min 24-hour clock	06:31
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 30

Form: 24 hour urine collections

Data signed: (hfarmer1) 26 Mar 2015 13:39:46

Generated On: 20 Jul 2016 10:56:43

Start Date	15 FEB 2014 DD/MMM/YYYY
------------	----------------------------

Start Time	08:37 hour:min 24-hour clock
------------	---------------------------------

End Date	16 FEB 2014 DD/MMM/YYYY
----------	----------------------------

End Time	09:02 hour:min 24-hour clock
----------	---------------------------------

Volume	893 mL
--------	-----------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 30

Form: Sample Urine Collection

Data signed: (hfarmer1) 26 Mar 2015 13:39:46

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Day 30

Form: Lab_BU_CCLS (1)

Data signed: (hfarmer1) 26 Mar 2015 13:39:47

Generated On: 20 Jul 2016 10:56:43

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	P274248
--------------	---------

Actual Collection Date	2014 02 16
------------------------	------------

Actual Collection Time	06:31
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	RC1029
------------	--------

Battery Name	TRIGLYCERIDES
--------------	---------------

Lab Test ID	RCT19
-------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 30

Form: Lab_BU_CCLS (1)

Data signed: (hfarmer1) 26 Mar 2015 13:39:47

Generated On: 20 Jul 2016 10:56:43

Lab Test Name	TRIGLYCERIDES (GPO)
---------------	---------------------

Test ID	<hr/>
---------	-------

Test Status	Done <input checked="" type="radio"/>
-------------	---------------------------------------

Reported Text Result	135
----------------------	-----

Reported Numeric Result	135
-------------------------	-----

Reference Range low	36
---------------------	----

Reference Range high	144
----------------------	-----

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: 1002**

Folder: Day 30

Form: Lab_BU_CCLS (1)

Data signed: (hfarmer1) 26 Mar 2015 13:39:47

Generated On: 20 Jul 2016 10:56:43

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 30

Form: Lab_BU_CCLS (2)

Data signed: (hfarmer1) 26 Mar 2015 13:39:47

Generated On: 20 Jul 2016 10:56:43

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	P274248
--------------	---------

Actual Collection Date	2014 02 16
------------------------	------------

Actual Collection Time	06:31
------------------------	-------

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: 1002**

Folder: Day 30

Form: Lab_BU_CCLS (2)

Data signed: (hfarmer1) 26 Mar 2015 13:39:47

Generated On: 20 Jul 2016 10:56:43

Lab Test Name	FASTING GLUCOSE
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	78
Reported Numeric Result	78
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: 1002**

Folder: Day 30

Form: Lab_BU_CCLS (2)

Data signed: (hfarmer1) 26 Mar 2015 13:39:47

Generated On: 20 Jul 2016 10:56:43

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 30

Form: Lab_BU_CCLS (3)

Data signed: (hfarmer1) 26 Mar 2015 13:39:47

Generated On: 20 Jul 2016 10:56:43

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex F

Subject Date of Birth (b) (6)

Visit Name _____

Visit Type Scheduled ☒

Accession ID P274248

Actual Collection Date 2014 02 16

Actual Collection Time 06:31

Specimen Condition _____

Battery ID RC272

Battery Name TOTAL CHOLESTEROL

Lab Test ID RCT20

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 30

Form: Lab_BU_CCLS (3)

Data signed: (hfarmer1) 26 Mar 2015 13:39:47

Generated On: 20 Jul 2016 10:56:43

Lab Test Name	CHOLESTEROL (HIGH PERFORMANCE)
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	174
Reported Numeric Result	174
Reference Range low	128
Reference Range high	218
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: 1002**

Folder: Day 30

Form: Lab_BU_CCLS (3)

Data signed: (hfarmer1) 26 Mar 2015 13:39:47

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Day 30

Form: Lab_BU_CCLS (4)

Data signed: (hfarmer1) 26 Mar 2015 13:39:47

Generated On: 20 Jul 2016 10:56:43

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	P274248
--------------	---------

Actual Collection Date	2014 02 16
------------------------	------------

Actual Collection Time	06:31
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	RC9255
------------	--------

Battery Name	CHEMISTRY PANEL
--------------	-----------------

Lab Test ID	RCT1
-------------	------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 30

Form: Lab_BU_CCLS (4)

Data signed: (hfarmer1) 26 Mar 2015 13:39:47

Generated On: 20 Jul 2016 10:56:43

Lab Test Name	TOTAL BILIRUBIN
Test ID	
Test Status	Done <input checked="" type="radio"/>
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: 1002**

Folder: Day 30

Form: Lab_BU_CCLS (4)

Data signed: (hfarmer1) 26 Mar 2015 13:39:47

Generated On: 20 Jul 2016 10:56:43

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 30

Form: Lab_BU_CCLS (5)

Data signed: (hfarmer1) 26 Mar 2015 13:39:47

Generated On: 20 Jul 2016 10:56:43

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	P274248
--------------	---------

Actual Collection Date	2014 02 16
------------------------	------------

Actual Collection Time	06:31
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	RC9255
------------	--------

Battery Name	CHEMISTRY PANEL
--------------	-----------------

Lab Test ID	RCT12
-------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 30

Form: Lab_BU_CCLS (5)

Data signed: (hfarmer1) 26 Mar 2015 13:39:47

Generated On: 20 Jul 2016 10:56:43

Lab Test Name	TOTAL PROTEIN
Test ID	
Test Status	Done <input checked="" 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: 1002**

Folder: Day 30

Form: Lab_BU_CCLS (5)

Data signed: (hfarmer1) 26 Mar 2015 13:39:47

Generated On: 20 Jul 2016 10:56:43

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 30

Form: Lab_BU_CCLS (6)

Data signed: (hfarmer1) 26 Mar 2015 13:39:47

Generated On: 20 Jul 2016 10:56:43

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	P274248
--------------	---------

Actual Collection Date	2014 02 16
------------------------	------------

Actual Collection Time	06:31
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	RC9255
------------	--------

Battery Name	CHEMISTRY PANEL
--------------	-----------------

Lab Test ID	RCT13
-------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 30

Form: Lab_BU_CCLS (6)

Data signed: (hfarmer1) 26 Mar 2015 13:39:47

Generated On: 20 Jul 2016 10:56:43

Lab Test Name	ALBUMIN
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	3.9
Reported Numeric Result	3.9
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: 1002**

Folder: Day 30

Form: Lab_BU_CCLS (6)

Data signed: (hfarmer1) 26 Mar 2015 13:39:47

Generated On: 20 Jul 2016 10:56:43

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 30

Form: Lab_BU_CCLS (7)

Data signed: (hfarmer1) 26 Mar 2015 13:39:47

Generated On: 20 Jul 2016 10:56:43

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	P274248
--------------	---------

Actual Collection Date	2014 02 16
------------------------	------------

Actual Collection Time	06:31
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	RC9255
------------	--------

Battery Name	CHEMISTRY PANEL
--------------	-----------------

Lab Test ID	RCT1407
-------------	---------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 30

Form: Lab_BU_CCLS (7)

Data signed: (hfarmer1) 26 Mar 2015 13:39:47

Generated On: 20 Jul 2016 10:56:43

Lab Test Name	ALKALINE PHOSPHATASE
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	67
Reported Numeric Result	67
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: 1002**

Folder: Day 30

Form: Lab_BU_CCLS (7)

Data signed: (hfarmer1) 26 Mar 2015 13:39:47

Generated On: 20 Jul 2016 10:56:43

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 30

Form: Lab_BU_CCLS (8)

Data signed: (hfarmer1) 26 Mar 2015 13:39:47

Generated On: 20 Jul 2016 10:56:43

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	P274248
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Actual Collection Date	2014 02 16
------------------------	------------

Actual Collection Time	06:31
------------------------	-------

Specimen Condition	<hr/>
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Battery ID	RC9255
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Battery Name	CHEMISTRY PANEL
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Lab Test ID	RCT1408
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 30

Form: Lab_BU_CCLS (8)

Data signed: (hfarmer1) 26 Mar 2015 13:39:47

Generated On: 20 Jul 2016 10:56:43

Lab Test Name	LDH
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	116
Reported Numeric Result	116
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: 1002**

Folder: Day 30

Form: Lab_BU_CCLS (8)

Data signed: (hfarmer1) 26 Mar 2015 13:39:47

Generated On: 20 Jul 2016 10:56:43

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 30

Form: Lab_BU_CCLS (9)

Data signed: (hfarmer1) 26 Mar 2015 13:39:47

Generated On: 20 Jul 2016 10:56:43

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	P274248
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Actual Collection Date	2014 02 16
------------------------	------------

Actual Collection Time	06:31
------------------------	-------

Specimen Condition	<hr/>
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Battery ID	RC9255
------------	--------

Battery Name	CHEMISTRY PANEL
--------------	-----------------

Lab Test ID	RCT15
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 30

Form: Lab_BU_CCLS (9)

Data signed: (hfarmer1) 26 Mar 2015 13:39:47

Generated On: 20 Jul 2016 10:56:43

Lab Test Name	SERUM SODIUM
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	141
Reported Numeric Result	141
Reference Range low	132
Reference Range high	147
Range Units	MEQ/L
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 30

Form: Lab_BU_CCLS (9)

Data signed: (hfarmer1) 26 Mar 2015 13:39:47

Generated On: 20 Jul 2016 10:56:43

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 30

Form: Lab_BU_CCLS (10)

Data signed: (hfarmer1) 26 Mar 2015 13:39:47

Generated On: 20 Jul 2016 10:56:43

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	P274248
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Actual Collection Date	2014 02 16
------------------------	------------

Actual Collection Time	06:31
------------------------	-------

Specimen Condition	<hr/>
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Battery ID	RC9255
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Battery Name	CHEMISTRY PANEL
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Lab Test ID	RCT16
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 30

Form: Lab_BU_CCLS (10)

Data signed: (hfarmer1) 26 Mar 2015 13:39:47

Generated On: 20 Jul 2016 10:56:43

Lab Test Name	SERUM POTASSIUM
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	4.8
Reported Numeric Result	4.8
Reference Range low	3.4
Reference Range high	5.4
Range Units	MEQ/L
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 30

Form: Lab_BU_CCLS (10)

Data signed: (hfarmer1) 26 Mar 2015 13:39:47

Generated On: 20 Jul 2016 10:56:43

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 30

Form: Lab_BU_CCLS (11)

Data signed: (hfarmer1) 26 Mar 2015 13:39:47

Generated On: 20 Jul 2016 10:56:43

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex F

Subject Date of Birth (b) (6)

Visit Name _____

Visit Type Scheduled ☒

Accession ID P274248

Actual Collection Date 2014 02 16

Actual Collection Time 06:31

Specimen Condition _____

Battery ID RC9255

Battery Name CHEMISTRY PANEL

Lab Test ID RCT29

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 30

Form: Lab_BU_CCLS (11)

Data signed: (hfarmer1) 26 Mar 2015 13:39:47

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Day 30

Form: Lab_BU_CCLS (11)

Data signed: (hfarmer1) 26 Mar 2015 13:39:47

Generated On: 20 Jul 2016 10:56:43

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 30

Form: Lab_BU_CCLS (12)

Data signed: (hfarmer1) 26 Mar 2015 13:39:47

Generated On: 20 Jul 2016 10:56:43

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	P274248
--------------	---------

Actual Collection Date	2014 02 16
------------------------	------------

Actual Collection Time	06:31
------------------------	-------

Specimen Condition	<hr/>
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Battery ID	RC9255
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Battery Name	CHEMISTRY PANEL
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Lab Test ID	RCT3
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 30

Form: Lab_BU_CCLS (12)

Data signed: (hfarmer1) 26 Mar 2015 13:39:47

Generated On: 20 Jul 2016 10:56:43

Lab Test Name	GGT
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	6
Reported Numeric Result	6
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: 1002**

Folder: Day 30

Form: Lab_BU_CCLS (12)

Data signed: (hfarmer1) 26 Mar 2015 13:39:47

Generated On: 20 Jul 2016 10:56:43

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 30

Form: Lab_BU_CCLS (13)

Data signed: (hfarmer1) 26 Mar 2015 13:39:47

Generated On: 20 Jul 2016 10:56:43

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	P274248
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Actual Collection Date	2014 02 16
------------------------	------------

Actual Collection Time	06:31
------------------------	-------

Specimen Condition	<hr/>
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Battery ID	RC9255
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Battery Name	CHEMISTRY PANEL
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Lab Test ID	RCT392
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 30

Form: Lab_BU_CCLS (13)

Data signed: (hfarmer1) 26 Mar 2015 13:39:47

Generated On: 20 Jul 2016 10:56:43

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	0.8
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Reported Numeric Result	0.8
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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/>
----------------------------------	-------

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: 1002**

Folder: Day 30

Form: Lab_BU_CCLS (13)

Data signed: (hfarmer1) 26 Mar 2015 13:39:47

Generated On: 20 Jul 2016 10:56:43

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 30

Form: Lab_BU_CCLS (14)

Data signed: (hfarmer1) 26 Mar 2015 13:39:47

Generated On: 20 Jul 2016 10:56:43

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	P274248
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Actual Collection Date	2014 02 16
------------------------	------------

Actual Collection Time	06:31
------------------------	-------

Specimen Condition	<hr/>
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Battery ID	RC9255
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Battery Name	CHEMISTRY PANEL
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Lab Test ID	RCT4
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 30

Form: Lab_BU_CCLS (14)

Data signed: (hfarmer1) 26 Mar 2015 13:39:47

Generated On: 20 Jul 2016 10:56:43

Lab Test Name	ALT (SGPT)
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	31
Reported Numeric Result	31
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: 1002**

Folder: Day 30

Form: Lab_BU_CCLS (14)

Data signed: (hfarmer1) 26 Mar 2015 13:39:47

Generated On: 20 Jul 2016 10:56:43

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 30

Form: Lab_BU_CCLS (15)

Data signed: (hfarmer1) 26 Mar 2015 13:39:47

Generated On: 20 Jul 2016 10:56:43

Transmission Type Cumulative ☒

Subject ID or Number

Subject Sex F

Subject Date of Birth (b) (6)

Visit Name

Visit Type Scheduled ☒

Accession ID P274248

Actual Collection Date 2014 02 16

Actual Collection Time 06:31

Specimen Condition

Battery ID RC9255

Battery Name CHEMISTRY PANEL

Lab Test ID RCT5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 30

Form: Lab_BU_CCLS (15)

Data signed: (hfarmer1) 26 Mar 2015 13:39:47

Generated On: 20 Jul 2016 10:56:43

Lab Test Name	AST (SGOT)
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	28
Reported Numeric Result	28
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: 1002**

Folder: Day 30

Form: Lab_BU_CCLS (15)

Data signed: (hfarmer1) 26 Mar 2015 13:39:47

Generated On: 20 Jul 2016 10:56:43

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 30

Form: Lab_BU_CCLS (16)

Data signed: (hfarmer1) 26 Mar 2015 13:39:47

Generated On: 20 Jul 2016 10:56:43

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	P274248
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Actual Collection Date	2014 02 16
------------------------	------------

Actual Collection Time	06:31
------------------------	-------

Specimen Condition	<hr/>
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Battery ID	RC9255
------------	--------

Battery Name	CHEMISTRY PANEL
--------------	-----------------

Lab Test ID	RCT6
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 30

Form: Lab_BU_CCLS (16)

Data signed: (hfarmer1) 26 Mar 2015 13:39:47

Generated On: 20 Jul 2016 10:56:43

Lab Test Name	UREA NITROGEN
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	10
Reported Numeric Result	10
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: 1002**

Folder: Day 30

Form: Lab_BU_CCLS (16)

Data signed: (hfarmer1) 26 Mar 2015 13:39:47

Generated On: 20 Jul 2016 10:56:43

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 30

Form: Lab_BU_CCLS (17)

Data signed: (hfarmer1) 26 Mar 2015 13:39:47

Generated On: 20 Jul 2016 10:56:43

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"/>
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Accession ID	P274248
--------------	---------

Actual Collection Date	2014 02 16
------------------------	------------

Actual Collection Time	06:31
------------------------	-------

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: 1002**

Folder: Day 30

Form: Lab_BU_CCLS (17)

Data signed: (hfarmer1) 26 Mar 2015 13:39:47

Generated On: 20 Jul 2016 10:56:43

Lab Test Name	MONOCYTES
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	0.31
Reported Numeric Result	0.31
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: 1002**

Folder: Day 30

Form: Lab_BU_CCLS (17)

Data signed: (hfarmer1) 26 Mar 2015 13:39:47

Generated On: 20 Jul 2016 10:56:43

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 30

Form: Lab_BU_CCLS (18)

Data signed: (hfarmer1) 26 Mar 2015 13:39:47

Generated On: 20 Jul 2016 10:56:43

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"/>
------------	--

Accession ID	P274248
--------------	---------

Actual Collection Date	2014 02 16
------------------------	------------

Actual Collection Time	06:31
------------------------	-------

Specimen Condition	<hr/>
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Battery ID	HM1604
------------	--------

Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
--------------	-----------------------------------

Lab Test ID	HMT100
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 30

Form: Lab_BU_CCLS (18)

Data signed: (hfarmer1) 26 Mar 2015 13:39:47

Generated On: 20 Jul 2016 10:56:43

Lab Test Name	MCH
Test ID	
Test Status	Done <input type="checkbox"/>
Reported Text Result	29
Reported Numeric Result	29
Reference Range low	26
Reference Range high	34
Range Units	PG
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 30

Form: Lab_BU_CCLS (18)

Data signed: (hfarmer1) 26 Mar 2015 13:39:47

Generated On: 20 Jul 2016 10:56:43

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 30

Form: Lab_BU_CCLS (19)

Data signed: (hfarmer1) 26 Mar 2015 13:39:47

Generated On: 20 Jul 2016 10:56:43

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	P274248
--------------	---------

Actual Collection Date	2014 02 16
------------------------	------------

Actual Collection Time	06:31
------------------------	-------

Specimen Condition	<hr/>
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Battery ID	HM1604
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Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
--------------	-----------------------------------

Lab Test ID	HMT102
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 30

Form: Lab_BU_CCLS (19)

Data signed: (hfarmer1) 26 Mar 2015 13:39:47

Generated On: 20 Jul 2016 10:56:43

Lab Test Name	MCHC
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	33
Reported Numeric Result	33
Reference Range low	31
Reference Range high	38
Range Units	G/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 30

Form: Lab_BU_CCLS (19)

Data signed: (hfarmer1) 26 Mar 2015 13:39:47

Generated On: 20 Jul 2016 10:56:43

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 30

Form: Lab_BU_CCLS (20)

Data signed: (hfarmer1) 26 Mar 2015 13:39:47

Generated On: 20 Jul 2016 10:56:43

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	P274248
--------------	---------

Actual Collection Date	2014 02 16
------------------------	------------

Actual Collection Time	06:31
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	HM1604
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Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
--------------	-----------------------------------

Lab Test ID	HMT11
-------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 30

Form: Lab_BU_CCLS (20)

Data signed: (hfarmer1) 26 Mar 2015 13:39:47

Generated On: 20 Jul 2016 10:56:43

Lab Test Name	EOSINOPHILS
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	0.39
Reported Numeric Result	0.39
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: 1002**

Folder: Day 30

Form: Lab_BU_CCLS (20)

Data signed: (hfarmer1) 26 Mar 2015 13:39:47

Generated On: 20 Jul 2016 10:56:43

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 30

Form: Lab_BU_CCLS (21)

Data signed: (hfarmer1) 26 Mar 2015 13:39:47

Generated On: 20 Jul 2016 10:56:43

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	P274248
--------------	---------

Actual Collection Date	2014 02 16
------------------------	------------

Actual Collection Time	06:31
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	HM1604
------------	--------

Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
--------------	-----------------------------------

Lab Test ID	HMT12
-------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 30

Form: Lab_BU_CCLS (21)

Data signed: (hfarmer1) 26 Mar 2015 13:39:47

Generated On: 20 Jul 2016 10:56:43

Lab Test Name	BASOPHILS
Test ID	
Test Status	Done <input type="checkbox"/>
Reported Text Result	0.04
Reported Numeric Result	0.04
Reference Range low	0.00
Reference Range high	0.20
Range Units	X10^3/UL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 30

Form: Lab_BU_CCLS (21)

Data signed: (hfarmer1) 26 Mar 2015 13:39:47

Generated On: 20 Jul 2016 10:56:43

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 30

Form: Lab_BU_CCLS (22)

Data signed: (hfarmer1) 26 Mar 2015 13:39:47

Generated On: 20 Jul 2016 10:56:43

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	P274248
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Actual Collection Date	2014 02 16
------------------------	------------

Actual Collection Time	06:31
------------------------	-------

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: 1002**

Folder: Day 30

Form: Lab_BU_CCLS (22)

Data signed: (hfarmer1) 26 Mar 2015 13:39:47

Generated On: 20 Jul 2016 10:56:43

Lab Test Name	PLATELETS
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	247
Reported Numeric Result	247
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: 1002**

Folder: Day 30

Form: Lab_BU_CCLS (22)

Data signed: (hfarmer1) 26 Mar 2015 13:39:47

Generated On: 20 Jul 2016 10:56:43

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 30

Form: Lab_BU_CCLS (23)

Data signed: (hfarmer1) 26 Mar 2015 13:39:47

Generated On: 20 Jul 2016 10:56:43

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	P274248
--------------	---------

Actual Collection Date	2014 02 16
------------------------	------------

Actual Collection Time	06:31
------------------------	-------

Specimen Condition	<hr/>
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Battery ID	HM1604
------------	--------

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: 1002**

Folder: Day 30

Form: Lab_BU_CCLS (23)

Data signed: (hfarmer1) 26 Mar 2015 13:39:47

Generated On: 20 Jul 2016 10:56:43

Lab Test Name	NEUTROPHILS (%)
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	37.5
Reported Numeric Result	37.5
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: 1002**

Folder: Day 30

Form: Lab_BU_CCLS (23)

Data signed: (hfarmer1) 26 Mar 2015 13:39:47

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Day 30

Form: Lab_BU_CCLS (24)

Data signed: (hfarmer1) 26 Mar 2015 13:39:47

Generated On: 20 Jul 2016 10:56:43

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	P274248
--------------	---------

Actual Collection Date	2014 02 16
------------------------	------------

Actual Collection Time	06:31
------------------------	-------

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: 1002**

Folder: Day 30

Form: Lab_BU_CCLS (24)

Data signed: (hfarmer1) 26 Mar 2015 13:39:47

Generated On: 20 Jul 2016 10:56:43

Lab Test Name	LYMPHOCYTES (%)
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	50.6
Reported Numeric Result	50.6
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: 1002**

Folder: Day 30

Form: Lab_BU_CCLS (24)

Data signed: (hfarmer1) 26 Mar 2015 13:39:47

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Day 30

Form: Lab_BU_CCLS (25)

Data signed: (hfarmer1) 26 Mar 2015 13:39:47

Generated On: 20 Jul 2016 10:56:43

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	P274248
--------------	---------

Actual Collection Date	2014 02 16
------------------------	------------

Actual Collection Time	06:31
------------------------	-------

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: 1002**

Folder: Day 30

Form: Lab_BU_CCLS (25)

Data signed: (hfarmer1) 26 Mar 2015 13:39:47

Generated On: 20 Jul 2016 10:56:43

Lab Test Name	MONOCYTES (%)
Test ID	
Test Status	Done <input checked="" type="checkbox"/>
Reported Text Result	4.9
Reported Numeric Result	4.9
Reference Range low	2.6
Reference Range high	10.1
Range Units	%
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 30

Form: Lab_BU_CCLS (25)

Data signed: (hfarmer1) 26 Mar 2015 13:39:47

Generated On: 20 Jul 2016 10:56:43

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 30

Form: Lab_BU_CCLS (26)

Data signed: (hfarmer1) 26 Mar 2015 13:39:47

Generated On: 20 Jul 2016 10:56:43

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	P274248
--------------	---------

Actual Collection Date	2014 02 16
------------------------	------------

Actual Collection Time	06:31
------------------------	-------

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: 1002**

Folder: Day 30

Form: Lab_BU_CCLS (26)

Data signed: (hfarmer1) 26 Mar 2015 13:39:47

Generated On: 20 Jul 2016 10:56:43

Lab Test Name	EOSINOPHILS (%)
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	6.3
Reported Numeric Result	6.3
Reference Range low	0.0
Reference Range high	6.8
Range Units	%
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 30

Form: Lab_BU_CCLS (26)

Data signed: (hfarmer1) 26 Mar 2015 13:39:47

Generated On: 20 Jul 2016 10:56:43

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 30

Form: Lab_BU_CCLS (27)

Data signed: (hfarmer1) 26 Mar 2015 13:39:47

Generated On: 20 Jul 2016 10:56:43

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"/>
------------	--

Accession ID	P274248
--------------	---------

Actual Collection Date	2014 02 16
------------------------	------------

Actual Collection Time	06:31
------------------------	-------

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: 1002**

Folder: Day 30

Form: Lab_BU_CCLS (27)

Data signed: (hfarmer1) 26 Mar 2015 13:39:47

Generated On: 20 Jul 2016 10:56:43

Lab Test Name	BASOPHILS (%)
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	0.7
Reported Numeric Result	0.7
Reference Range low	0.0
Reference Range high	2.0
Range Units	%
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 30

Form: Lab_BU_CCLS (27)

Data signed: (hfarmer1) 26 Mar 2015 13:39:47

Generated On: 20 Jul 2016 10:56:43

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 30

Form: Lab_BU_CCLS (28)

Data signed: (hfarmer1) 26 Mar 2015 13:39:47

Generated On: 20 Jul 2016 10:56:43

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	P274248
--------------	---------

Actual Collection Date	2014 02 16
------------------------	------------

Actual Collection Time	06:31
------------------------	-------

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: 1002**

Folder: Day 30

Form: Lab_BU_CCLS (28)

Data signed: (hfarmer1) 26 Mar 2015 13:39:47

Generated On: 20 Jul 2016 10:56:43

Lab Test Name	HEMATOCRIT
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	44
Reported Numeric Result	44
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: 1002**

Folder: Day 30

Form: Lab_BU_CCLS (28)

Data signed: (hfarmer1) 26 Mar 2015 13:39:47

Generated On: 20 Jul 2016 10:56:43

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 30

Form: Lab_BU_CCLS (29)

Data signed: (hfarmer1) 26 Mar 2015 13:39:47

Generated On: 20 Jul 2016 10:56:43

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	P274248
--------------	---------

Actual Collection Date	2014 02 16
------------------------	------------

Actual Collection Time	06:31
------------------------	-------

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: 1002**

Folder: Day 30

Form: Lab_BU_CCLS (29)

Data signed: (hfarmer1) 26 Mar 2015 13:39:47

Generated On: 20 Jul 2016 10:56:43

Lab Test Name	RBC
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	5.0
Reported Numeric Result	5.0
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: 1002**

Folder: Day 30

Form: Lab_BU_CCLS (29)

Data signed: (hfarmer1) 26 Mar 2015 13:39:47

Generated On: 20 Jul 2016 10:56:43

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 30

Form: Lab_BU_CCLS (30)

Data signed: (hfarmer1) 26 Mar 2015 13:39:47

Generated On: 20 Jul 2016 10:56:43

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	P274248
--------------	---------

Actual Collection Date	2014 02 16
------------------------	------------

Actual Collection Time	06:31
------------------------	-------

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: 1002**

Folder: Day 30

Form: Lab_BU_CCLS (30)

Data signed: (hfarmer1) 26 Mar 2015 13:39:47

Generated On: 20 Jul 2016 10:56:43

Lab Test Name	MCV
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	87
Reported Numeric Result	87
Reference Range low	79
Reference Range high	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: 1002**

Folder: Day 30

Form: Lab_BU_CCLS (30)

Data signed: (hfarmer1) 26 Mar 2015 13:39:47

Generated On: 20 Jul 2016 10:56:43

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 30

Form: Lab_BU_CCLS (31)

Data signed: (hfarmer1) 26 Mar 2015 13:39:47

Generated On: 20 Jul 2016 10:56:43

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"/>
------------	--

Accession ID	P274248
--------------	---------

Actual Collection Date	2014 02 16
------------------------	------------

Actual Collection Time	06:31
------------------------	-------

Specimen Condition	<hr/>
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Battery ID	HM1604
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Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
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Lab Test ID	HMT40
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 30

Form: Lab_BU_CCLS (31)

Data signed: (hfarmer1) 26 Mar 2015 13:39:47

Generated On: 20 Jul 2016 10:56:43

Lab Test Name	HEMOGLOBIN
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	14.3
Reported Numeric Result	14.3
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: 1002**

Folder: Day 30

Form: Lab_BU_CCLS (31)

Data signed: (hfarmer1) 26 Mar 2015 13:39:47

Generated On: 20 Jul 2016 10:56:43

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 30

Form: Lab_BU_CCLS (32)

Data signed: (hfarmer1) 26 Mar 2015 13:39:47

Generated On: 20 Jul 2016 10:56:43

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	P274248
--------------	---------

Actual Collection Date	2014 02 16
------------------------	------------

Actual Collection Time	06:31
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	HM1604
------------	--------

Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
--------------	-----------------------------------

Lab Test ID	HMT7
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 30

Form: Lab_BU_CCLS (32)

Data signed: (hfarmer1) 26 Mar 2015 13:39:47

Generated On: 20 Jul 2016 10:56:43

Lab Test Name	WBC
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	6.26
Reported Numeric Result	6.26
Reference Range low	3.80
Reference Range high	10.70
Range Units	X10^3/UL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 30

Form: Lab_BU_CCLS (32)

Data signed: (hfarmer1) 26 Mar 2015 13:39:47

Generated On: 20 Jul 2016 10:56:43

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 30

Form: Lab_BU_CCLS (33)

Data signed: (hfarmer1) 26 Mar 2015 13:39:47

Generated On: 20 Jul 2016 10:56:43

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	P274248
--------------	---------

Actual Collection Date	2014 02 16
------------------------	------------

Actual Collection Time	06:31
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	HM1604
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Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
--------------	-----------------------------------

Lab Test ID	HMT71
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 30

Form: Lab_BU_CCLS (33)

Data signed: (hfarmer1) 26 Mar 2015 13:39:47


Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Day 30

Form: Lab_BU_CCLS (33)

Data signed: (hfarmer1) 26 Mar 2015 13:39:47

Generated On: 20 Jul 2016 10:56:43

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 30

Form: Lab_BU_CCLS (34)

Data signed: (hfarmer1) 26 Mar 2015 13:39:47

Generated On: 20 Jul 2016 10:56:43

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	P274248
--------------	---------

Actual Collection Date	2014 02 16
------------------------	------------

Actual Collection Time	06:31
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	HM1604
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Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
--------------	-----------------------------------

Lab Test ID	HMT8
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 30

Form: Lab_BU_CCLS (34)

Data signed: (hfarmer1) 26 Mar 2015 13:39:47

Generated On: 20 Jul 2016 10:56:43

Lab Test Name	NEUTROPHILS
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	2.35
Reported Numeric Result	2.35
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: 1002**

Folder: Day 30

Form: Lab_BU_CCLS (34)

Data signed: (hfarmer1) 26 Mar 2015 13:39:47

Generated On: 20 Jul 2016 10:56:43

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 30

Form: Lab_BU_CCLS (35)

Data signed: (hfarmer1) 26 Mar 2015 13:39:47

Generated On: 20 Jul 2016 10:56:43

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	P274248
--------------	---------

Actual Collection Date	2014 02 16
------------------------	------------

Actual Collection Time	06:31
------------------------	-------

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: 1002**

Folder: Day 30

Form: Lab_BU_CCLS (35)

Data signed: (hfarmer1) 26 Mar 2015 13:39:47

Generated On: 20 Jul 2016 10:56:43

Lab Test Name	LYMPHOCYTES
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	3.16
Reported Numeric Result	3.16
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: 1002**

Folder: Day 30

Form: Lab_BU_CCLS (35)

Data signed: (hfarmer1) 26 Mar 2015 13:39:47

Generated On: 20 Jul 2016 10:56:43

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 30

Form: Lab_BU_CCLS (36)

Data signed: (hfarmer1) 26 Mar 2015 13:39:47

Generated On: 20 Jul 2016 10:56:43

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	P274248
--------------	---------

Actual Collection Date	2014 02 16
------------------------	------------

Actual Collection Time	06:31
------------------------	-------

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: 1002**

Folder: Day 30

Form: Lab_BU_CCLS (36)

Data signed: (hfarmer1) 26 Mar 2015 13:39:47


Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Day 30

Form: Lab_BU_CCLS (36)

Data signed: (hfarmer1) 26 Mar 2015 13:39:47

Generated On: 20 Jul 2016 10:56:43

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 30

Form: Lab_BU_CCLS (37)

Data signed: (hfarmer1) 26 Mar 2015 13:39:47

Generated On: 20 Jul 2016 10:56:43

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	P274248
--------------	---------

Actual Collection Date	2014 02 16
------------------------	------------

Actual Collection Time	06:31
------------------------	-------

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: 1002**

Folder: Day 30

Form: Lab_BU_CCLS (37)

Data signed: (hfarmer1) 26 Mar 2015 13:39:47

Generated On: 20 Jul 2016 10:56:43

Lab Test Name	UR SPECIFIC GRAVITY
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	1.005
Reported Numeric Result	1.005
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: 1002**

Folder: Day 30

Form: Lab_BU_CCLS (37)

Data signed: (hfarmer1) 26 Mar 2015 13:39:47

Generated On: 20 Jul 2016 10:56:43

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 30

Form: Lab_BU_CCLS (38)

Data signed: (hfarmer1) 26 Mar 2015 13:39:47

Generated On: 20 Jul 2016 10:56:43

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	P274248
--------------	---------

Actual Collection Date	2014 02 16
------------------------	------------

Actual Collection Time	06:31
------------------------	-------

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: 1002**

Folder: Day 30

Form: Lab_BU_CCLS (38)

Data signed: (hfarmer1) 26 Mar 2015 13:39:47

Generated On: 20 Jul 2016 10:56:43

Lab Test Name	UR PH
Test ID	
Test Status	Done <input type="checkbox"/>
Reported Text Result	5.0
Reported Numeric Result	5.0
Reference Range low	5.0
Reference Range high	8.0
Range Units	
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 30

Form: Lab_BU_CCLS (38)

Data signed: (hfarmer1) 26 Mar 2015 13:39:47

Generated On: 20 Jul 2016 10:56:43

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 30

Form: Lab_BU_CCLS (39)

Data signed: (hfarmer1) 26 Mar 2015 13:39:47

Generated On: 20 Jul 2016 10:56:43

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex F

Subject Date of Birth (b) (6)

Visit Name _____

Visit Type Scheduled ☒

Accession ID P274248

Actual Collection Date 2014 02 16

Actual Collection Time 06:31

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: 1002**

Folder: Day 30

Form: Lab_BU_CCLS (39)

Data signed: (hfarmer1) 26 Mar 2015 13:39:47

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Day 30

Form: Lab_BU_CCLS (39)

Data signed: (hfarmer1) 26 Mar 2015 13:39:47

Generated On: 20 Jul 2016 10:56:43

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 30

Form: Lab_BU_CCLS (40)

Data signed: (hfarmer1) 26 Mar 2015 13:39:47

Generated On: 20 Jul 2016 10:56:43

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	P274248
--------------	---------

Actual Collection Date	2014 02 16
------------------------	------------

Actual Collection Time	06:31
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	UA1538
------------	--------

Battery Name	URINE MACRO PANEL
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Lab Test ID	UAT49
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 30

Form: Lab_BU_CCLS (40)

Data signed: (hfarmer1) 26 Mar 2015 13:39:47


Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Day 30

Form: Lab_BU_CCLS (40)

Data signed: (hfarmer1) 26 Mar 2015 13:39:47

Generated On: 20 Jul 2016 10:56:43

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 30

Form: Lab_BU_CCLS (41)

Data signed: (hfarmer1) 26 Mar 2015 13:39:47

Generated On: 20 Jul 2016 10:56:43

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	P274248
--------------	---------

Actual Collection Date	2014 02 16
------------------------	------------

Actual Collection Time	06:31
------------------------	-------

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: 1002**

Folder: Day 30

Form: Lab_BU_CCLS (41)

Data signed: (hfarmer1) 26 Mar 2015 13:39:47


Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Day 30

Form: Lab_BU_CCLS (41)

Data signed: (hfarmer1) 26 Mar 2015 13:39:47

Generated On: 20 Jul 2016 10:56:43

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 30

Form: Lab_BU_CCLS (42)

Data signed: (hfarmer1) 26 Mar 2015 13:39:47

Generated On: 20 Jul 2016 10:56:43

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	P274248
--------------	---------

Actual Collection Date	2014 02 16
------------------------	------------

Actual Collection Time	06:31
------------------------	-------

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: 1002**

Folder: Day 30

Form: Lab_BU_CCLS (42)

Data signed: (hfarmer1) 26 Mar 2015 13:39:47


Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Day 30

Form: Lab_BU_CCLS (42)

Data signed: (hfarmer1) 26 Mar 2015 13:39:47

Generated On: 20 Jul 2016 10:56:43

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 30

Form: Lab_BU_COHB (1)

Data signed: (hfarmer1) 26 Mar 2015 13:40:10

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05115150000029
----------------	----------------

Analyte	CARBOXYHEMOGLOBIN
---------	-------------------

Sample type	BLOOD
-------------	-------

Result	10.0
--------	------

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-FEB-15
--------------------	-------------

Timepoint-minutes	
-------------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 30

Form: Lab_BU_COHB (1)

Data signed: (hfarmer1) 26 Mar 2015 13:40:10

Generated On: 20 Jul 2016 10:56:43

Start Day (24 hour urine only) _____

End Day (24 hour Urine Only) _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 30

Form: Cough Assessment (Paper)

Data signed: (hfarmer1) 26 Mar 2015 13:39:44

Generated On: 20 Jul 2016 10:56:43

Was paper questionnaire used? Yes ☒

Reason not done _____

Date of assessment 16 FEB 2014
DD/MMM/YYYY DD/MMM/YYYY

Time of assessment 06:59
hour:min 24-hour clock

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 24
How much is your cough bothering you?

Second Question: Cough Intensity Scale: Mild ☒
How intense is your cough?

Third Question: Cough Frequency Scale: Sometimes ☒
How frequently do you normally have to cough each
day?

Fourth Question: Sputum Production No sputum ☒
To what extent do you produce sputum when coughing?

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 30

Form: Cough Assessment (Paper)

Data signed: (hfarmer1) 26 Mar 2015 13:39:44

Generated On: 20 Jul 2016 10:56:43

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: 1002

Folder: Day 30

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS) (Paper)

Data signed: (hfarmer1) 26 Mar 2015 13:39:45

Generated On: 20 Jul 2016 10:56:43

Was paper questionnaire used?

Yes ☒

Reason not done

Date of assessment
DD/MMM/YYYY

16 FEB 2014
DD/MMM/YYYY

Time of assessment

07:01
hour:min 24-hour clock

Please indicate for each of the items below, how you have been feeling over the past 24 hours

Result

1. Angry, irritable, frustrated

None

2. Anxious, tense

None

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1002

Folder: Day 30

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS) (Paper) (3)

Data signed: (hfarmer1) 26 Mar 2015 13:39:45

Generated On: 20 Jul 2016 10:56:43

	Result
3. Depressed Mood, sad	None
4. Desire or craving to smoke	Mild
5. Difficulty concentrating	None
6. Increased appetite, hungry, weight gain	Mild
7. Insomnia, sleep problems, awakening at night	None
8. Restless	None
9. Impatient	None

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1002

Folder: Day 30

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS) (Paper) (10)

Data signed: (hfarmer1) 26 Mar 2015 13:39:45

Generated On: 20 Jul 2016 10:56:43

	Result
10. Constipation	None
11. Dizziness	None
12. Coughing	Slight
13. Dreaming or nightmares	None
14. Nausea	None
15. Sore throat	None

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 30

**Form: Prochaska "Stage of Change" Questionnaire: Intention to Quit
Smoking**

Data signed: (hfarmer1) 26 Mar 2015 13:39:46

Generated On: 20 Jul 2016 10:56:43

Was paper questionnaire used? Yes ☒

Reason not done _____

Type PROCHASKA STAGE OF
CHANGE QUESTIONNAIRE:
INTENTION TO QUIT
SMOKING

Date of assessment 15 FEB 2014
DD/MMM/YYYY

Time of assessment 20:06
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: 1002**

Folder: Day 30

Form: Human Smoking Topography Questionnaire

Data signed: (hfarmer1) 26 Mar 2015 13:39:46

Generated On: 20 Jul 2016 10:56:43

Type	HUMAN SMOKING TOPOGRAPHY QUESTIONNAIRE
------	--

Was paper questionnaire used?	Yes <input type="radio"/>
-------------------------------	---------------------------

Reason not done	<hr/>
-----------------	-------

Date of assessment	15 FEB 2014 DD/MMM/YYYY
--------------------	----------------------------

Time of assessment	20:04 hour:min 24-hour clock
--------------------	---------------------------------

How do you agree with the following sentences/affirmations :

1. The smoking of the conventional cigarettes/products is different with the device.	Neither agree nor disagree <input type="radio"/>
--	--

If you agree or strongly agree, please describe :	<hr/>
---	-------

2. You enjoy smoking with the device as much as without it.	Neither agree nor disagree <input type="radio"/>
---	--

If you disagree or strongly disagree, please describe :	<hr/>
---	-------

3. The taste of the conventional cigarettes/products is different with the device.	Strongly disagree <input type="radio"/>
--	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 30

Form: Human Smoking Topography Questionnaire

Data signed: (hfarmer1) 26 Mar 2015 13:39:46

Generated On: 20 Jul 2016 10:56:43

If you agree or strongly agree, please describe : _____

4. The device is easy to use.

Neither agree nor disagree ☒

If you disagree or strongly disagree, please describe : _____

5. Your smoking is disturbed by the device.

Neither agree nor disagree ☒

If you agree or strongly agree, please describe : _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 30

Form: Questionnaire on smoking urges (QSU) (Paper)

Data signed: (hfarmer1) 26 Mar 2015 13:39:46

Generated On: 20 Jul 2016 10:56:43

Type	QUESTIONNAIRE ON SMOKING URGES
------	-----------------------------------

Was paper questionnaire used?	Yes <input type="radio"/>
-------------------------------	---------------------------

Reason not done	<hr/>
-----------------	-------

Date of assessment	15 FEB 2014
--------------------	-------------

DD/MMM/YYYY

Time of assessment	20:06
--------------------	-------

hour:min 24-hour clock

1. I have a desire for a cigarette right now	Somewhat agree <input type="radio"/>
--	--------------------------------------

2. Nothing would be better than smoking a cigarette right now	Do not agree or disagree <input type="radio"/>
--	--

3. If it were possible I would probably smoke now	Do not agree or disagree <input type="radio"/>
---	--

4. I could control things better right now if I could smoke	Somewhat disagree <input type="radio"/>
---	---

5. All I want right now is a cigarette	Somewhat disagree <input type="radio"/>
--	---

6. I have an urge for a cigarette	Somewhat disagree <input type="radio"/>
-----------------------------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 30

Form: Questionnaire on smoking urges (QSU) (Paper)

Data signed: (hfarmer1) 26 Mar 2015 13:39:46

Generated On: 20 Jul 2016 10:56:43

7. A cigarette would taste good now Somewhat disagree ☐

8. I would do almost anything for a cigarette now Disagree ☐

9. Smoking would make me less depressed Somewhat disagree ☐

10. I am going to smoke as soon as possible Somewhat disagree ☐

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 30

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper)

Data signed: (hfarmer1) 26 Mar 2015 13:39:44

Generated On: 20 Jul 2016 10:56:43

Was paper questionnaire used?

Yes ☒

Reason not done

Date of assessment

15 FEB 2014
DD/MMM/YYYY

DD/MMM/YYYY

Time of assessment

20:02
hour:min 24-hour clock

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 30

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper) (1)

Data signed: (hfarmer1) 26 Mar 2015 13:39:44

Generated On: 20 Jul 2016 10:56:43

Was paper questionnaire used? Yes ☒

Reason not done _____

Date of assessment 15 FEB 2014
DD/MMM/YYYY

Time of assessment 20:02
hour:min 24-hour clock

If you have smoked since you last completed this questionnaire,
please mark what best represents how smoking made you feel

Was smoking satisfying? ☒

Response Quite a lot ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 30

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper) (2)

Data signed: (hfarmer1) 26 Mar 2015 13:39:44

Generated On: 20 Jul 2016 10:56:43

Was paper questionnaire used? Yes ☒

Reason not done _____

Date of assessment 15 FEB 2014
DD/MMM/YYYY

Time of assessment 20:02
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 Quite a lot ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 30

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper) (3)

Data signed: (hfarmer1) 26 Mar 2015 13:39:44

Generated On: 20 Jul 2016 10:56:43

Was paper questionnaire used? Yes ☒

Reason not done _____

Date of assessment 15 FEB 2014
DD/MMM/YYYY

Time of assessment 20:02
hour:min 24-hour clock

If you have smoked since you last completed this questionnaire,
please mark what best represents how smoking made you feel

Did you enjoy the sensation in your throat and chest? ☒

Response Moderately ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 30

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper) (4)

Data signed: (hfarmer1) 26 Mar 2015 13:39:44

Generated On: 20 Jul 2016 10:56:43

Was paper questionnaire used? Yes ☐

Reason not done _____

Date of assessment 15 FEB 2014
DD/MMM/YYYY

Time of assessment 20:02
hour:min 24-hour clock

If you have smoked since you last completed this questionnaire,
please mark what best represents how smoking made you feel Did smoking calm you
down? ☐

Response A lot ☐

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 30

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper) (5)

Data signed: (hfarmer1) 26 Mar 2015 13:39:44

Generated On: 20 Jul 2016 10:56:43

Was paper questionnaire used? Yes ☒

Reason not done _____

Date of assessment 15 FEB 2014
DD/MMM/YYYY

Time of assessment 20:02
hour:min 24-hour clock

If you have smoked since you last completed this questionnaire,
please mark what best represents how smoking made you feel

Did smoking make you feel more awake? ☒

Response Moderately ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 30

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper) (6)

Data signed: (hfarmer1) 26 Mar 2015 13:39:44

Generated On: 20 Jul 2016 10:56:43

Was paper questionnaire used? Yes ☐

Reason not done _____

Date of assessment 15 FEB 2014
DD/MMM/YYYY

Time of assessment 20:02
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 A lot ☐

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 30

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper) (7)

Data signed: (hfarmer1) 26 Mar 2015 13:39:44

Generated On: 20 Jul 2016 10:56:43

Was paper questionnaire used? Yes ☒

Reason not done _____

Date of assessment 15 FEB 2014
DD/MMM/YYYY

Time of assessment 20:02
hour:min 24-hour clock

If you have smoked since you last completed this questionnaire,
please mark what best represents how smoking made you feel

Did smoking help you concentrate? ☒

Response Moderately ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 30

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper) (8)

Data signed: (hfarmer1) 26 Mar 2015 13:39:44

Generated On: 20 Jul 2016 10:56:43

Was paper questionnaire used? Yes ☐

Reason not done _____

Date of assessment 15 FEB 2014
DD/MMM/YYYY

Time of assessment 20:02
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: 1002**

Folder: Day 30

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper) (9)

Data signed: (hfarmer1) 26 Mar 2015 13:39:44

Generated On: 20 Jul 2016 10:56:43

Was paper questionnaire used? Yes ☐

Reason not done _____

Date of assessment 15 FEB 2014
DD/MMM/YYYY

Time of assessment 20:02
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: 1002**

Folder: Day 30

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper) (10)

Data signed: (hfarmer1) 26 Mar 2015 13:39:44

Generated On: 20 Jul 2016 10:56:43

Was paper questionnaire used? Yes ☐

Reason not done _____

Date of assessment 15 FEB 2014
DD/MMM/YYYY

Time of assessment 20:02
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: 1002**

Folder: Day 30

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper) (11)

Data signed: (hfarmer1) 26 Mar 2015 13:39:44

Generated On: 20 Jul 2016 10:56:43

Was paper questionnaire used? Yes ☒

Reason not done _____

Date of assessment 15 FEB 2014
DD/MMM/YYYY

Time of assessment 20:02
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 Quite a lot ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 30

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper) (12)

Data signed: (hfarmer1) 26 Mar 2015 13:39:44

Generated On: 20 Jul 2016 10:56:43

Was paper questionnaire used? Yes ☒

Reason not done _____

Date of assessment 15 FEB 2014
DD/MMM/YYYY

Time of assessment 20:02
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 Quite a lot ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 30

Form: Risk Markers(CCLS) (1)

Data signed: (hfarmer1) 26 Mar 2015 13:40:07

Generated On: 20 Jul 2016 10:56:43

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	1002
----------------------	------

Subject Sex	F
-------------	---

Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	DAY30
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	P274248
--------------	---------

Actual Collection Date	2014 02 16
------------------------	------------

Actual Collection Time	06:31
------------------------	-------

Specimen Condition	
--------------------	--

Battery ID	RC6871
------------	--------

Battery Name	HDL
--------------	-----

Lab Test ID	RCT1684
-------------	---------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 30

Form: Risk Markers(CCLS) (1)

Data signed: (hfarmer1) 26 Mar 2015 13:40:07


Generated On: 20 Jul 2016 10:56:43

Lab Test Name

DIRECT HDL-C 3RD
GENERATION

Test ID

Test Status

Done 

Reported Text Result

52

Reported Numeric Result

52

Reference Range low

33

Reference Range high

79

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: 1002**

Folder: Day 30

Form: Risk Markers(CCLS) (1)

Data signed: (hfarmer1) 26 Mar 2015 13:40:07

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Day 30

Form: Risk Markers(CCLS) (2)

Data signed: (hfarmer1) 26 Mar 2015 13:40:07

Generated On: 20 Jul 2016 10:56:43

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	1002
----------------------	------

Subject Sex	F
-------------	---

Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	DAY30
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	P274248
--------------	---------

Actual Collection Date	2014 02 16
------------------------	------------

Actual Collection Time	06:31
------------------------	-------

Specimen Condition	
--------------------	--

Battery ID	SC3249
------------	--------

Battery Name	HS-CRP
--------------	--------

Lab Test ID	SCT1528
-------------	---------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 30

Form: Risk Markers(CCLS) (2)

Data signed: (hfarmer1) 26 Mar 2015 13:40:07


Generated On: 20 Jul 2016 10:56:43

Lab Test Name

C-REACTIVE PROTEIN (N
HS)-QT

Test ID

Test Status

Done 

Reported Text Result

0.365

Reported Numeric Result

0.365

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: 1002**

Folder: Day 30

Form: Risk Markers(CCLS) (2)

Data signed: (hfarmer1) 26 Mar 2015 13:40:07

Generated On: 20 Jul 2016 10:56:43

SI Text Result

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: 1002**

Folder: Day 30

Form: Risk Markers(CCLS) (3)

Data signed: (hfarmer1) 26 Mar 2015 13:40:07

Generated On: 20 Jul 2016 10:56:43

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	1002
----------------------	------

Subject Sex	F
-------------	---

Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	DAY30
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	P274248
--------------	---------

Actual Collection Date	2014 02 16
------------------------	------------

Actual Collection Time	06:31
------------------------	-------

Specimen Condition	
--------------------	--

Battery ID	CG267
------------	-------

Battery Name	FIBRINOGEN
--------------	------------

Lab Test ID	CGT285
-------------	--------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 30

Form: Risk Markers(CCLS) (3)

Data signed: (hfarmer1) 26 Mar 2015 13:40:07

Generated On: 20 Jul 2016 10:56:43

Lab Test Name	FIBRINOGEN
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	259
Reported Numeric Result	259
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: 1002**

Folder: Day 30

Form: Risk Markers(CCLS) (3)

Data signed: (hfarmer1) 26 Mar 2015 13:40:07

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Day 30

Form: Risk Markers(CCLS) (4)

Data signed: (hfarmer1) 26 Mar 2015 13:40:07

Generated On: 20 Jul 2016 10:56:43

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	1002
----------------------	------

Subject Sex	F
-------------	---

Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	DAY30
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	P274248
--------------	---------

Actual Collection Date	2014 02 16
------------------------	------------

Actual Collection Time	06:31
------------------------	-------

Specimen Condition	
--------------------	--

Battery ID	CN236
------------	-------

Battery Name	HOMOCYSTEINE
--------------	--------------

Lab Test ID	CNT145
-------------	--------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 30

Form: Risk Markers(CCLS) (4)

Data signed: (hfarmer1) 26 Mar 2015 13:40:07

Generated On: 20 Jul 2016 10:56:43

Lab Test Name	HOMOCYSTEINE, EDTAPL
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	8.19
Reported Numeric Result	8.19
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: 1002**

Folder: Day 30

Form: Risk Markers(CCLS) (4)

Data signed: (hfarmer1) 26 Mar 2015 13:40:07

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Day 30

Form: Risk Markers(CCLS) (5)

Data signed: (hfarmer1) 26 Mar 2015 13:40:07

Generated On: 20 Jul 2016 10:56:43

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	1002
----------------------	------

Subject Sex	F
-------------	---

Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	DAY30
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	P274248
--------------	---------

Actual Collection Date	2014 02 16
------------------------	------------

Actual Collection Time	06:31
------------------------	-------

Specimen Condition	
--------------------	--

Battery ID	IM2293
------------	--------

Battery Name	SICAM-1
--------------	---------

Lab Test ID	IMT1768
-------------	---------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 30

Form: Risk Markers(CCLS) (5)

Data signed: (hfarmer1) 26 Mar 2015 13:40:07

Generated On: 20 Jul 2016 10:56:43

Lab Test Name	SICAM-1-RUO
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	362.2
Reported Numeric Result	362.2
Reference Range low	98.8
Reference Range high	320.0
Range Units	NG/ML
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 30

Form: Risk Markers(CCLS) (5)

Data signed: (hfarmer1) 26 Mar 2015 13:40:07

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Day 30

Form: Risk Markers(CCLS) (6)

Data signed: (hfarmer1) 26 Mar 2015 13:40:07

Generated On: 20 Jul 2016 10:56:43

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	1002
----------------------	------

Subject Sex	F
-------------	---

Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	DAY30
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	P274248
--------------	---------

Actual Collection Date	2014 02 16
------------------------	------------

Actual Collection Time	06:31
------------------------	-------

Specimen Condition	
--------------------	--

Battery ID	RC9267
------------	--------

Battery Name	LDL
--------------	-----

Lab Test ID	RCT2394
-------------	---------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 30

Form: Risk Markers(CCLS) (6)

Data signed: (hfarmer1) 26 Mar 2015 13:40:07

Generated On: 20 Jul 2016 10:56:43

Lab Test Name	DIRECT LDL-C 2ND GEN (-70)
---------------	----------------------------

Test ID	<hr/>
---------	-------

Test Status	Done <input checked="" type="radio"/>
-------------	---------------------------------------

Reported Text Result	98
----------------------	----

Reported Numeric Result	98
-------------------------	----

Reference Range low	60
---------------------	----

Reference Range high	148
----------------------	-----

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: 1002**

Folder: Day 30

Form: Risk Markers(CCLS) (6)

Data signed: (hfarmer1) 26 Mar 2015 13:40:07

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Day 30

Form: Biomarker-Urine (CEMA, HPMA, HBMA)

Data signed: (hfarmer1) 26 Mar 2015 13:40:11

Generated On: 20 Jul 2016 10:56:43

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 30

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (1)

Data signed: (hfarmer1) 26 Mar 2015 13:40:11

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05112450000020
----------------	----------------

Analyte	HPMA
---------	------

Sample type	URINE
-------------	-------

Result	1050
--------	------

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-FEB-15
--------------------	-------------

Timepoint-minutes	
-------------------	--

Urine Start Day	30
-----------------	----

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 30

Form: Biomarker-Urine (CEMA, HPMa, HBMA) (1)

Data signed: (hfarmer1) 26 Mar 2015 13:40:11

Generated On: 20 Jul 2016 10:56:43

Urine End Day

31

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 30

Form: Biomarker-Urine (CEMA, HPMa, HBMA) (2)

Data signed: (hfarmer1) 26 Mar 2015 13:40:11

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05112450000020
----------------	----------------

Analyte	CEMA
---------	------

Sample type	URINE
-------------	-------

Result	312
--------	-----

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-FEB-15
--------------------	-------------

Timepoint-minutes	
-------------------	--

Urine Start Day	30
-----------------	----

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 30

Form: Biomarker-Urine (CEMA, HPMa, HBMA) (2)

Data signed: (hfarmer1) 26 Mar 2015 13:40:11

Generated On: 20 Jul 2016 10:56:43

Urine End Day

31

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 30

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (3)

Data signed: (hfarmer1) 26 Mar 2015 13:40:11

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05112450000020
----------------	----------------

Analyte	HBMA
---------	------

Sample type	URINE
-------------	-------

Result	670
--------	-----

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-FEB-15
--------------------	-------------

Timepoint-minutes	
-------------------	--

Urine Start Day	30
-----------------	----

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 30

Form: Biomarker-Urine (CEMA, HPMa, HBMA) (3)

Data signed: (hfarmer1) 26 Mar 2015 13:40:11

Generated On: 20 Jul 2016 10:56:43

Urine End Day

31

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 30

Form: Biomarker-Urine (NNN, NNAL)

Data signed: (hfarmer1) 26 Mar 2015 13:40:10

Generated On: 20 Jul 2016 10:56:43

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 30

Form: Biomarker-Urine (NNN, NNAL) (1)

Data signed: (hfarmer1) 26 Mar 2015 13:40:10

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05112460000020
----------------	----------------

Analyte	NNAL
---------	------

Sample type	URINE
-------------	-------

Result	1280
--------	------

Result Unit	PG/ML
-------------	-------

Lab Status	OK
------------	----

Sample comment	
----------------	--

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	30
--------------	----

Celerion Study Number	AA99128-04
-----------------------	------------

Date of Collection	2014-FEB-15
--------------------	-------------

Timepoint-minutes	
-------------------	--

Urine Start Day	30
-----------------	----

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 30

Form: Biomarker-Urine (NNN, NNAL) (1)

Data signed: (hfarmer1) 26 Mar 2015 13:40:10

Generated On: 20 Jul 2016 10:56:43

Urine End Day

31

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 30

Form: Biomarker-Urine (NNN, NNAL) (2)

Data signed: (hfarmer1) 26 Mar 2015 13:40:10

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05112460000020
----------------	----------------

Analyte	NNN
---------	-----

Sample type	URINE
-------------	-------

Result	31.6
--------	------

Result Unit	PG/ML
-------------	-------

Lab Status	OK
------------	----

Sample comment	
----------------	--

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	30
--------------	----

Celerion Study Number	AA99128-04
-----------------------	------------

Date of Collection	2014-FEB-15
--------------------	-------------

Timepoint-minutes	
-------------------	--

Urine Start Day	30
-----------------	----

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 30

Form: Biomarker-Urine (NNN, NNAL) (2)

Data signed: (hfarmer1) 26 Mar 2015 13:40:10

Generated On: 20 Jul 2016 10:56:43

Urine End Day

31

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 30

Form: Biomarker-Urine (HEMA)

Data signed: (hfarmer1) 26 Mar 2015 13:40:11

Generated On: 20 Jul 2016 10:56:43

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 30

Form: Biomarker-Urine (HEMA) (1)

Data signed: (hfarmer1) 26 Mar 2015 13:40:11

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05112470000020
----------------	----------------

Analyte	HEMA
---------	------

Sample type	URINE
-------------	-------

Result	23.1
--------	------

Result Unit	NG/ML
-------------	-------

Lab Status	OK
------------	----

Sample comment	
----------------	--

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	30
--------------	----

Celerion Study Number	AA99128-05
-----------------------	------------

Date of Collection	2014-FEB-15
--------------------	-------------

Timepoint-minutes	
-------------------	--

Urine Start Day	30
-----------------	----

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 30

Form: Biomarker-Urine (HEMA) (1)

Data signed: (hfarmer1) 26 Mar 2015 13:40:11

Generated On: 20 Jul 2016 10:56:43

Urine End Day

31

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 30

Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)

Data signed: (hfarmer1) 26 Mar 2015 13:40:12

Generated On: 20 Jul 2016 10:56:43

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 30

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(1)**

Data signed: (hfarmer1) 26 Mar 2015 13:40:12

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05112480000020
Analyte	COT
Sample type	URINE
Result	1610
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-FEB-15
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 30

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(1)**

Data signed: (hfarmer1) 26 Mar 2015 13:40:12

Generated On: 20 Jul 2016 10:56:43

Urine Start Day	30
<hr/>	
Urine End Day	31
<hr/>	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 30

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(2)**

Data signed: (hfarmer1) 26 Mar 2015 13:40:12

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05112480000020
Analyte	COT-GLUC
Sample type	URINE
Result	19600
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-FEB-15
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 30

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(2)**

Data signed: (hfarmer1) 26 Mar 2015 13:40:12

Generated On: 20 Jul 2016 10:56:43

Urine Start Day	30
<hr/>	
Urine End Day	31
<hr/>	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 30

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(3)**

Data signed: (hfarmer1) 26 Mar 2015 13:40:12

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05112480000020
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Analyte	NIC
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Sample type	URINE
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Result	1760
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Result Unit	NG/ML
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Lab Status	OK
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Sample comment	
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Detection method	LC-MS/MS
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Planned time point (Hour)	0
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Day of Visit	30
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Celerion Study Number	AA99128-06
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Date of Collection	2014-FEB-15
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Timepoint-minutes	
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 30

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(3)**

Data signed: (hfarmer1) 26 Mar 2015 13:40:12

Generated On: 20 Jul 2016 10:56:43

Urine Start Day	30
<hr/>	
Urine End Day	31
<hr/>	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 30

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(4)**

Data signed: (hfarmer1) 26 Mar 2015 13:40:12

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05112480000020
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Analyte	NIC-GLUC
---------	----------

Sample type	URINE
-------------	-------

Result	2240
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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	30
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Celerion Study Number	AA99128-06
-----------------------	------------

Date of Collection	2014-FEB-15
--------------------	-------------

Timepoint-minutes	
-------------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 30

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(4)**

Data signed: (hfarmer1) 26 Mar 2015 13:40:12

Generated On: 20 Jul 2016 10:56:43

Urine Start Day	30
<hr/>	
Urine End Day	31
<hr/>	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 30

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(5)**

Data signed: (hfarmer1) 26 Mar 2015 13:40:12

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05112480000020
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Analyte	THCOT
---------	-------

Sample type	URINE
-------------	-------

Result	4920
--------	------

Result Unit	NG/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	AA99128-06
-----------------------	------------

Date of Collection	2014-FEB-15
--------------------	-------------

Timepoint-minutes	
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 30

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(5)**

Data signed: (hfarmer1) 26 Mar 2015 13:40:12

Generated On: 20 Jul 2016 10:56:43

Urine Start Day	30
<hr/>	
Urine End Day	31
<hr/>	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 30

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(6)**

Data signed: (hfarmer1) 26 Mar 2015 13:40:12

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05112480000020
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Analyte	THCOT-GLUC
---------	------------

Sample type	URINE
-------------	-------

Result	4900
--------	------

Result Unit	NG/ML
-------------	-------

Lab Status	OK
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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-FEB-15
--------------------	-------------

Timepoint-minutes	
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 30

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(6)**

Data signed: (hfarmer1) 26 Mar 2015 13:40:12

Generated On: 20 Jul 2016 10:56:43

Urine Start Day	30
<hr/>	
Urine End Day	31
<hr/>	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 30

Form: Biomarker-Urine (3-OH BaP)

Data signed: (hfarmer1) 26 Mar 2015 13:40:12

Generated On: 20 Jul 2016 10:56:43

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 30

Form: Biomarker-Urine (3-OH BaP) (1)

Data signed: (hfarmer1) 26 Mar 2015 13:40:12

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05112490000020
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Analyte	3-OH BAP
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Sample type	URINE
-------------	-------

Result	172
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Result Unit	FG/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	AA99128-07
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Date of Collection	2014-FEB-15
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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: 1002**

Folder: Day 30

Form: Biomarker-Urine (3-OH BaP) (1)

Data signed: (hfarmer1) 26 Mar 2015 13:40:12

Generated On: 20 Jul 2016 10:56:43

Urine End Day

31

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 30

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP)

Data signed: (hfarmer1) 26 Mar 2015 13:40:12

Generated On: 20 Jul 2016 10:56:43

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 30

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (1)

Data signed: (hfarmer1) 26 Mar 2015 13:40:12

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05112510000020
Analyte	1-NA
Sample type	URINE
Result	121
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-FEB-15
Timepoint-minutes	
Urine Start Day	30

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 30

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (1)

Data signed: (hfarmer1) 26 Mar 2015 13:40:12

Generated On: 20 Jul 2016 10:56:43

Urine End Day

31

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 30

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (2)

Data signed: (hfarmer1) 26 Mar 2015 13:40:12

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05112510000020
Analyte	2-NA
Sample type	URINE
Result	43.1
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-FEB-15
Timepoint-minutes	
Urine Start Day	30

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 30

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (2)

Data signed: (hfarmer1) 26 Mar 2015 13:40:12

Generated On: 20 Jul 2016 10:56:43

Urine End Day

31

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 30

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (3)

Data signed: (hfarmer1) 26 Mar 2015 13:40:12

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05112510000020
Analyte	4-ABP
Sample type	URINE
Result	25.4
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-FEB-15
Timepoint-minutes	
Urine Start Day	30

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 30

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (3)

Data signed: (hfarmer1) 26 Mar 2015 13:40:12

Generated On: 20 Jul 2016 10:56:43

Urine End Day

31

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 30

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (4)

Data signed: (hfarmer1) 26 Mar 2015 13:40:12

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05112510000020
Analyte	O-TOL
Sample type	URINE
Result	186
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-FEB-15
Timepoint-minutes	
Urine Start Day	30

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 30

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (4)

Data signed: (hfarmer1) 26 Mar 2015 13:40:12

Generated On: 20 Jul 2016 10:56:43

Urine End Day

31

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 30

Form: Biomarker-Urine (11-dTXb2)

Data signed: (hfarmer1) 26 Mar 2015 13:40:11

Generated On: 20 Jul 2016 10:56:43

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 30

Form: Biomarker-Urine (11-dTXb2) (1)

Data signed: (hfarmer1) 26 Mar 2015 13:40:11

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05112530000012
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Analyte	11-DTXB2
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Sample type	URINE
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Result	839
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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	AA99128-11
-----------------------	------------

Date of Collection	2014-FEB-15
--------------------	-------------

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: 1002**

Folder: Day 30

Form: Biomarker-Urine (11-dTXb2) (1)

Data signed: (hfarmer1) 26 Mar 2015 13:40:11

Generated On: 20 Jul 2016 10:56:43

Urine End Day

31

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 30

Form: Biomarker-Urine (iPF2a-III)

Data signed: (hfarmer1) 26 Mar 2015 13:40:11

Generated On: 20 Jul 2016 10:56:43

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 30

Form: Biomarker-Urine (iPF2a-III) (1)

Data signed: (hfarmer1) 26 Mar 2015 13:40:11

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05112540000012
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Analyte	IPF2A-III
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Sample type	URINE
-------------	-------

Result	317
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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
--------------	----

Celerion Study Number	AA99128-12
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Date of Collection	2014-FEB-15
--------------------	-------------

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: 1002**

Folder: Day 30

Form: Biomarker-Urine (iPF2a-III) (1)

Data signed: (hfarmer1) 26 Mar 2015 13:40:11

Generated On: 20 Jul 2016 10:56:43

Urine End Day

31

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 30

Form: Biomarker-Urine (1-OHP)

Data signed: (hfarmer1) 26 Mar 2015 13:40:12

Generated On: 20 Jul 2016 10:56:43

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 30

Form: Biomarker-Urine (1-OHP) (1)

Data signed: (hfarmer1) 26 Mar 2015 13:40:12

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05115190001109
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Analyte	1-OHP
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Sample type	URINE
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Result	184
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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
------------------	----------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	30
--------------	----

Celerion Study Number	AA99598-03
-----------------------	------------

Date of Collection	2014-FEB-15
--------------------	-------------

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: 1002**

Folder: Day 30

Form: Biomarker-Urine (1-OHP) (1)

Data signed: (hfarmer1) 26 Mar 2015 13:40:12

Generated On: 20 Jul 2016 10:56:43

Urine End Day

31

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 30

Form: Biomarker-Urine (SPMA, SBMA)

Data signed: (hfarmer1) 26 Mar 2015 13:40:11

Generated On: 20 Jul 2016 10:56:43

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 30

Form: Biomarker-Urine (SPMA, SBMA) (1)

Data signed: (hfarmer1) 26 Mar 2015 13:40:11

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05115170001776
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Analyte	SBMA
---------	------

Sample type	URINE
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Result	9.01
--------	------

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-FEB-15
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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: 1002**

Folder: Day 30

Form: Biomarker-Urine (SPMA, SBMA) (1)

Data signed: (hfarmer1) 26 Mar 2015 13:40:11

Generated On: 20 Jul 2016 10:56:43

Urine End Day

31

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 30

Form: Biomarker-Urine (SPMA, SBMA) (2)

Data signed: (hfarmer1) 26 Mar 2015 13:40:11

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05115170001776
----------------	----------------

Analyte	SPMA
---------	------

Sample type	URINE
-------------	-------

Result	6.12
--------	------

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-FEB-15
--------------------	-------------

Timepoint-minutes	
-------------------	--

Urine Start Day	30
-----------------	----

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 30

Form: Biomarker-Urine (SPMA, SBMA) (2)

Data signed: (hfarmer1) 26 Mar 2015 13:40:11

Generated On: 20 Jul 2016 10:56:43

Urine End Day

31

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 30

Form: Biomarker-Urine (MHBMA)

Data signed: (hfarmer1) 26 Mar 2015 13:40:11

Generated On: 20 Jul 2016 10:56:43

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 30

Form: Biomarker-Urine (MHBMA) (1)

Data signed: (hfarmer1) 26 Mar 2015 13:40:11

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05115180000020
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Analyte	MHBMA
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Sample type	URINE
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Result	3.39
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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	30
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Celerion Study Number	AA99598-02
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Date of Collection	2014-FEB-15
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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: 1002**

Folder: Day 30

Form: Biomarker-Urine (MHBMA) (1)

Data signed: (hfarmer1) 26 Mar 2015 13:40:11

Generated On: 20 Jul 2016 10:56:43

Urine End Day

31

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 30

Form: Biomarker-Urine (Creatinine)

Data signed: (hfarmer1) 26 Mar 2015 13:40:12

Generated On: 20 Jul 2016 10:56:43

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 30

Form: Biomarker-Urine (Creatinine) (1)

Data signed: (hfarmer1) 26 Mar 2015 13:40:12

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05115160000020
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Analyte	CREATININE
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Sample type	URINE
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Result	120
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Result Unit	MG/DL
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Lab Status	OK
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Sample comment	
----------------	--

Detection method	SPECTROPHOTOMETRIC
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Planned time point (Hour)	0
---------------------------	---

Day of Visit	30
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Celerion Study Number	AA99128-14
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Date of Collection	2014-FEB-15
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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: 1002**

Folder: Day 30

Form: Biomarker-Urine (Creatinine) (1)

Data signed: (hfarmer1) 26 Mar 2015 13:40:12

Generated On: 20 Jul 2016 10:56:43

Urine End Day

31

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 30

Form: Biomarker-Plasma (Nic, Cot, tHCot)

Data signed: (hfarmer1) 26 Mar 2015 13:40:11

Generated On: 20 Jul 2016 10:56:43

Sample type

PLASMA

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 30

Form: Biomarker-Plasma (Nic, Cot, tHCot) (1)

Data signed: (hfarmer1) 26 Mar 2015 13:40:11

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05112430000036
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Analyte	COT
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Sample type	PLASMA
-------------	--------

Result	284
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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	30
--------------	----

Celerion Study Number	AA99128-01
-----------------------	------------

Date of Collection	2014-FEB-15
--------------------	-------------

Timepoint-minutes	0
-------------------	---

Urine Start Day	
-----------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 30

Form: Biomarker-Plasma (Nic, Cot, tHCot) (1)

Data signed: (hfarmer1) 26 Mar 2015 13:40:11

Generated On: 20 Jul 2016 10:56:43

Urine End Day

30

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 30

Form: Biomarker-Plasma (Nic, Cot, tHCot) (2)

Data signed: (hfarmer1) 26 Mar 2015 13:40:11

Generated On: 20 Jul 2016 10:56:43

Sample Barcode	05112430000036
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Analyte	NIC
---------	-----

Sample type	PLASMA
-------------	--------

Result	14.3
--------	------

Result Unit	NG/ML
-------------	-------

Lab Status	OK
------------	----

Sample comment	
----------------	--

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	30
--------------	----

Celerion Study Number	AA99128-01
-----------------------	------------

Date of Collection	2014-FEB-15
--------------------	-------------

Timepoint-minutes	0
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Urine Start Day	
-----------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Day 30

Form: Biomarker-Plasma (Nic, Cot, tHCot) (2)

Data signed: (hfarmer1) 26 Mar 2015 13:40:11

Generated On: 20 Jul 2016 10:56:43

Urine End Day

30

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Product Use

Form: Product administration-mCC

Data signed: (hcoleman1) 18 Jun 2015 19:27:32

Generated On: 20 Jul 2016 10:56:43

At Day 0, Day 1 and Day 4, complete all SODIM related 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: 1002**

Folder: Product Use

Form: Product administration-mCC (1)

Data signed: (hcoleman1) 18 Jun 2015 19:27:32

Generated On: 20 Jul 2016 10:56:43

Date of product use DD/MMM/YYYY	15 JAN 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	06:37
----------------------	-------

Time of butt return	06:48
---------------------	-------

CC with SODIM?	True
----------------	------

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: 1002

Folder: Product Use

Form: Product administration-mCC (1)

Data signed: (hcoleman1) 18 Jun 2015 19:27:32

Generated On: 20 Jul 2016 10:56:43

At Day 0, Day 1 and Day 4, complete all SODIM related 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: 1002**

Folder: Product Use

Form: Product administration-mCC (2)

Data signed: (hcoleman1) 18 Jun 2015 19:27:32

Generated On: 20 Jul 2016 10:56:43

Date of product use DD/MMM/YYYY	15 JAN 2014
------------------------------------	-------------

Visit	Day -1 <input checked="" type="radio"/>
-------	---

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	07:12
----------------------	-------

Time of butt return	07:21
---------------------	-------

CC with SODIM?	True
----------------	------

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: 1002

Folder: Product Use

Form: Product administration-mCC (2)

Data signed: (hcoleman1) 18 Jun 2015 19:27:32

Generated On: 20 Jul 2016 10:56:43

At Day 0, Day 1 and Day 4, complete all SODIM related 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: 1002**

Folder: Product Use

Form: Product administration-mCC (3)

Data signed: (hcoleman1) 18 Jun 2015 19:27:32

Generated On: 20 Jul 2016 10:56:43

Date of product use DD/MMM/YYYY	15 JAN 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	08:02
----------------------	-------

Time of butt return	08:11
---------------------	-------

CC with SODIM?	True
----------------	------

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: 1002

Folder: Product Use

Form: Product administration-mCC (3)

Data signed: (hcoleman1) 18 Jun 2015 19:27:32

Generated On: 20 Jul 2016 10:56:43

At Day 0, Day 1 and Day 4, complete all SODIM related 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: 1002**

Folder: Product Use

Form: Product administration-mCC (4)

Data signed: (hcoleman1) 18 Jun 2015 19:27:32

Generated On: 20 Jul 2016 10:56:43

Date of product use DD/MMM/YYYY	15 JAN 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	09:28
----------------------	-------

Time of butt return	09:36
---------------------	-------

CC with SODIM?	True
----------------	------

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: 1002

Folder: Product Use

Form: Product administration-mCC (4)

Data signed: (hcoleman1) 18 Jun 2015 19:27:32

Generated On: 20 Jul 2016 10:56:43

At Day 0, Day 1 and Day 4, complete all SODIM related 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: 1002**

Folder: Product Use

Form: Product administration-mCC (5)

Data signed: (hcoleman1) 18 Jun 2015 19:27:32

Generated On: 20 Jul 2016 10:56:43

Date of product use DD/MMM/YYYY	15 JAN 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	13:01
----------------------	-------

Time of butt return	13:12
---------------------	-------

CC with SODIM?	True
----------------	------

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: 1002

Folder: Product Use

Form: Product administration-mCC (5)

Data signed: (hcoleman1) 18 Jun 2015 19:27:32

Generated On: 20 Jul 2016 10:56:43

At Day 0, Day 1 and Day 4, complete all SODIM related 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: 1002**

Folder: Product Use

Form: Product administration-mCC (6)

Data signed: (hcoleman1) 18 Jun 2015 19:27:32

Generated On: 20 Jul 2016 10:56:43

Date of product use DD/MMM/YYYY	15 JAN 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	16:06
----------------------	-------

Time of butt return	16:18
---------------------	-------

CC with SODIM?	True
----------------	------

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: 1002

Folder: Product Use

Form: Product administration-mCC (6)

Data signed: (hcoleman1) 18 Jun 2015 19:27:32

Generated On: 20 Jul 2016 10:56:43

At Day 0, Day 1 and Day 4, complete all SODIM related 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: 1002**

Folder: Product Use

Form: Product administration-mCC (7)

Data signed: (hcoleman1) 18 Jun 2015 19:27:32

Generated On: 20 Jul 2016 10:56:43

Date of product use DD/MMM/YYYY	15 JAN 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	16:42
----------------------	-------

Time of butt return	16:52
---------------------	-------

CC with SODIM?	True
----------------	------

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: 1002

Folder: Product Use

Form: Product administration-mCC (7)

Data signed: (hcoleman1) 18 Jun 2015 19:27:32

Generated On: 20 Jul 2016 10:56:43

At Day 0, Day 1 and Day 4, complete all SODIM related 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: 1002**

Folder: Product Use

Form: Product administration-mCC (8)

Data signed: (hcoleman1) 18 Jun 2015 19:27:32

Generated On: 20 Jul 2016 10:56:43

Date of product use DD/MMM/YYYY	15 JAN 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	17:43
----------------------	-------

Time of butt return	17:52
---------------------	-------

CC with SODIM?	True
----------------	------

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: 1002

Folder: Product Use

Form: Product administration-mCC (8)

Data signed: (hcoleman1) 18 Jun 2015 19:27:32

Generated On: 20 Jul 2016 10:56:43

At Day 0, Day 1 and Day 4, complete all SODIM related 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: 1002**

Folder: Product Use

Form: Product administration-mCC (9)

Data signed: (hcoleman1) 18 Jun 2015 19:27:32

Generated On: 20 Jul 2016 10:56:43

Date of product use DD/MMM/YYYY	15 JAN 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	18:33
----------------------	-------

Time of butt return	18:42
---------------------	-------

CC with SODIM?	True
----------------	------

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: 1002

Folder: Product Use

Form: Product administration-mCC (9)

Data signed: (hcoleman1) 18 Jun 2015 19:27:32

Generated On: 20 Jul 2016 10:56:43

At Day 0, Day 1 and Day 4, complete all SODIM related 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: 1002**

Folder: Product Use

Form: Product administration-mCC (10)

Data signed: (hcoleman1) 18 Jun 2015 19:27:32

Generated On: 20 Jul 2016 10:56:43

Date of product use DD/MMM/YYYY	15 JAN 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	21:48
----------------------	-------

Time of butt return	21:56
---------------------	-------

CC with SODIM?	True
----------------	------

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: 1002

Folder: Product Use

Form: Product administration-mCC (10)

Data signed: (hcoleman1) 18 Jun 2015 19:27:32

Generated On: 20 Jul 2016 10:56:43

At Day 0, Day 1 and Day 4, complete all SODIM related 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: 1002**

Folder: Product Use

Form: Product administration-mCC (11)

Data signed: (hcoleman1) 18 Jun 2015 19:27:32

Generated On: 20 Jul 2016 10:56:43

Date of product use DD/MMM/YYYY	16 JAN 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	07:41
----------------------	-------

Time of butt return	07:48
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	163
---------------------	-----

SODIM sample holder number	0200
----------------------------	------

SODIM file number	08DY0163COHA10200001
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1002

Folder: Product Use

Form: Product administration-mCC (11)

Data signed: (hcoleman1) 18 Jun 2015 19:27:32

Generated On: 20 Jul 2016 10:56:43

At Day 0, Day 1 and Day 4, complete all SODIM related 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: 1002**

Folder: Product Use

Form: Product administration-mCC (12)

Data signed: (hcoleman1) 18 Jun 2015 19:27:32

Generated On: 20 Jul 2016 10:56:43

Date of product use DD/MMM/YYYY	16 JAN 2014
------------------------------------	-------------

Visit	Day 0 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	08:26
----------------------	-------

Time of butt return	08:33
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	163
---------------------	-----

SODIM sample holder number	0200
----------------------------	------

SODIM file number	08DY0163COHA10200002
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1002

Folder: Product Use

Form: Product administration-mCC (12)

Data signed: (hcoleman1) 18 Jun 2015 19:27:32

Generated On: 20 Jul 2016 10:56:43

At Day 0, Day 1 and Day 4, complete all SODIM related 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: 1002**

Folder: Product Use

Form: Product administration-mCC (13)

Data signed: (hcoleman1) 18 Jun 2015 19:27:32

Generated On: 20 Jul 2016 10:56:43

Date of product use DD/MMM/YYYY	16 JAN 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	09:08
----------------------	-------

Time of butt return	09:19
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	163
---------------------	-----

SODIM sample holder number	0200
----------------------------	------

SODIM file number	08DY0163COHA10200003
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1002

Folder: Product Use

Form: Product administration-mCC (13)

Data signed: (hcoleman1) 18 Jun 2015 19:27:32

Generated On: 20 Jul 2016 10:56:43

At Day 0, Day 1 and Day 4, complete all SODIM related 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: 1002**

Folder: Product Use

Form: Product administration-mCC (14)

Data signed: (hcoleman1) 18 Jun 2015 19:27:32

Generated On: 20 Jul 2016 10:56:43

Date of product use DD/MMM/YYYY	16 JAN 2014
------------------------------------	-------------

Visit	Day 0 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	10:17
----------------------	-------

Time of butt return	10:24
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	163
---------------------	-----

SODIM sample holder number	0200
----------------------------	------

SODIM file number	08DY0163COHA10200004
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1002

Folder: Product Use

Form: Product administration-mCC (14)

Data signed: (hcoleman1) 18 Jun 2015 19:27:32

Generated On: 20 Jul 2016 10:56:43

At Day 0, Day 1 and Day 4, complete all SODIM related 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: 1002**

Folder: Product Use

Form: Product administration-mCC (15)

Data signed: (hcoleman1) 18 Jun 2015 19:27:32

Generated On: 20 Jul 2016 10:56:43

Date of product use DD/MMM/YYYY	16 JAN 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	11:32
----------------------	-------

Time of butt return	11:40
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	163
---------------------	-----

SODIM sample holder number	0200
----------------------------	------

SODIM file number	08DY0163COHA10200005
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1002

Folder: Product Use

Form: Product administration-mCC (15)

Data signed: (hcoleman1) 18 Jun 2015 19:27:32

Generated On: 20 Jul 2016 10:56:43

At Day 0, Day 1 and Day 4, complete all SODIM related 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: 1002**

Folder: Product Use

Form: Product administration-mCC (16)

Data signed: (hcoleman1) 18 Jun 2015 19:27:32

Generated On: 20 Jul 2016 10:56:43

Date of product use DD/MMM/YYYY	16 JAN 2014
------------------------------------	-------------

Visit	Day 0 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	12:17
----------------------	-------

Time of butt return	12:28
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	163
---------------------	-----

SODIM sample holder number	0200
----------------------------	------

SODIM file number	08DY0163COHA10200006
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1002

Folder: Product Use

Form: Product administration-mCC (16)

Data signed: (hcoleman1) 18 Jun 2015 19:27:32

Generated On: 20 Jul 2016 10:56:43

At Day 0, Day 1 and Day 4, complete all SODIM related 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: 1002**

Folder: Product Use

Form: Product administration-mCC (17)

Data signed: (hcoleman1) 18 Jun 2015 19:27:32

Generated On: 20 Jul 2016 10:56:43

Date of product use DD/MMM/YYYY	16 JAN 2014
------------------------------------	-------------

Visit	Day 0 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	13:21
----------------------	-------

Time of butt return	13:29
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	163
---------------------	-----

SODIM sample holder number	0200
----------------------------	------

SODIM file number	08DY0163COHA10200007
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1002

Folder: Product Use

Form: Product administration-mCC (17)

Data signed: (hcoleman1) 18 Jun 2015 19:27:32

Generated On: 20 Jul 2016 10:56:43

At Day 0, Day 1 and Day 4, complete all SODIM related 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: 1002**

Folder: Product Use

Form: Product administration-mCC (18)

Data signed: (hcoleman1) 18 Jun 2015 19:27:32

Generated On: 20 Jul 2016 10:56:43

Date of product use DD/MMM/YYYY	16 JAN 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	14:13
----------------------	-------

Time of butt return	14:21
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	163
---------------------	-----

SODIM sample holder number	0200
----------------------------	------

SODIM file number	08DY0163COHA10200008
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1002

Folder: Product Use

Form: Product administration-mCC (18)

Data signed: (hcoleman1) 18 Jun 2015 19:27:32

Generated On: 20 Jul 2016 10:56:43

At Day 0, Day 1 and Day 4, complete all SODIM related 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: 1002**

Folder: Product Use

Form: Product administration-mCC (19)

Data signed: (hcoleman1) 18 Jun 2015 19:27:32

Generated On: 20 Jul 2016 10:56:43

Date of product use DD/MMM/YYYY	16 JAN 2014
------------------------------------	-------------

Visit	Day 0 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	16:30
----------------------	-------

Time of butt return	16:39
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	163
---------------------	-----

SODIM sample holder number	0200
----------------------------	------

SODIM file number	08DY0163COHA10200009
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1002

Folder: Product Use

Form: Product administration-mCC (19)

Data signed: (hcoleman1) 18 Jun 2015 19:27:32

Generated On: 20 Jul 2016 10:56:43

At Day 0, Day 1 and Day 4, complete all SODIM related 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: 1002**

Folder: Product Use

Form: Product administration-mCC (20)

Data signed: (hcoleman1) 18 Jun 2015 19:27:32

Generated On: 20 Jul 2016 10:56:43

Date of product use DD/MMM/YYYY	16 JAN 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	17:43
----------------------	-------

Time of butt return	17:52
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	163
---------------------	-----

SODIM sample holder number	0200
----------------------------	------

SODIM file number	08DY0163COHA10200010
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1002

Folder: Product Use

Form: Product administration-mCC (20)

Data signed: (hcoleman1) 18 Jun 2015 19:27:32

Generated On: 20 Jul 2016 10:56:43

At Day 0, Day 1 and Day 4, complete all SODIM related 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: 1002**

Folder: Product Use

Form: Product administration-mCC (21)

Data signed: (hcoleman1) 18 Jun 2015 19:27:32

Generated On: 20 Jul 2016 10:56:43

Date of product use DD/MMM/YYYY	16 JAN 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	18:47
----------------------	-------

Time of butt return	18:59
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	163
---------------------	-----

SODIM sample holder number	0200
----------------------------	------

SODIM file number	08DY0163COHA10200011
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1002

Folder: Product Use

Form: Product administration-mCC (21)

Data signed: (hcoleman1) 18 Jun 2015 19:27:32

Generated On: 20 Jul 2016 10:56:43

At Day 0, Day 1 and Day 4, complete all SODIM related 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: 1002**

Folder: Product Use

Form: Product administration-mCC (22)

Data signed: (hcoleman1) 18 Jun 2015 19:27:32

Generated On: 20 Jul 2016 10:56:43

Date of product use DD/MMM/YYYY	16 JAN 2014
------------------------------------	-------------

Visit	Day 0 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	19:50
----------------------	-------

Time of butt return	19:59
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	163
---------------------	-----

SODIM sample holder number	0200
----------------------------	------

SODIM file number	08DY0163COHA10200012
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1002

Folder: Product Use

Form: Product administration-mCC (22)

Data signed: (hcoleman1) 18 Jun 2015 19:27:32

Generated On: 20 Jul 2016 10:56:43

At Day 0, Day 1 and Day 4, complete all SODIM related 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: 1002**

Folder: Product Use

Form: Product administration-mCC (23)

Data signed: (hcoleman1) 18 Jun 2015 19:27:32

Generated On: 20 Jul 2016 10:56:43

Date of product use DD/MMM/YYYY	16 JAN 2014
------------------------------------	-------------

Visit	Day 0 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	21:05
----------------------	-------

Time of butt return	21:13
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	163
---------------------	-----

SODIM sample holder number	0200
----------------------------	------

SODIM file number	08DY0163COHA10200013
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1002

Folder: Product Use

Form: Product administration-mCC (23)

Data signed: (hcoleman1) 18 Jun 2015 19:27:32

Generated On: 20 Jul 2016 10:56:43

At Day 0, Day 1 and Day 4, complete all SODIM related 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: 1002**

Folder: Product Use

Form: Product administration-mCC (24)

Data signed: (hcoleman1) 18 Jun 2015 19:27:32

Generated On: 20 Jul 2016 10:56:43

Date of product use DD/MMM/YYYY	17 JAN 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	06:41
----------------------	-------

Time of butt return	06:49
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	163
---------------------	-----

SODIM sample holder number	0200
----------------------------	------

SODIM file number	08DY0163COHA10200014
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1002

Folder: Product Use

Form: Product administration-mCC (24)

Data signed: (hcoleman1) 18 Jun 2015 19:27:32

Generated On: 20 Jul 2016 10:56:43

At Day 0, Day 1 and Day 4, complete all SODIM related 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: 1002**

Folder: Product Use

Form: Product administration-mCC (25)

Data signed: (hcoleman1) 18 Jun 2015 19:27:32

Generated On: 20 Jul 2016 10:56:43

Date of product use DD/MMM/YYYY	17 JAN 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	08:01
----------------------	-------

Time of butt return	08:08
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	163
---------------------	-----

SODIM sample holder number	0200
----------------------------	------

SODIM file number	08DY0163COHA10200015
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1002

Folder: Product Use

Form: Product administration-mCC (25)

Data signed: (hcoleman1) 18 Jun 2015 19:27:32

Generated On: 20 Jul 2016 10:56:43

At Day 0, Day 1 and Day 4, complete all SODIM related 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: 1002**

Folder: Product Use

Form: Product administration-mCC (26)

Data signed: (hcoleman1) 18 Jun 2015 19:27:32

Generated On: 20 Jul 2016 10:56:43

Date of product use DD/MMM/YYYY	17 JAN 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	08:49
----------------------	-------

Time of butt return	08:58
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	163
---------------------	-----

SODIM sample holder number	0200
----------------------------	------

SODIM file number	08DY0163COHA10200016
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1002

Folder: Product Use

Form: Product administration-mCC (26)

Data signed: (hcoleman1) 18 Jun 2015 19:27:32

Generated On: 20 Jul 2016 10:56:43

At Day 0, Day 1 and Day 4, complete all SODIM related 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: 1002**

Folder: Product Use

Form: Product administration-mCC (27)

Data signed: (hcoleman1) 18 Jun 2015 19:27:32

Generated On: 20 Jul 2016 10:56:43

Date of product use DD/MMM/YYYY	17 JAN 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	09:43
----------------------	-------

Time of butt return	09:51
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	163
---------------------	-----

SODIM sample holder number	0200
----------------------------	------

SODIM file number	08DY0163COHA10200017
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1002

Folder: Product Use

Form: Product administration-mCC (27)

Data signed: (hcoleman1) 18 Jun 2015 19:27:32

Generated On: 20 Jul 2016 10:56:43

At Day 0, Day 1 and Day 4, complete all SODIM related 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: 1002**

Folder: Product Use

Form: Product administration-mCC (28)

Data signed: (hcoleman1) 18 Jun 2015 19:27:32

Generated On: 20 Jul 2016 10:56:43

Date of product use DD/MMM/YYYY	17 JAN 2014
------------------------------------	-------------

Visit	Day 1 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	13:22
----------------------	-------

Time of butt return	13:30
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	163
---------------------	-----

SODIM sample holder number	0200
----------------------------	------

SODIM file number	08DY0163COHA10200018
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1002

Folder: Product Use

Form: Product administration-mCC (28)

Data signed: (hcoleman1) 18 Jun 2015 19:27:32

Generated On: 20 Jul 2016 10:56:43

At Day 0, Day 1 and Day 4, complete all SODIM related 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: 1002**

Folder: Product Use

Form: Product administration-mCC (29)

Data signed: (hcoleman1) 18 Jun 2015 19:27:32

Generated On: 20 Jul 2016 10:56:43

Date of product use DD/MMM/YYYY	17 JAN 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	17:35
----------------------	-------

Time of butt return	17:43
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	163
---------------------	-----

SODIM sample holder number	0200
----------------------------	------

SODIM file number	08DY0163COHA10200019
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1002

Folder: Product Use

Form: Product administration-mCC (29)

Data signed: (hcoleman1) 18 Jun 2015 19:27:32

Generated On: 20 Jul 2016 10:56:43

At Day 0, Day 1 and Day 4, complete all SODIM related 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: 1002**

Folder: Product Use

Form: Product administration-mCC (30)

Data signed: (hcoleman1) 18 Jun 2015 19:27:32

Generated On: 20 Jul 2016 10:56:43

Date of product use DD/MMM/YYYY	17 JAN 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	20:06
----------------------	-------

Time of butt return	20:14
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	163
---------------------	-----

SODIM sample holder number	0200
----------------------------	------

SODIM file number	08DY0163COHA10200020
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1002

Folder: Product Use

Form: Product administration-mCC (30)

Data signed: (hcoleman1) 18 Jun 2015 19:27:32

Generated On: 20 Jul 2016 10:56:43

At Day 0, Day 1 and Day 4, complete all SODIM related 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: 1002**

Folder: Product Use

Form: Product administration-mCC (31)

Data signed: (hcoleman1) 18 Jun 2015 19:27:32

Generated On: 20 Jul 2016 10:56:43

Date of product use DD/MMM/YYYY	17 JAN 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	20:49
----------------------	-------

Time of butt return	20:55
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	163
---------------------	-----

SODIM sample holder number	0200
----------------------------	------

SODIM file number	08DY0163COHA10200021
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1002

Folder: Product Use

Form: Product administration-mCC (31)

Data signed: (hcoleman1) 18 Jun 2015 19:27:32

Generated On: 20 Jul 2016 10:56:43

At Day 0, Day 1 and Day 4, complete all SODIM related 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: 1002**

Folder: Product Use

Form: Product administration-mCC (32)

Data signed: (hcoleman1) 18 Jun 2015 19:27:32

Generated On: 20 Jul 2016 10:56:43

Date of product use DD/MMM/YYYY	18 JAN 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	06:33
----------------------	-------

Time of butt return	06:39
---------------------	-------

CC with SODIM?	True
----------------	------

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: 1002

Folder: Product Use

Form: Product administration-mCC (32)

Data signed: (hcoleman1) 18 Jun 2015 19:27:32

Generated On: 20 Jul 2016 10:56:43

At Day 0, Day 1 and Day 4, complete all SODIM related 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: 1002**

Folder: Product Use

Form: Product administration-mCC (33)

Data signed: (hcoleman1) 18 Jun 2015 19:27:32

Generated On: 20 Jul 2016 10:56:43

Date of product use DD/MMM/YYYY	18 JAN 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	07:06
----------------------	-------

Time of butt return	07:12
---------------------	-------

CC with SODIM?	True
----------------	------

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: 1002

Folder: Product Use

Form: Product administration-mCC (33)

Data signed: (hcoleman1) 18 Jun 2015 19:27:32

Generated On: 20 Jul 2016 10:56:43

At Day 0, Day 1 and Day 4, complete all SODIM related 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: 1002**

Folder: Product Use

Form: Product administration-mCC (34)

Data signed: (hcoleman1) 18 Jun 2015 19:27:32

Generated On: 20 Jul 2016 10:56:43

Date of product use DD/MMM/YYYY	18 JAN 2014
------------------------------------	-------------

Visit	Day 2 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	08:02
----------------------	-------

Time of butt return	08:10
---------------------	-------

CC with SODIM?	True
----------------	------

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: 1002

Folder: Product Use

Form: Product administration-mCC (34)

Data signed: (hcoleman1) 18 Jun 2015 19:27:32

Generated On: 20 Jul 2016 10:56:43

At Day 0, Day 1 and Day 4, complete all SODIM related 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: 1002**

Folder: Product Use

Form: Product administration-mCC (35)

Data signed: (hcoleman1) 18 Jun 2015 19:27:32

Generated On: 20 Jul 2016 10:56:43

Date of product use DD/MMM/YYYY	18 JAN 2014
------------------------------------	-------------

Visit	Day 2 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	08:36
----------------------	-------

Time of butt return	08:43
---------------------	-------

CC with SODIM?	True
----------------	------

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: 1002

Folder: Product Use

Form: Product administration-mCC (35)

Data signed: (hcoleman1) 18 Jun 2015 19:27:32

Generated On: 20 Jul 2016 10:56:43

At Day 0, Day 1 and Day 4, complete all SODIM related 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: 1002**

Folder: Product Use

Form: Product administration-mCC (36)

Data signed: (hcoleman1) 18 Jun 2015 19:27:32

Generated On: 20 Jul 2016 10:56:43

Date of product use DD/MMM/YYYY	18 JAN 2014
------------------------------------	-------------

Visit	Day 2 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	09:35
----------------------	-------

Time of butt return	09:43
---------------------	-------

CC with SODIM?	True
----------------	------

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: 1002

Folder: Product Use

Form: Product administration-mCC (36)

Data signed: (hcoleman1) 18 Jun 2015 19:27:32

Generated On: 20 Jul 2016 10:56:43

At Day 0, Day 1 and Day 4, complete all SODIM related 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: 1002**

Folder: Product Use

Form: Product administration-mCC (37)

Data signed: (hcoleman1) 18 Jun 2015 19:27:32

Generated On: 20 Jul 2016 10:56:43

Date of product use DD/MMM/YYYY	18 JAN 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	11:14
----------------------	-------

Time of butt return	11:23
---------------------	-------

CC with SODIM?	True
----------------	------

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: 1002

Folder: Product Use

Form: Product administration-mCC (37)

Data signed: (hcoleman1) 18 Jun 2015 19:27:32

Generated On: 20 Jul 2016 10:56:43

At Day 0, Day 1 and Day 4, complete all SODIM related 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: 1002**

Folder: Product Use

Form: Product administration-mCC (38)

Data signed: (hcoleman1) 18 Jun 2015 19:27:32

Generated On: 20 Jul 2016 10:56:43

Date of product use DD/MMM/YYYY	18 JAN 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	12:11
----------------------	-------

Time of butt return	12:19
---------------------	-------

CC with SODIM?	True
----------------	------

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: 1002

Folder: Product Use

Form: Product administration-mCC (38)

Data signed: (hcoleman1) 18 Jun 2015 19:27:32

Generated On: 20 Jul 2016 10:56:43

At Day 0, Day 1 and Day 4, complete all SODIM related 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: 1002**

Folder: Product Use

Form: Product administration-mCC (39)

Data signed: (hcoleman1) 18 Jun 2015 19:27:32

Generated On: 20 Jul 2016 10:56:43

Date of product use DD/MMM/YYYY	18 JAN 2014
------------------------------------	-------------

Visit	Day 2 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	13:13
----------------------	-------

Time of butt return	13:21
---------------------	-------

CC with SODIM?	True
----------------	------

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: 1002

Folder: Product Use

Form: Product administration-mCC (39)

Data signed: (hcoleman1) 18 Jun 2015 19:27:32

Generated On: 20 Jul 2016 10:56:43

At Day 0, Day 1 and Day 4, complete all SODIM related 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: 1002**

Folder: Product Use

Form: Product administration-mCC (40)

Data signed: (hcoleman1) 18 Jun 2015 19:27:32

Generated On: 20 Jul 2016 10:56:43

Date of product use DD/MMM/YYYY	18 JAN 2014
------------------------------------	-------------

Visit	Day 2 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	14:37
----------------------	-------

Time of butt return	14:46
---------------------	-------

CC with SODIM?	True
----------------	------

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: 1002

Folder: Product Use

Form: Product administration-mCC (40)

Data signed: (hcoleman1) 18 Jun 2015 19:27:32

Generated On: 20 Jul 2016 10:56:43

At Day 0, Day 1 and Day 4, complete all SODIM related 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: 1002**

Folder: Product Use

Form: Product administration-mCC (41)

Data signed: (hcoleman1) 18 Jun 2015 19:27:32

Generated On: 20 Jul 2016 10:56:43

Date of product use DD/MMM/YYYY	18 JAN 2014
------------------------------------	-------------

Visit	Day 2 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	16:44
----------------------	-------

Time of butt return	16:53
---------------------	-------

CC with SODIM?	True
----------------	------

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: 1002

Folder: Product Use

Form: Product administration-mCC (41)

Data signed: (hcoleman1) 18 Jun 2015 19:27:32

Generated On: 20 Jul 2016 10:56:43

At Day 0, Day 1 and Day 4, complete all SODIM related 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: 1002**

Folder: Product Use

Form: Product administration-mCC (42)

Data signed: (hcoleman1) 18 Jun 2015 19:27:32

Generated On: 20 Jul 2016 10:56:43

Date of product use DD/MMM/YYYY	18 JAN 2014
------------------------------------	-------------

Visit	Day 2 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	18:15
----------------------	-------

Time of butt return	18:23
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

SODIM file number	_____
-------------------	-------

Comment	_____
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1002

Folder: Product Use

Form: Product administration-mCC (42)

Data signed: (hcoleman1) 18 Jun 2015 19:27:32

Generated On: 20 Jul 2016 10:56:43

At Day 0, Day 1 and Day 4, complete all SODIM related 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: 1002**

Folder: Product Use

Form: Product administration-mCC (43)

Data signed: (hcoleman1) 18 Jun 2015 19:27:32

Generated On: 20 Jul 2016 10:56:43

Date of product use DD/MMM/YYYY	18 JAN 2014
------------------------------------	-------------

Visit	Day 2 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	19:16
----------------------	-------

Time of butt return	19:22
---------------------	-------

CC with SODIM?	True
----------------	------

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: 1002

Folder: Product Use

Form: Product administration-mCC (43)

Data signed: (hcoleman1) 18 Jun 2015 19:27:32

Generated On: 20 Jul 2016 10:56:43

At Day 0, Day 1 and Day 4, complete all SODIM related 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: 1002**

Folder: Product Use

Form: Product administration-mCC (44)

Data signed: (hcoleman1) 18 Jun 2015 19:27:32

Generated On: 20 Jul 2016 10:56:43

Date of product use DD/MMM/YYYY	18 JAN 2014
------------------------------------	-------------

Visit	Day 2 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	20:23
----------------------	-------

Time of butt return	_____
---------------------	-------

CC with SODIM?	True
----------------	------

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: 1002

Folder: Product Use

Form: Product administration-mCC (44)

Data signed: (hcoleman1) 18 Jun 2015 19:27:32

Generated On: 20 Jul 2016 10:56:43

At Day 0, Day 1 and Day 4, complete all SODIM related 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: 1002**

Folder: Product Use

Form: Product administration-mCC (45)

Data signed: (hcoleman1) 18 Jun 2015 19:27:32

Generated On: 20 Jul 2016 10:56:43

Date of product use DD/MMM/YYYY	19 JAN 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	06:37
----------------------	-------

Time of butt return	06:45
---------------------	-------

CC with SODIM?	True
----------------	------

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: 1002

Folder: Product Use

Form: Product administration-mCC (45)

Data signed: (hcoleman1) 18 Jun 2015 19:27:32

Generated On: 20 Jul 2016 10:56:43

At Day 0, Day 1 and Day 4, complete all SODIM related 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: 1002**

Folder: Product Use

Form: Product administration-mCC (46)

Data signed: (hcoleman1) 18 Jun 2015 19:27:32

Generated On: 20 Jul 2016 10:56:43

Date of product use DD/MMM/YYYY	19 JAN 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	07:53
----------------------	-------

Time of butt return	07:59
---------------------	-------

CC with SODIM?	True
----------------	------

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: 1002

Folder: Product Use

Form: Product administration-mCC (46)

Data signed: (hcoleman1) 18 Jun 2015 19:27:32

Generated On: 20 Jul 2016 10:56:43

At Day 0, Day 1 and Day 4, complete all SODIM related 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: 1002**

Folder: Product Use

Form: Product administration-mCC (47)

Data signed: (hcoleman1) 18 Jun 2015 19:27:32

Generated On: 20 Jul 2016 10:56:43

Date of product use DD/MMM/YYYY	19 JAN 2014
------------------------------------	-------------

Visit	Day 3 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	08:54
----------------------	-------

Time of butt return	09:02
---------------------	-------

CC with SODIM?	True
----------------	------

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: 1002

Folder: Product Use

Form: Product administration-mCC (47)

Data signed: (hcoleman1) 18 Jun 2015 19:27:32

Generated On: 20 Jul 2016 10:56:43

At Day 0, Day 1 and Day 4, complete all SODIM related 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: 1002**

Folder: Product Use

Form: Product administration-mCC (48)

Data signed: (hcoleman1) 18 Jun 2015 19:27:32

Generated On: 20 Jul 2016 10:56:43

Date of product use DD/MMM/YYYY	19 JAN 2014
------------------------------------	-------------

Visit	Day 3 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	10:24
----------------------	-------

Time of butt return	10:31
---------------------	-------

CC with SODIM?	True
----------------	------

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: 1002

Folder: Product Use

Form: Product administration-mCC (48)

Data signed: (hcoleman1) 18 Jun 2015 19:27:32

Generated On: 20 Jul 2016 10:56:43

At Day 0, Day 1 and Day 4, complete all SODIM related 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: 1002**

Folder: Product Use

Form: Product administration-mCC (49)

Data signed: (hcoleman1) 18 Jun 2015 19:27:32

Generated On: 20 Jul 2016 10:56:43

Date of product use DD/MMM/YYYY	19 JAN 2014
------------------------------------	-------------

Visit	Day 3 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	12:03
----------------------	-------

Time of butt return	12:09
---------------------	-------

CC with SODIM?	True
----------------	------

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: 1002

Folder: Product Use

Form: Product administration-mCC (49)

Data signed: (hcoleman1) 18 Jun 2015 19:27:32

Generated On: 20 Jul 2016 10:56:43

At Day 0, Day 1 and Day 4, complete all SODIM related 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: 1002**

Folder: Product Use

Form: Product administration-mCC (50)

Data signed: (hcoleman1) 18 Jun 2015 19:27:32

Generated On: 20 Jul 2016 10:56:43

Date of product use DD/MMM/YYYY	19 JAN 2014
------------------------------------	-------------

Visit	Day 3 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	13:24
----------------------	-------

Time of butt return	13:29
---------------------	-------

CC with SODIM?	True
----------------	------

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: 1002

Folder: Product Use

Form: Product administration-mCC (50)

Data signed: (hcoleman1) 18 Jun 2015 19:27:32

Generated On: 20 Jul 2016 10:56:43

At Day 0, Day 1 and Day 4, complete all SODIM related 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: 1002**

Folder: Product Use

Form: Product administration-mCC (51)

Data signed: (hcoleman1) 18 Jun 2015 19:27:32

Generated On: 20 Jul 2016 10:56:43

Date of product use DD/MMM/YYYY	19 JAN 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	14:41
----------------------	-------

Time of butt return	14:50
---------------------	-------

CC with SODIM?	True
----------------	------

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: 1002

Folder: Product Use

Form: Product administration-mCC (51)

Data signed: (hcoleman1) 18 Jun 2015 19:27:32

Generated On: 20 Jul 2016 10:56:43

At Day 0, Day 1 and Day 4, complete all SODIM related 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: 1002**

Folder: Product Use

Form: Product administration-mCC (52)

Data signed: (hcoleman1) 18 Jun 2015 19:27:32

Generated On: 20 Jul 2016 10:56:43

Date of product use DD/MMM/YYYY	19 JAN 2014
------------------------------------	-------------

Visit	Day 3 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	15:57
----------------------	-------

Time of butt return	16:07
---------------------	-------

CC with SODIM?	True
----------------	------

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: 1002

Folder: Product Use

Form: Product administration-mCC (52)

Data signed: (hcoleman1) 18 Jun 2015 19:27:32

Generated On: 20 Jul 2016 10:56:43

At Day 0, Day 1 and Day 4, complete all SODIM related 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: 1002**

Folder: Product Use

Form: Product administration-mCC (53)

Data signed: (hcoleman1) 18 Jun 2015 19:27:32

Generated On: 20 Jul 2016 10:56:43

Date of product use DD/MMM/YYYY	19 JAN 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	17:25
----------------------	-------

Time of butt return	17:32
---------------------	-------

CC with SODIM?	True
----------------	------

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: 1002

Folder: Product Use

Form: Product administration-mCC (53)

Data signed: (hcoleman1) 18 Jun 2015 19:27:32

Generated On: 20 Jul 2016 10:56:43

At Day 0, Day 1 and Day 4, complete all SODIM related 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: 1002**

Folder: Product Use

Form: Product administration-mCC (54)

Data signed: (hcoleman1) 18 Jun 2015 19:27:32

Generated On: 20 Jul 2016 10:56:43

Date of product use DD/MMM/YYYY	19 JAN 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	17:32
----------------------	-------

Time of butt return	17:40
---------------------	-------

CC with SODIM?	True
----------------	------

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: 1002

Folder: Product Use

Form: Product administration-mCC (54)

Data signed: (hcoleman1) 18 Jun 2015 19:27:32

Generated On: 20 Jul 2016 10:56:43

At Day 0, Day 1 and Day 4, complete all SODIM related 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: 1002**

Folder: Product Use

Form: Product administration-mCC (55)

Data signed: (hcoleman1) 18 Jun 2015 19:27:32

Generated On: 20 Jul 2016 10:56:43

Date of product use DD/MMM/YYYY	19 JAN 2014
------------------------------------	-------------

Visit	Day 3 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	19:23
----------------------	-------

Time of butt return	19:30
---------------------	-------

CC with SODIM?	True
----------------	------

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: 1002

Folder: Product Use

Form: Product administration-mCC (55)

Data signed: (hcoleman1) 18 Jun 2015 19:27:32

Generated On: 20 Jul 2016 10:56:43

At Day 0, Day 1 and Day 4, complete all SODIM related 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: 1002**

Folder: Product Use

Form: Product administration-mCC (56)

Data signed: (hcoleman1) 18 Jun 2015 19:27:32

Generated On: 20 Jul 2016 10:56:43

Date of product use DD/MMM/YYYY	19 JAN 2014
------------------------------------	-------------

Visit	Day 3 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	20:21
----------------------	-------

Time of butt return	20:27
---------------------	-------

CC with SODIM?	True
----------------	------

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: 1002

Folder: Product Use

Form: Product administration-mCC (56)

Data signed: (hcoleman1) 18 Jun 2015 19:27:32

Generated On: 20 Jul 2016 10:56:43

At Day 0, Day 1 and Day 4, complete all SODIM related 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: 1002**

Folder: Product Use

Form: Product administration-mCC (57)

Data signed: (hcoleman1) 18 Jun 2015 19:27:32

Generated On: 20 Jul 2016 10:56:43

Date of product use DD/MMM/YYYY	20 JAN 2014
------------------------------------	-------------

Visit	Day 4 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	06:39
----------------------	-------

Time of butt return	06:47
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	163
---------------------	-----

SODIM sample holder number	0200
----------------------------	------

SODIM file number	08DY0163COHA10200022
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1002

Folder: Product Use

Form: Product administration-mCC (57)

Data signed: (hcoleman1) 18 Jun 2015 19:27:32

Generated On: 20 Jul 2016 10:56:43

At Day 0, Day 1 and Day 4, complete all SODIM related 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: 1002**

Folder: Product Use

Form: Product administration-mCC (58)

Data signed: (hcoleman1) 18 Jun 2015 19:27:32

Generated On: 20 Jul 2016 10:56:43

Date of product use DD/MMM/YYYY	20 JAN 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	09:07
----------------------	-------

Time of butt return	09:16
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	163
---------------------	-----

SODIM sample holder number	0200
----------------------------	------

SODIM file number	08DY0163COHA10200023
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1002

Folder: Product Use

Form: Product administration-mCC (58)

Data signed: (hcoleman1) 18 Jun 2015 19:27:32

Generated On: 20 Jul 2016 10:56:43

At Day 0, Day 1 and Day 4, complete all SODIM related 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: 1002**

Folder: Product Use

Form: Product administration-mCC (59)

Data signed: (hcoleman1) 18 Jun 2015 19:27:32

Generated On: 20 Jul 2016 10:56:43

Date of product use DD/MMM/YYYY	20 JAN 2014
------------------------------------	-------------

Visit	Day 4 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	10:40
----------------------	-------

Time of butt return	10:47
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	163
---------------------	-----

SODIM sample holder number	0200
----------------------------	------

SODIM file number	08DY0163COHA10200024
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1002

Folder: Product Use

Form: Product administration-mCC (59)

Data signed: (hcoleman1) 18 Jun 2015 19:27:32

Generated On: 20 Jul 2016 10:56:43

At Day 0, Day 1 and Day 4, complete all SODIM related 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: 1002**

Folder: Product Use

Form: Product administration-mCC (60)

Data signed: (hcoleman1) 18 Jun 2015 19:27:32

Generated On: 20 Jul 2016 10:56:43

Date of product use DD/MMM/YYYY	20 JAN 2014
------------------------------------	-------------

Visit	Day 4 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	11:19
----------------------	-------

Time of butt return	11:28
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	163
---------------------	-----

SODIM sample holder number	0200
----------------------------	------

SODIM file number	08DY0163COHA10200025
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1002

Folder: Product Use

Form: Product administration-mCC (60)

Data signed: (hcoleman1) 18 Jun 2015 19:27:32

Generated On: 20 Jul 2016 10:56:43

At Day 0, Day 1 and Day 4, complete all SODIM related 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: 1002**

Folder: Product Use

Form: Product administration-mCC (61)

Data signed: (hcoleman1) 18 Jun 2015 19:27:32

Generated On: 20 Jul 2016 10:56:43

Date of product use DD/MMM/YYYY	20 JAN 2014
------------------------------------	-------------

Visit	Day 4 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	13:36
----------------------	-------

Time of butt return	13:42
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	163
---------------------	-----

SODIM sample holder number	0200
----------------------------	------

SODIM file number	08DY0163COHA10200026
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1002

Folder: Product Use

Form: Product administration-mCC (61)

Data signed: (hcoleman1) 18 Jun 2015 19:27:32

Generated On: 20 Jul 2016 10:56:43

At Day 0, Day 1 and Day 4, complete all SODIM related 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: 1002**

Folder: Product Use

Form: Product administration-mCC (62)

Data signed: (hcoleman1) 18 Jun 2015 19:27:32

Generated On: 20 Jul 2016 10:56:43

Date of product use DD/MMM/YYYY	20 JAN 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	14:50
----------------------	-------

Time of butt return	14:57
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	163
---------------------	-----

SODIM sample holder number	0200
----------------------------	------

SODIM file number	08DY0163COHA10200027
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1002

Folder: Product Use

Form: Product administration-mCC (62)

Data signed: (hcoleman1) 18 Jun 2015 19:27:32

Generated On: 20 Jul 2016 10:56:43

At Day 0, Day 1 and Day 4, complete all SODIM related 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: 1002**

Folder: Product Use

Form: Product administration-mCC (63)

Data signed: (hcoleman1) 18 Jun 2015 19:27:32

Generated On: 20 Jul 2016 10:56:43

Date of product use DD/MMM/YYYY	20 JAN 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	16:56
----------------------	-------

Time of butt return	17:04
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	163
---------------------	-----

SODIM sample holder number	0200
----------------------------	------

SODIM file number	08DY0163COHA10200028
-------------------	----------------------

Comment	_____
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1002

Folder: Product Use

Form: Product administration-mCC (63)

Data signed: (hcoleman1) 18 Jun 2015 19:27:32

Generated On: 20 Jul 2016 10:56:43

At Day 0, Day 1 and Day 4, complete all SODIM related 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: 1002**

Folder: Product Use

Form: Product administration-mCC (64)

Data signed: (hcoleman1) 18 Jun 2015 19:27:32

Generated On: 20 Jul 2016 10:56:43

Date of product use DD/MMM/YYYY	20 JAN 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	17:43
----------------------	-------

Time of butt return	17:51
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	163
---------------------	-----

SODIM sample holder number	0200
----------------------------	------

SODIM file number	08DY0163COHA10200029
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1002

Folder: Product Use

Form: Product administration-mCC (64)

Data signed: (hcoleman1) 18 Jun 2015 19:27:32

Generated On: 20 Jul 2016 10:56:43

At Day 0, Day 1 and Day 4, complete all SODIM related 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: 1002**

Folder: Product Use

Form: Product administration-mCC (65)

Data signed: (hcoleman1) 18 Jun 2015 19:27:32

Generated On: 20 Jul 2016 10:56:43

Date of product use DD/MMM/YYYY	20 JAN 2014
------------------------------------	-------------

Visit	Day 4 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	19:00
----------------------	-------

Time of butt return	19:07
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	163
---------------------	-----

SODIM sample holder number	0200
----------------------------	------

SODIM file number	08DY0163COHA10200030
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1002

Folder: Product Use

Form: Product administration-mCC (65)

Data signed: (hcoleman1) 18 Jun 2015 19:27:32

Generated On: 20 Jul 2016 10:56:43

At Day 0, Day 1 and Day 4, complete all SODIM related 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: 1002**

Folder: Product Use

Form: Product administration-mCC (66)

Data signed: (hcoleman1) 18 Jun 2015 19:27:32

Generated On: 20 Jul 2016 10:56:43

Date of product use DD/MMM/YYYY	20 JAN 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	21:19
----------------------	-------

Time of butt return	21:26
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	163
---------------------	-----

SODIM sample holder number	0200
----------------------------	------

SODIM file number	08DY0163COHA10200031
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1002

Folder: Product Use

Form: Product administration-mCC (66)

Data signed: (hcoleman1) 18 Jun 2015 19:27:32

Generated On: 20 Jul 2016 10:56:43

At Day 0, Day 1 and Day 4, complete all SODIM related 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: 1002**

Folder: Product Use

Form: Product administration-mCC (67)

Data signed: (hcoleman1) 18 Jun 2015 19:27:32

Generated On: 20 Jul 2016 10:56:43

Date of product use DD/MMM/YYYY	21 JAN 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	06:37
----------------------	-------

Time of butt return	06:45
---------------------	-------

CC with SODIM?	True
----------------	------

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: 1002

Folder: Product Use

Form: Product administration-mCC (67)

Data signed: (hcoleman1) 18 Jun 2015 19:27:32

Generated On: 20 Jul 2016 10:56:43

At Day 0, Day 1 and Day 4, complete all SODIM related 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: 1002**

Folder: Product Use

Form: Product administration-mCC (68)

Data signed: (hcoleman1) 18 Jun 2015 19:27:32

Generated On: 20 Jul 2016 10:56:43

Date of product use DD/MMM/YYYY	21 JAN 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	07:29
----------------------	-------

Time of butt return	07:37
---------------------	-------

CC with SODIM?	True
----------------	------

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: 1002

Folder: Product Use

Form: Product administration-mCC (68)

Data signed: (hcoleman1) 18 Jun 2015 19:27:32

Generated On: 20 Jul 2016 10:56:43

At Day 0, Day 1 and Day 4, complete all SODIM related 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: 1002**

Folder: Product Use

Form: Product administration-mCC (69)

Data signed: (hcoleman1) 18 Jun 2015 19:27:32

Generated On: 20 Jul 2016 10:56:43

Date of product use DD/MMM/YYYY	21 JAN 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	08:46
----------------------	-------

Time of butt return	08:53
---------------------	-------

CC with SODIM?	True
----------------	------

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: 1002

Folder: Product Use

Form: Product administration-mCC (69)

Data signed: (hcoleman1) 18 Jun 2015 19:27:32

Generated On: 20 Jul 2016 10:56:43

At Day 0, Day 1 and Day 4, complete all SODIM related 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: 1002**

Folder: Product Use

Form: Product administration-mCC (70)

Data signed: (hcoleman1) 18 Jun 2015 19:27:32

Generated On: 20 Jul 2016 10:56:43

Date of product use DD/MMM/YYYY	21 JAN 2014
------------------------------------	-------------

Visit	Day 5 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	10:41
----------------------	-------

Time of butt return	10:48
---------------------	-------

CC with SODIM?	True
----------------	------

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: 1002

Folder: Product Use

Form: Product administration-mCC (70)

Data signed: (hcoleman1) 18 Jun 2015 19:27:32

Generated On: 20 Jul 2016 10:56:43

At Day 0, Day 1 and Day 4, complete all SODIM related 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: 1002**

Folder: Product Use

Form: Product administration-mCC (71)

Data signed: (hcoleman1) 18 Jun 2015 19:27:32

Generated On: 20 Jul 2016 10:56:43

Date of product use DD/MMM/YYYY	21 JAN 2014
------------------------------------	-------------

Visit	Day 5 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	12:05
----------------------	-------

Time of butt return	12:11
---------------------	-------

CC with SODIM?	True
----------------	------

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: 1002

Folder: Product Use

Form: Product administration-mCC (71)

Data signed: (hcoleman1) 18 Jun 2015 19:27:32

Generated On: 20 Jul 2016 10:56:43

At Day 0, Day 1 and Day 4, complete all SODIM related 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: 1002**

Folder: Product Use

Form: Product administration-mCC (72)

Data signed: (hcoleman1) 18 Jun 2015 19:27:32

Generated On: 20 Jul 2016 10:56:43

Date of product use DD/MMM/YYYY	21 JAN 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	13:56
----------------------	-------

Time of butt return	14:03
---------------------	-------

CC with SODIM?	True
----------------	------

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: 1002

Folder: Product Use

Form: Product administration-mCC (72)

Data signed: (hcoleman1) 18 Jun 2015 19:27:32

Generated On: 20 Jul 2016 10:56:43

At Day 0, Day 1 and Day 4, complete all SODIM related 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: 1002**

Folder: Product Use

Form: Product administration-mCC (73)

Data signed: (hcoleman1) 18 Jun 2015 19:27:32

Generated On: 20 Jul 2016 10:56:43

Date of product use DD/MMM/YYYY	21 JAN 2014
------------------------------------	-------------

Visit	Day 5 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	15:14
----------------------	-------

Time of butt return	15:22
---------------------	-------

CC with SODIM?	True
----------------	------

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: 1002

Folder: Product Use

Form: Product administration-mCC (73)

Data signed: (hcoleman1) 18 Jun 2015 19:27:32

Generated On: 20 Jul 2016 10:56:43

At Day 0, Day 1 and Day 4, complete all SODIM related 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: 1002**

Folder: Product Use

Form: Product administration-mCC (74)

Data signed: (hcoleman1) 18 Jun 2015 19:27:32

Generated On: 20 Jul 2016 10:56:43

Date of product use DD/MMM/YYYY	21 JAN 2014
------------------------------------	-------------

Visit	Day 5 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	15:49
----------------------	-------

Time of butt return	15:57
---------------------	-------

CC with SODIM?	True
----------------	------

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: 1002

Folder: Product Use

Form: Product administration-mCC (74)

Data signed: (hcoleman1) 18 Jun 2015 19:27:32

Generated On: 20 Jul 2016 10:56:43

At Day 0, Day 1 and Day 4, complete all SODIM related 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: 1002**

Folder: Product Use

Form: Product administration-mCC (75)

Data signed: (hcoleman1) 18 Jun 2015 19:27:32

Generated On: 20 Jul 2016 10:56:43

Date of product use DD/MMM/YYYY	21 JAN 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	18:02
----------------------	-------

Time of butt return	18:10
---------------------	-------

CC with SODIM?	True
----------------	------

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: 1002

Folder: Product Use

Form: Product administration-mCC (75)

Data signed: (hcoleman1) 18 Jun 2015 19:27:32

Generated On: 20 Jul 2016 10:56:43

At Day 0, Day 1 and Day 4, complete all SODIM related 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: 1002

Folder: Product Use

Form: Product administration-mCC (76)

Data signed: (hcoleman1) 18 Jun 2015 19:27:32

Generated On: 20 Jul 2016 10:56:43

Date of product use DD/MMM/YYYY	21 JAN 2014
------------------------------------	-------------

Visit	Day 5 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	19:52
----------------------	-------

Time of butt return	19:59
---------------------	-------

CC with SODIM?	True
----------------	------

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: 1002

Folder: Product Use

Form: Product administration-mCC (76)

Data signed: (hcoleman1) 18 Jun 2015 19:27:32

Generated On: 20 Jul 2016 10:56:43

At Day 0, Day 1 and Day 4, complete all SODIM related 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: 1002**

Folder: Product Use

Form: Product administration-mCC (77)

Data signed: (hcoleman1) 18 Jun 2015 19:27:32

Generated On: 20 Jul 2016 10:56:43

Date of product use DD/MMM/YYYY	21 JAN 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	20:52
----------------------	-------

Time of butt return	20:59
---------------------	-------

CC with SODIM?	True
----------------	------

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: 1002

Folder: Product Use

Form: Product administration-mCC (77)

Data signed: (hcoleman1) 18 Jun 2015 19:27:32

Generated On: 20 Jul 2016 10:56:43

At Day 0, Day 1 and Day 4, complete all SODIM related 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: 1002**

Folder: Product Use

Form: Product administration-mCC (78)

Data signed: (hcoleman1) 18 Jun 2015 19:27:32

Generated On: 20 Jul 2016 10:56:43

Date of product use DD/MMM/YYYY	21 JAN 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	22:36
----------------------	-------

Time of butt return	22:43
---------------------	-------

CC with SODIM?	True
----------------	------

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: 1002

Folder: Product Use

Form: Product administration-mCC (78)

Data signed: (hcoleman1) 18 Jun 2015 19:27:32

Generated On: 20 Jul 2016 10:56:43

At Day 0, Day 1 and Day 4, complete all SODIM related 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: 1002**

Folder: Product Use

Form: Product administration-mCC (79)

Data signed: (hcoleman1) 18 Jun 2015 19:27:32

Generated On: 20 Jul 2016 10:56:43

Date of product use DD/MMM/YYYY	22 JAN 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	07:52
----------------------	-------

Time of butt return	07:59
---------------------	-------

CC with SODIM?	True
----------------	------

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: 1002

Folder: Product Use

Form: Product administration-mCC (79)

Data signed: (hcoleman1) 18 Jun 2015 19:27:32

Generated On: 20 Jul 2016 10:56:43

At Day 0, Day 1 and Day 4, complete all SODIM related 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: 1002**

Folder: Product Use

Form: Product administration-mCC (80)

Data signed: (hcoleman1) 18 Jun 2015 19:27:32

Generated On: 20 Jul 2016 10:56:43

Date of product use DD/MMM/YYYY	22 JAN 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	08:43
----------------------	-------

Time of butt return	08:49
---------------------	-------

CC with SODIM?	True
----------------	------

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: 1002

Folder: Product Use

Form: Product administration-mCC (80)

Data signed: (hcoleman1) 18 Jun 2015 19:27:32

Generated On: 20 Jul 2016 10:56:43

At Day 0, Day 1 and Day 4, complete all SODIM related 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: 1002**

Folder: Product Use

Form: Product administration-mCC (81)

Data signed: (hcoleman1) 18 Jun 2015 19:27:32

Generated On: 20 Jul 2016 10:56:43

Date of product use DD/MMM/YYYY	22 JAN 2014
------------------------------------	-------------

Visit	Day 6 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	10:20
----------------------	-------

Time of butt return	10:28
---------------------	-------

CC with SODIM?	True
----------------	------

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: 1002

Folder: Product Use

Form: Product administration-mCC (81)

Data signed: (hcoleman1) 18 Jun 2015 19:27:32

Generated On: 20 Jul 2016 10:56:43

At Day 0, Day 1 and Day 4, complete all SODIM related 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: 1002**

Folder: Product Use

Form: Product administration-mCC (82)

Data signed: (hcoleman1) 18 Jun 2015 19:27:32

Generated On: 20 Jul 2016 10:56:43

Date of product use DD/MMM/YYYY	22 JAN 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	11:46
----------------------	-------

Time of butt return	11:54
---------------------	-------

CC with SODIM?	True
----------------	------

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: 1002

Folder: Product Use

Form: Product administration-mCC (82)

Data signed: (hcoleman1) 18 Jun 2015 19:27:32

Generated On: 20 Jul 2016 10:56:43

At Day 0, Day 1 and Day 4, complete all SODIM related 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: 1002**

Folder: Product Use

Form: Product administration-mCC (83)

Data signed: (hcoleman1) 18 Jun 2015 19:27:32

Generated On: 20 Jul 2016 10:56:43

Date of product use DD/MMM/YYYY	15 FEB 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	163
---------------------	-----

SODIM sample holder number	200
----------------------------	-----

SODIM file number	08DY0163COHA30200001
-------------------	----------------------

Comment	<hr/>
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1002

Folder: Product Use

Form: Product administration-mCC (83)

Data signed: (hcoleman1) 18 Jun 2015 19:27:32

Generated On: 20 Jul 2016 10:56:43

At Day 0, Day 1 and Day 4, complete all SODIM related 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: 1002**

Folder: Product Use

Form: Product administration-mCC (84)

Data signed: (hcoleman1) 18 Jun 2015 19:27:32

Generated On: 20 Jul 2016 10:56:43

Date of product use DD/MMM/YYYY	15 FEB 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	163
---------------------	-----

SODIM sample holder number	200
----------------------------	-----

SODIM file number	08DY0163COHA30200002
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Comment	<hr/>
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1002

Folder: Product Use

Form: Product administration-mCC (84)

Data signed: (hcoleman1) 18 Jun 2015 19:27:32

Generated On: 20 Jul 2016 10:56:43

At Day 0, Day 1 and Day 4, complete all SODIM related 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: 1002**

Folder: Product Use

Form: Product administration-THS menthol

Data signed: (hfarmer1) 26 Mar 2015 13:40:23

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Product Use

Form: Product administration-THS menthol (1)

Data signed: (hfarmer1) 26 Mar 2015 13:40:23

Generated On: 20 Jul 2016 10:56:43

Date of product use DD/MMM/YYYY	14 JAN 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	18:10
----------------------	-------

Time of product return	<hr/>
------------------------	-------

SODIM device number	<hr/>
---------------------	-------

SODIM sample holder number	<hr/>
----------------------------	-------

Tobacco plug kit number	<hr/>
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Tobacco plug vial number	<hr/>
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SODIM file number	<hr/>
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Comment	<hr/>
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Batch Number	B08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1002

Folder: Product Use

Form: Product administration-THS menthol (1)

Data signed: (hfarmer1) 26 Mar 2015 13:40:23

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Product Use

Form: HST 4 hours (1)

Data signed: (hfarmer1) 26 Mar 2015 13:40:24

Generated On: 20 Jul 2016 10:56:43

Visit	Day 30 <input type="radio"/>
-------	------------------------------

Not Done	False
----------	-------

If Not Done, please specify _____

Date	15 FEB 2014
DD/MMM/YYYY	

SODIM device distribution time	08:59
hour:min 24-hour clock	

SODIM device collection time	12:59
hour:min 24-hour clock	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Product Use

Form: HST 4 hours (2)

Data signed: (hfarmer1) 26 Mar 2015 13:40:24

Generated On: 20 Jul 2016 10:56:43

Visit	Day 60 <input checked="" type="radio"/>
-------	---

Not Done	True
----------	------

If Not Done, please specify	SUBJECT EARLY TERMED
-----------------------------	----------------------

Date DD/MMM/YYYY	<hr/>
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SODIM device distribution time hour:min 24-hour clock	<hr/>
--	-------

SODIM device collection time hour:min 24-hour clock	<hr/>
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Product Use

Form: HST 4 hours (3)

Data signed: (hfarmer1) 26 Mar 2015 13:40:24

Generated On: 20 Jul 2016 10:56:43

Visit	Day 90 <input checked="" type="radio"/>
-------	---

Not Done	True
----------	------

If Not Done, please specify	SUBJECT EARLY TERMED
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Date DD/MMM/YYYY	<hr/>
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SODIM device distribution time hour:min 24-hour clock	<hr/>
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SODIM device collection time hour:min 24-hour clock	<hr/>
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Product Use

Form: Topography files status for mCC (1)

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Product Use

Form: Topography files status for mCC (2)

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Product Use

Form: Topography files status for mCC (3)

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Product Use

Form: Topography files status for mCC (4)

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Product Use

Form: Topography files status for mCC (5)

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Product Use

Form: Topography files status for mCC (6)

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Product Use

Form: Topography files status for mCC (7)

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Product Use

Form: Topography files status for mCC (8)

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Product Use

Form: Topography files status for mCC (9)

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Product Use

Form: Topography files status for mCC (10)

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Product Use

Form: Topography files status for mCC (11)

Generated On: 20 Jul 2016 10:56:43

SODIM file number	08DY0163COHA10200001
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File Status	Rejected 
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Rejection / Error reason	START RTD TOO HIGH
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Date of analysis DD/MMM/YYYY	18 AUG 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: 1002**

Folder: Product Use

Form: Topography files status for mCC (12)

Generated On: 20 Jul 2016 10:56:43

SODIM file number	08DY0163COHA10200002
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File Status	Rejected 
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Rejection / Error reason	START RTD TOO HIGH
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Date of analysis DD/MMM/YYYY	18 AUG 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: 1002**

Folder: Product Use

Form: Topography files status for mCC (13)

Generated On: 20 Jul 2016 10:56:43

SODIM file number	08DY0163COHA10200003
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File Status	Rejected 
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Rejection / Error reason	BASELINE DEVIATION
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Date of analysis DD/MMM/YYYY	18 AUG 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: 1002**

Folder: Product Use

Form: Topography files status for mCC (14)

Generated On: 20 Jul 2016 10:56:43

SODIM file number	08DY0163COHA10200004
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File Status	Rejected 
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Rejection / Error reason	START RTD TOO HIGH
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Date of analysis DD/MMM/YYYY	18 AUG 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: 1002**

Folder: Product Use

Form: Topography files status for mCC (15)

Generated On: 20 Jul 2016 10:56:43

SODIM file number	08DY0163COHA10200005
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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	18 AUG 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: 1002**

Folder: Product Use

Form: Topography files status for mCC (16)

Generated On: 20 Jul 2016 10:56:43

SODIM file number	08DY0163COHA10200006
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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	18 AUG 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: 1002**

Folder: Product Use

Form: Topography files status for mCC (17)

Generated On: 20 Jul 2016 10:56:43

SODIM file number	08DY0163COHA10200007
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File Status	Rejected 
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Rejection / Error reason	START RTD TOO HIGH
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Date of analysis DD/MMM/YYYY	18 AUG 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: 1002**

Folder: Product Use

Form: Topography files status for mCC (18)

Generated On: 20 Jul 2016 10:56:43

SODIM file number	08DY0163COHA10200008
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File Status	Rejected 
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Rejection / Error reason	START RTD TOO HIGH
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Date of analysis DD/MMM/YYYY	18 AUG 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: 1002**

Folder: Product Use

Form: Topography files status for mCC (19)

Generated On: 20 Jul 2016 10:56:43

SODIM file number	08DY0163COHA10200009
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File Status	Rejected 
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Rejection / Error reason	START RTD TOO HIGH
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Date of analysis DD/MMM/YYYY	18 AUG 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: 1002**

Folder: Product Use

Form: Topography files status for mCC (20)

Generated On: 20 Jul 2016 10:56:43

SODIM file number	08DY0163COHA10200010
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File Status	Rejected 
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Rejection / Error reason	START RTD TOO HIGH
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Date of analysis DD/MMM/YYYY	18 AUG 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: 1002**

Folder: Product Use

Form: Topography files status for mCC (21)

Generated On: 20 Jul 2016 10:56:43

SODIM file number	08DY0163COHA10200011
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File Status	Rejected 
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Rejection / Error reason	START RTD TOO HIGH
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Date of analysis DD/MMM/YYYY	18 AUG 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: 1002**

Folder: Product Use

Form: Topography files status for mCC (22)

Generated On: 20 Jul 2016 10:56:43

SODIM file number	08DY0163COHA10200012
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File Status	Rejected 
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Rejection / Error reason	START RTD TOO HIGH
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Date of analysis DD/MMM/YYYY	18 AUG 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: 1002**

Folder: Product Use

Form: Topography files status for mCC (23)

Generated On: 20 Jul 2016 10:56:43

SODIM file number	08DY0163COHA10200013
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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	18 AUG 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: 1002**

Folder: Product Use

Form: Topography files status for mCC (24)

Generated On: 20 Jul 2016 10:56:43

SODIM file number	08DY0163COHA10200014
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File Status	Rejected 
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Rejection / Error reason	START RTD TOO HIGH
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Date of analysis DD/MMM/YYYY	18 AUG 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: 1002**

Folder: Product Use

Form: Topography files status for mCC (25)

Generated On: 20 Jul 2016 10:56:43

SODIM file number	08DY0163COHA10200015
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File Status	Rejected 
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Rejection / Error reason	START RTD TOO HIGH
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Date of analysis DD/MMM/YYYY	18 AUG 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: 1002**

Folder: Product Use

Form: Topography files status for mCC (26)

Generated On: 20 Jul 2016 10:56:43

SODIM file number	08DY0163COHA10200016
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File Status	Rejected 
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Rejection / Error reason	START RTD TOO HIGH
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Date of analysis DD/MMM/YYYY	18 AUG 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: 1002**

Folder: Product Use

Form: Topography files status for mCC (27)

Generated On: 20 Jul 2016 10:56:43

SODIM file number	08DY0163COHA10200017
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File Status	Rejected 
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Rejection / Error reason	BASELINE DEVIATION
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Date of analysis DD/MMM/YYYY	18 AUG 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: 1002**

Folder: Product Use

Form: Topography files status for mCC (28)

Generated On: 20 Jul 2016 10:56:43

SODIM file number	08DY0163COHA10200018
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File Status	Rejected 
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Rejection / Error reason	START RTD TOO HIGH
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Date of analysis DD/MMM/YYYY	18 AUG 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: 1002**

Folder: Product Use

Form: Topography files status for mCC (29)

Generated On: 20 Jul 2016 10:56:43

SODIM file number	08DY0163COHA10200019
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File Status	Rejected 
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Rejection / Error reason	START RTD TOO HIGH
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Date of analysis DD/MMM/YYYY	18 AUG 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: 1002**

Folder: Product Use

Form: Topography files status for mCC (30)

Generated On: 20 Jul 2016 10:56:43

SODIM file number	08DY0163COHA10200020
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File Status	Rejected 
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Rejection / Error reason	BASELINE DEVIATION
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Date of analysis DD/MMM/YYYY	18 AUG 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: 1002**

Folder: Product Use

Form: Topography files status for mCC (31)


Generated On: 20 Jul 2016 10:56:43

SODIM file number	08DY0163COHA10200021
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File Status	Rejected 
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Rejection / Error reason	START RTD TOO HIGH
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Date of analysis DD/MMM/YYYY	18 AUG 2014
---------------------------------	-------------

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: 1002**

Folder: Product Use

Form: Topography files status for mCC (32)

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Product Use

Form: Topography files status for mCC (33)

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Product Use

Form: Topography files status for mCC (34)

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Product Use

Form: Topography files status for mCC (35)

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Product Use

Form: Topography files status for mCC (36)

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Product Use

Form: Topography files status for mCC (37)

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Product Use

Form: Topography files status for mCC (38)

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Product Use

Form: Topography files status for mCC (39)

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Product Use

Form: Topography files status for mCC (40)

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Product Use

Form: Topography files status for mCC (41)

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Product Use

Form: Topography files status for mCC (42)

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Product Use

Form: Topography files status for mCC (43)

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Product Use

Form: Topography files status for mCC (44)

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Product Use

Form: Topography files status for mCC (45)

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Product Use

Form: Topography files status for mCC (46)

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Product Use

Form: Topography files status for mCC (47)

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Product Use

Form: Topography files status for mCC (48)

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Product Use

Form: Topography files status for mCC (49)

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Product Use

Form: Topography files status for mCC (50)

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Product Use

Form: Topography files status for mCC (51)

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Product Use

Form: Topography files status for mCC (52)

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Product Use

Form: Topography files status for mCC (53)

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Product Use

Form: Topography files status for mCC (54)

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Product Use

Form: Topography files status for mCC (55)

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Product Use

Form: Topography files status for mCC (56)

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Product Use

Form: Topography files status for mCC (57)

Generated On: 20 Jul 2016 10:56:43

SODIM file number	08DY0163COHA10200022
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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	18 AUG 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: 1002**

Folder: Product Use

Form: Topography files status for mCC (58)

Generated On: 20 Jul 2016 10:56:43

SODIM file number	08DY0163COHA10200023
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File Status	Rejected 
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Rejection / Error reason	BASELINE DEVIATION
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Date of analysis DD/MMM/YYYY	18 AUG 2014
---------------------------------	-------------

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: 1002**

Folder: Product Use

Form: Topography files status for mCC (59)

Generated On: 20 Jul 2016 10:56:43

SODIM file number	08DY0163COHA10200024
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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	18 AUG 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: 1002**

Folder: Product Use

Form: Topography files status for mCC (60)

Generated On: 20 Jul 2016 10:56:43

SODIM file number	08DY0163COHA10200025
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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	18 AUG 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: 1002**

Folder: Product Use

Form: Topography files status for mCC (61)

Generated On: 20 Jul 2016 10:56:43

SODIM file number	08DY0163COHA10200026
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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	18 AUG 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: 1002**

Folder: Product Use

Form: Topography files status for mCC (62)

Generated On: 20 Jul 2016 10:56:43

SODIM file number	08DY0163COHA10200027
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File Status	Rejected 
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Rejection / Error reason	BASELINE DEVIATION
--------------------------	--------------------

Date of analysis DD/MMM/YYYY	18 AUG 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: 1002**

Folder: Product Use

Form: Topography files status for mCC (63)

Generated On: 20 Jul 2016 10:56:43

SODIM file number	08DY0163COHA10200028
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File Status	Rejected 
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Rejection / Error reason	START RTD TOO HIGH
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Date of analysis DD/MMM/YYYY	18 AUG 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: 1002**

Folder: Product Use

Form: Topography files status for mCC (64)

Generated On: 20 Jul 2016 10:56:43

SODIM file number	08DY0163COHA10200029
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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	18 AUG 2014
---------------------------------	-------------

Operator	Thierry Bachmann <input checked="" type="radio"/>
----------	---

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: 1002**

Folder: Product Use

Form: Topography files status for mCC (65)

Generated On: 20 Jul 2016 10:56:43

SODIM file number	08DY0163COHA10200030
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File Status	Rejected 
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Rejection / Error reason	START RTD TOO HIGH
--------------------------	--------------------

Date of analysis DD/MMM/YYYY	18 AUG 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: 1002**

Folder: Product Use

Form: Topography files status for mCC (66)

Generated On: 20 Jul 2016 10:56:43

SODIM file number	08DY0163COHA10200031
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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	18 AUG 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: 1002**

Folder: Product Use

Form: Topography files status for mCC (67)

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Product Use

Form: Topography files status for mCC (68)

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Product Use

Form: Topography files status for mCC (69)

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Product Use

Form: Topography files status for mCC (70)

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Product Use

Form: Topography files status for mCC (71)

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Product Use

Form: Topography files status for mCC (72)

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Product Use

Form: Topography files status for mCC (73)

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Product Use

Form: Topography files status for mCC (74)

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Product Use

Form: Topography files status for mCC (75)

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Product Use

Form: Topography files status for mCC (76)

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Product Use

Form: Topography files status for mCC (77)

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Product Use

Form: Topography files status for mCC (78)

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Product Use

Form: Topography files status for mCC (79)

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Product Use

Form: Topography files status for mCC (80)

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Product Use

Form: Topography files status for mCC (81)

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Product Use

Form: Topography files status for mCC (82)

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Product Use

Form: Topography files status for mCC (83)

Generated On: 20 Jul 2016 10:56:43

SODIM file number	08DY0163COHA30200001
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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	15 AUG 2014
---------------------------------	-------------

Operator	Thierry Bachmann <input checked="" type="radio"/>
----------	---

Comment	<hr/>
---------	-------

Modified File Number	<hr/>
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Product Use

Form: Topography files status for mCC (84)

Generated On: 20 Jul 2016 10:56:43

SODIM file number	08DY0163COHA30200002
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File Status	Rejected 
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Rejection / Error reason	BASELINE DEVIATION
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Date of analysis DD/MMM/YYYY	15 AUG 2014
---------------------------------	-------------

Operator	Thierry Bachmann 
----------	--

Comment	<hr/>
---------	-------

Modified File Number	<hr/>
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Product Use

Form: Product use diary(Paper)

Data signed: (hfarmer1) 26 Mar 2015 13:40:23

Generated On: 20 Jul 2016 10:56:43

Was paper questionnaire used?

No ☒

Reason not done

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Product Use

Form: Product use diary(Paper) (1)

Data signed: (hfarmer1) 26 Mar 2015 13:40:23

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Product Use

Form: Product use diary(Paper) (1)

Data signed: (hfarmer1) 26 Mar 2015 13:40:23

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Folder: Adverse Events

Form: Adverse Events Y/N

Data signed: (hfarmer1) 26 Mar 2015 13:40:24

Generated On: 20 Jul 2016 10:56:43

Was there any Adverse Event for this subject?

Yes ☒

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1002

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (hfarmer1) 26 Mar 2015 13:40:24

Generated On: 20 Jul 2016 10:56:43

AE Identifier	001
---------------	-----

Adverse Event	EMESIS
---------------	--------

Start Date	15 JAN 2014
------------	-------------

DD/MMM/YYYY

End Date	15 JAN 2014
----------	-------------

DD/MMM/YYYY

Ongoing at final contact	No <input checked="" type="radio"/>
--------------------------	-------------------------------------

Severity	Mild Adverse Event <input checked="" type="radio"/>
----------	---

Serious AE	No <input checked="" type="radio"/>
------------	-------------------------------------

Seriousness Criteria

Treatment given	No <input checked="" type="radio"/>
-----------------	-------------------------------------

AE related to Study Procedure	Not Related <input checked="" type="radio"/>
-------------------------------	--

Relationship to mCC/THS	Not Related <input checked="" type="radio"/>
-------------------------	--

AE expectedness

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (hfarmer1) 26 Mar 2015 13:40:24

Generated On: 20 Jul 2016 10:56:43

Action taken with study product

None ☒

Other action taken

Outcome

Recovered or Resolved ☒

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1002

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (hfarmer1) 26 Mar 2015 13:40:24

Generated On: 20 Jul 2016 10:56:43

AE Identifier	002
---------------	-----

Adverse Event	HEADACHE
---------------	----------

Start Date	15 JAN 2014
------------	-------------

DD/MMM/YYYY

End Date	16 JAN 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: 1002**

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (hfarmer1) 26 Mar 2015 13:40:24

Generated On: 20 Jul 2016 10:56:43

Action taken with study product

None ☒

Other action taken

Outcome

Recovered or Resolved ☒

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1002

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (hfarmer1) 26 Mar 2015 13:40:24

Generated On: 20 Jul 2016 10:56:43

AE Identifier	003
---------------	-----

Adverse Event	NAUSEA
---------------	--------

Start Date	15 JAN 2014
------------	-------------

DD/MMM/YYYY

End Date	15 JAN 2014
----------	-------------

DD/MMM/YYYY

Ongoing at final contact	No <input checked="" type="radio"/>
--------------------------	-------------------------------------

Severity	Mild Adverse Event <input checked="" type="radio"/>
----------	---

Serious AE	No <input checked="" type="radio"/>
------------	-------------------------------------

Seriousness Criteria

Treatment given	No <input checked="" type="radio"/>
-----------------	-------------------------------------

AE related to Study Procedure	Not Related <input checked="" type="radio"/>
-------------------------------	--

Relationship to mCC/THS	Not Related <input checked="" type="radio"/>
-------------------------	--

AE expectedness

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (hfarmer1) 26 Mar 2015 13:40:24

Generated On: 20 Jul 2016 10:56:43

Action taken with study product

None ☒

Other action taken

Outcome

Recovered or Resolved ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Folder: Previous and Concomitant Medication

Form: Previous and Concomitant Medication Y/N

Data signed: (hfarmer1) 26 Mar 2015 13:40:24

Generated On: 20 Jul 2016 10:56:43

Has the subject taken previous or concomitant
medication?

Yes ☒

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1002

Folder: Previous and Concomitant Medication

Form: Previous and Concomitant Medication (1)

Data signed: (hfarmer1) 26 Mar 2015 13:40:24

Generated On: 20 Jul 2016 10:56:43

Brand Name	LIDOCAINE HCL
------------	---------------

Start Date DD/MMM/YYYY	22 JAN 2014
---------------------------	-------------

Stop Date DD/MMM/YYYY	22 JAN 2014
--------------------------	-------------

Ongoing at final contact	False
--------------------------	-------

Total Daily dose - Dose	1
-------------------------	---

Total Daily dose - Unit	Other Dosing Unit <input checked="" type="radio"/>
-------------------------	--

Route	Topical Route of Administration <input checked="" type="radio"/>
-------	--

Indication	ANESTHETIC FOR LEFT NOSTRIL
------------	-----------------------------

Concomitant Disease Number	<hr/>
----------------------------	-------

AE Number	<hr/>
-----------	-------

Other	<hr/>
-------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Form: Product use diary (1)

Data signed: (hcoleman1) 18 Jun 2015 19:27:29

Generated On: 20 Jul 2016 10:56:43

Date of Birth

(b) (6)

Date of completion
DD/MMM/YYYY

2014 JAN 22

Time of completion
hh:mm

19:51

Date the questionnaire was completed for
DD/MMM/YYYY

2014 JAN 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?

14

What NRT product did you used today?

Not Applicable ☒

How many times did you use an inhaler today?

-9

How many times did you use a nasal spray today?

-9

How many gums did you use today?

-9

How many lozenges did you use today?

-9

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1002

Form: Product use diary (1)

Data signed: (hcoleman1) 18 Jun 2015 19:27:29

Generated On: 20 Jul 2016 10:56:43

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: 1002

Form: Product use diary (2)

Data signed: (hcoleman1) 18 Jun 2015 19:27:29

Generated On: 20 Jul 2016 10:56:43

Date of Birth

(b) (6)

Date of completion
DD/MMM/YYYY

2014 JAN 23

Time of completion
hh:mm

22:01

Date the questionnaire was completed for
DD/MMM/YYYY

2014 JAN 23

Assessment Status

Completed ☒

What tobacco/nicotine product did you use today?

CC ☒

How many THS 2.2 tobacco sticks did you use today?

-9

How many CC/ roll-your-own did you smoke today?

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: 1002**

Form: Product use diary (2)

Data signed: (hcoleman1) 18 Jun 2015 19:27:29

Generated On: 20 Jul 2016 10:56:43

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: 1002

Form: Product use diary (3)

Data signed: (hcoleman1) 18 Jun 2015 19:27:29

Generated On: 20 Jul 2016 10:56:43

Date of Birth	(b) (6)
Date of completion DD/MMM/YYYY	2014 JAN 24
Time of completion hh:mm	19:11
Date the questionnaire was completed for DD/MMM/YYYY	2014 JAN 24
Assessment Status	Completed <input checked="" type="radio"/>
What tobacco/nicotine product did you use today?	CC <input checked="" type="radio"/>
How many THS 2.2 tobacco sticks did you use today?	-9
How many CC/ roll-your-own did you smoke today?	18
What NRT product did you used today?	Not Applicable <input checked="" type="radio"/>
How many times did you use an inhaler today?	-9
How many times did you use a nasal spray today?	-9
How many gums did you use today?	-9
How many lozenges did you use today?	-9

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1002

Form: Product use diary (3)

Data signed: (hcoleman1) 18 Jun 2015 19:27:29

Generated On: 20 Jul 2016 10:56:43

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: 1002

Form: Product use diary (4)

Data signed: (hcoleman1) 18 Jun 2015 19:27:29

Generated On: 20 Jul 2016 10:56:43

Date of Birth	(b) (6)
Date of completion DD/MMM/YYYY	2014 JAN 25
Time of completion hh:mm	19:05
Date the questionnaire was completed for DD/MMM/YYYY	2014 JAN 25
Assessment Status	Completed <input checked="" type="radio"/>
What tobacco/nicotine product did you use today?	CC <input checked="" type="radio"/>
How many THS 2.2 tobacco sticks did you use today?	-9
How many CC/ roll-your-own did you smoke today?	12
What NRT product did you used today?	Not Applicable <input checked="" type="radio"/>
How many times did you use an inhaler today?	-9
How many times did you use a nasal spray today?	-9
How many gums did you use today?	-9
How many lozenges did you use today?	-9

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1002

Form: Product use diary (4)

Data signed: (hcoleman1) 18 Jun 2015 19:27:29

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Form: Product use diary (5)

Data signed: (hcoleman1) 18 Jun 2015 19:27:29

Generated On: 20 Jul 2016 10:56:43

Date of Birth	(b) (6)
Date of completion DD/MMM/YYYY	2014 JAN 26
Time of completion hh:mm	19:27
Date the questionnaire was completed for DD/MMM/YYYY	2014 JAN 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?	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: 1002

Form: Product use diary (5)

Data signed: (hcoleman1) 18 Jun 2015 19:27:29

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Form: Product use diary (6)

Data signed: (hcoleman1) 18 Jun 2015 19:27:29

Generated On: 20 Jul 2016 10:56:43

Date of Birth	(b) (6)
Date of completion DD/MMM/YYYY	2014 JAN 27
Time of completion hh:mm	20:00
Date the questionnaire was completed for DD/MMM/YYYY	2014 JAN 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?	11
What NRT product did you used today?	Not Applicable <input checked="" type="radio"/>
How many times did you use an inhaler today?	-9
How many times did you use a nasal spray today?	-9
How many gums did you use today?	-9
How many lozenges did you use today?	-9

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1002

Form: Product use diary (6)

Data signed: (hcoleman1) 18 Jun 2015 19:27:29

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Form: Product use diary (7)

Data signed: (hcoleman1) 18 Jun 2015 19:27:29

Generated On: 20 Jul 2016 10:56:43

Date of Birth	(b) (6)
Date of completion DD/MMM/YYYY	2014 JAN 28
Time of completion hh:mm	20:01
Date the questionnaire was completed for DD/MMM/YYYY	2014 JAN 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?	18
What NRT product did you used today?	Not Applicable <input checked="" type="radio"/>
How many times did you use an inhaler today?	-9
How many times did you use a nasal spray today?	-9
How many gums did you use today?	-9
How many lozenges did you use today?	-9

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1002

Form: Product use diary (7)

Data signed: (hcoleman1) 18 Jun 2015 19:27:29

Generated On: 20 Jul 2016 10:56:43

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: 1002

Form: Product use diary (8)

Data signed: (hcoleman1) 18 Jun 2015 19:27:29

Generated On: 20 Jul 2016 10:56:43

Date of Birth

(b) (6)

Date of completion
DD/MMM/YYYY

2014 JAN 29

Time of completion
hh:mm

20:01

Date the questionnaire was completed for
DD/MMM/YYYY

2014 JAN 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?

12

What NRT product did you used today?

Not Applicable ☒

How many times did you use an inhaler today?

-9

How many times did you use a nasal spray today?

-9

How many gums did you use today?

-9

How many lozenges did you use today?

-9

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1002

Form: Product use diary (8)

Data signed: (hcoleman1) 18 Jun 2015 19:27:29

Generated On: 20 Jul 2016 10:56:43

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: 1002

Form: Product use diary (9)

Data signed: (hcoleman1) 18 Jun 2015 19:27:29

Generated On: 20 Jul 2016 10:56:43

Date of Birth	(b) (6)
Date of completion DD/MMM/YYYY	2014 JAN 30
Time of completion hh:mm	20:00
Date the questionnaire was completed for DD/MMM/YYYY	2014 JAN 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?	14
What NRT product did you used today?	Not Applicable <input checked="" type="radio"/>
How many times did you use an inhaler today?	-9
How many times did you use a nasal spray today?	-9
How many gums did you use today?	-9
How many lozenges did you use today?	-9

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1002

Form: Product use diary (9)

Data signed: (hcoleman1) 18 Jun 2015 19:27:29

Generated On: 20 Jul 2016 10:56:43

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: 1002

Form: Product use diary (10)

Data signed: (hcoleman1) 18 Jun 2015 19:27:29

Generated On: 20 Jul 2016 10:56:43

Date of Birth	(b) (6)
Date of completion DD/MMM/YYYY	2014 JAN 31
Time of completion hh:mm	20:00
Date the questionnaire was completed for DD/MMM/YYYY	2014 JAN 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?	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: 1002

Form: Product use diary (10)

Data signed: (hcoleman1) 18 Jun 2015 19:27:29

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Form: Product use diary (11)

Data signed: (hcoleman1) 18 Jun 2015 19:27:29

Generated On: 20 Jul 2016 10:56:43

Date of Birth

(b) (6)

Date of completion
DD/MMM/YYYY

2014 FEB 01

Time of completion
hh:mm

20:00

Date the questionnaire was completed for
DD/MMM/YYYY

2014 FEB 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?

12

What NRT product did you used today?

Not Applicable ☒

How many times did you use an inhaler today?

-9

How many times did you use a nasal spray today?

-9

How many gums did you use today?

-9

How many lozenges did you use today?

-9

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1002

Form: Product use diary (11)

Data signed: (hcoleman1) 18 Jun 2015 19:27:29

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Form: Product use diary (12)

Data signed: (hcoleman1) 18 Jun 2015 19:27:29

Generated On: 20 Jul 2016 10:56:43

Date of Birth	(b) (6)
Date of completion DD/MMM/YYYY	2014 FEB 02
Time of completion hh:mm	19:54
Date the questionnaire was completed for DD/MMM/YYYY	2014 FEB 02
Assessment Status	Completed <input checked="" type="radio"/>
What tobacco/nicotine product did you use today?	CC <input checked="" type="radio"/>
How many THS 2.2 tobacco sticks did you use today?	-9
How many CC/ roll-your-own did you smoke today?	9
What NRT product did you used today?	Not Applicable <input checked="" type="radio"/>
How many times did you use an inhaler today?	-9
How many times did you use a nasal spray today?	-9
How many gums did you use today?	-9
How many lozenges did you use today?	-9

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1002

Form: Product use diary (12)

Data signed: (hcoleman1) 18 Jun 2015 19:27:29

Generated On: 20 Jul 2016 10:56:43

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: 1002

Form: Product use diary (13)

Data signed: (hcoleman1) 18 Jun 2015 19:27:29

Generated On: 20 Jul 2016 10:56:43

Date of Birth	(b) (6)
Date of completion DD/MMM/YYYY	2014 FEB 03
Time of completion hh:mm	20:04
Date the questionnaire was completed for DD/MMM/YYYY	2014 FEB 03
Assessment Status	Completed <input checked="" type="radio"/>
What tobacco/nicotine product did you use today?	CC <input checked="" type="radio"/>
How many THS 2.2 tobacco sticks did you use today?	-9
How many CC/ roll-your-own did you smoke today?	8
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: 1002**

Form: Product use diary (13)

Data signed: (hcoleman1) 18 Jun 2015 19:27:29

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Form: Product use diary (14)

Data signed: (hcoleman1) 18 Jun 2015 19:27:29

Generated On: 20 Jul 2016 10:56:43

Date of Birth	(b) (6)
Date of completion DD/MMM/YYYY	2014 FEB 04
Time of completion hh:mm	19:54
Date the questionnaire was completed for DD/MMM/YYYY	2014 FEB 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?	14
What NRT product did you used today?	Not Applicable <input checked="" type="radio"/>
How many times did you use an inhaler today?	-9
How many times did you use a nasal spray today?	-9
How many gums did you use today?	-9
How many lozenges did you use today?	-9

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1002

Form: Product use diary (14)

Data signed: (hcoleman1) 18 Jun 2015 19:27:29

Generated On: 20 Jul 2016 10:56:43

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: 1002

Form: Product use diary (15)

Data signed: (hcoleman1) 18 Jun 2015 19:27:29

Generated On: 20 Jul 2016 10:56:43

Date of Birth	(b) (6)
Date of completion DD/MMM/YYYY	2014 FEB 05
Time of completion hh:mm	21:02
Date the questionnaire was completed for DD/MMM/YYYY	2014 FEB 05
Assessment Status	Completed <input checked="" type="radio"/>
What tobacco/nicotine product did you use today?	CC <input checked="" type="radio"/>
How many THS 2.2 tobacco sticks did you use today?	-9
How many CC/ roll-your-own did you smoke today?	18
What NRT product did you used today?	Not Applicable <input checked="" type="radio"/>
How many times did you use an inhaler today?	-9
How many times did you use a nasal spray today?	-9
How many gums did you use today?	-9
How many lozenges did you use today?	-9

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Form: Product use diary (15)

Data signed: (hcoleman1) 18 Jun 2015 19:27:29

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Form: Product use diary (16)

Data signed: (hcoleman1) 18 Jun 2015 19:27:29

Generated On: 20 Jul 2016 10:56:43

Date of Birth	(b) (6)
Date of completion DD/MMM/YYYY	2014 FEB 06
Time of completion hh:mm	20:05
Date the questionnaire was completed for DD/MMM/YYYY	2014 FEB 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?	13
What NRT product did you used today?	Not Applicable <input checked="" type="radio"/>
How many times did you use an inhaler today?	-9
How many times did you use a nasal spray today?	-9
How many gums did you use today?	-9
How many lozenges did you use today?	-9

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1002

Form: Product use diary (16)

Data signed: (hcoleman1) 18 Jun 2015 19:27:29

Generated On: 20 Jul 2016 10:56:43

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: 1002

Form: Product use diary (17)

Data signed: (hcoleman1) 18 Jun 2015 19:27:29

Generated On: 20 Jul 2016 10:56:43

Date of Birth	(b) (6)
Date of completion DD/MMM/YYYY	2014 FEB 07
Time of completion hh:mm	20:02
Date the questionnaire was completed for DD/MMM/YYYY	2014 FEB 07
Assessment Status	Completed <input checked="" type="radio"/>
What tobacco/nicotine product did you use today?	CC <input checked="" type="radio"/>
How many THS 2.2 tobacco sticks did you use today?	-9
How many CC/ roll-your-own did you smoke today?	11
What NRT product did you used today?	Not Applicable <input checked="" type="radio"/>
How many times did you use an inhaler today?	-9
How many times did you use a nasal spray today?	-9
How many gums did you use today?	-9
How many lozenges did you use today?	-9

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1002

Form: Product use diary (17)

Data signed: (hcoleman1) 18 Jun 2015 19:27:29

Generated On: 20 Jul 2016 10:56:43

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: 1002

Form: Product use diary (18)

Data signed: (hcoleman1) 18 Jun 2015 19:27:29

Generated On: 20 Jul 2016 10:56:43

Date of Birth	(b) (6)
Date of completion DD/MMM/YYYY	2014 FEB 08
Time of completion hh:mm	20:01
Date the questionnaire was completed for DD/MMM/YYYY	2014 FEB 08
Assessment Status	Completed <input checked="" type="radio"/>
What tobacco/nicotine product did you use today?	CC <input checked="" type="radio"/>
How many THS 2.2 tobacco sticks did you use today?	-9
How many CC/ roll-your-own did you smoke today?	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: 1002**

Form: Product use diary (18)

Data signed: (hcoleman1) 18 Jun 2015 19:27:29

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Form: Product use diary (19)

Data signed: (hcoleman1) 18 Jun 2015 19:27:29

Generated On: 20 Jul 2016 10:56:43

Date of Birth	(b) (6)
Date of completion DD/MMM/YYYY	2014 FEB 09
Time of completion hh:mm	20:00
Date the questionnaire was completed for DD/MMM/YYYY	2014 FEB 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?	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: 1002

Form: Product use diary (19)

Data signed: (hcoleman1) 18 Jun 2015 19:27:29

Generated On: 20 Jul 2016 10:56:43

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: 1002

Form: Product use diary (20)

Data signed: (hcoleman1) 18 Jun 2015 19:27:29

Generated On: 20 Jul 2016 10:56:43

Date of Birth

(b) (6)

Date of completion
DD/MMM/YYYY

2014 FEB 10

Time of completion
hh:mm

20:00

Date the questionnaire was completed for
DD/MMM/YYYY

2014 FEB 10

Assessment Status

Completed ☒

What tobacco/nicotine product did you use today?

CC ☒

How many THS 2.2 tobacco sticks did you use today?

-9

How many CC/ roll-your-own did you smoke today?

19

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: 1002**

Form: Product use diary (20)

Data signed: (hcoleman1) 18 Jun 2015 19:27:29

Generated On: 20 Jul 2016 10:56:43

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: 1002

Form: Product use diary (21)

Data signed: (hcoleman1) 18 Jun 2015 19:27:29

Generated On: 20 Jul 2016 10:56:43

Date of Birth	(b) (6)
Date of completion DD/MMM/YYYY	2014 FEB 11
Time of completion hh:mm	20:00
Date the questionnaire was completed for DD/MMM/YYYY	2014 FEB 11
Assessment Status	Completed <input checked="" type="radio"/>
What tobacco/nicotine product did you use today?	CC <input checked="" type="radio"/>
How many THS 2.2 tobacco sticks did you use today?	-9
How many CC/ roll-your-own did you smoke today?	20
What NRT product did you used today?	Not Applicable <input checked="" type="radio"/>
How many times did you use an inhaler today?	-9
How many times did you use a nasal spray today?	-9
How many gums did you use today?	-9
How many lozenges did you use today?	-9

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Form: Product use diary (21)

Data signed: (hcoleman1) 18 Jun 2015 19:27:29

Generated On: 20 Jul 2016 10:56:43

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: 1002

Form: Product use diary (22)

Data signed: (hcoleman1) 18 Jun 2015 19:27:29

Generated On: 20 Jul 2016 10:56:43

Date of Birth	(b) (6)
Date of completion DD/MMM/YYYY	2014 FEB 12
Time of completion hh:mm	20:00
Date the questionnaire was completed for DD/MMM/YYYY	2014 FEB 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?	18
What NRT product did you used today?	Not Applicable <input checked="" type="radio"/>
How many times did you use an inhaler today?	-9
How many times did you use a nasal spray today?	-9
How many gums did you use today?	-9
How many lozenges did you use today?	-9

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Form: Product use diary (22)

Data signed: (hcoleman1) 18 Jun 2015 19:27:29

Generated On: 20 Jul 2016 10:56:43

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: 1002

Form: Product use diary (23)

Data signed: (hcoleman1) 18 Jun 2015 19:27:29

Generated On: 20 Jul 2016 10:56:43

Date of Birth

(b) (6)

Date of completion
DD/MMM/YYYY

2014 FEB 13

Time of completion
hh:mm

20:00

Date the questionnaire was completed for
DD/MMM/YYYY

2014 FEB 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?

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: 1002

Form: Product use diary (23)

Data signed: (hcoleman1) 18 Jun 2015 19:27:29

Generated On: 20 Jul 2016 10:56:43

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: 1002

Form: Product use diary (24)

Data signed: (hcoleman1) 18 Jun 2015 19:27:29

Generated On: 20 Jul 2016 10:56:43

Date of Birth

(b) (6)

Date of completion
DD/MMM/YYYY

2014 FEB 14

Time of completion
hh:mm

20:00

Date the questionnaire was completed for
DD/MMM/YYYY

2014 FEB 14

Assessment Status

Completed ☒

What tobacco/nicotine product did you use today?

CC ☒

How many THS 2.2 tobacco sticks did you use today?

-9

How many CC/ roll-your-own did you smoke today?

18

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: 1002

Form: Product use diary (24)

Data signed: (hcoleman1) 18 Jun 2015 19:27:29

Generated On: 20 Jul 2016 10:56:43

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: 1002

Form: Product use diary (25)

Data signed: (hcoleman1) 18 Jun 2015 19:27:29

Generated On: 20 Jul 2016 10:56:43

Date of Birth

(b) (6)

Date of completion
DD/MMM/YYYY

2014 FEB 15

Time of completion
hh:mm

19:43

Date the questionnaire was completed for
DD/MMM/YYYY

2014 FEB 15

Assessment Status

Completed ☒

What tobacco/nicotine product did you use today?

CC ☒

How many THS 2.2 tobacco sticks did you use today?

-9

How many CC/ roll-your-own did you smoke today?

8

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: 1002**

Form: Product use diary (25)

Data signed: (hcoleman1) 18 Jun 2015 19:27:29

Generated On: 20 Jul 2016 10:56:43

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: 1002

Form: Product use diary (26)

Data signed: (hcoleman1) 18 Jun 2015 19:27:29

Generated On: 20 Jul 2016 10:56:43

Date of Birth	(b) (6)
Date of completion DD/MMM/YYYY	2014 FEB 16
Time of completion hh:mm	20:00
Date the questionnaire was completed for DD/MMM/YYYY	2014 FEB 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?	12
What NRT product did you used today?	Not Applicable <input checked="" type="radio"/>
How many times did you use an inhaler today?	-9
How many times did you use a nasal spray today?	-9
How many gums did you use today?	-9
How many lozenges did you use today?	-9

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Form: Product use diary (26)

Data signed: (hcoleman1) 18 Jun 2015 19:27:29

Generated On: 20 Jul 2016 10:56:43

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: 1002

Form: Product use diary (27)

Data signed: (hcoleman1) 18 Jun 2015 19:27:29

Generated On: 20 Jul 2016 10:56:43

Date of Birth

(b) (6)

Date of completion
DD/MMM/YYYY

2014 FEB 17

Time of completion
hh:mm

20:01

Date the questionnaire was completed for
DD/MMM/YYYY

2014 FEB 17

Assessment Status

Completed ☒

What tobacco/nicotine product did you use today?

CC ☒

How many THS 2.2 tobacco sticks did you use today?

-9

How many CC/ roll-your-own did you smoke today?

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: 1002

Form: Product use diary (27)

Data signed: (hcoleman1) 18 Jun 2015 19:27:29

Generated On: 20 Jul 2016 10:56:43

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: 1002

Form: Product use diary (28)

Data signed: (hcoleman1) 18 Jun 2015 19:27:29

Generated On: 20 Jul 2016 10:56:43

Date of Birth	(b) (6)
Date of completion DD/MMM/YYYY	2014 FEB 18
Time of completion hh:mm	20:00
Date the questionnaire was completed for DD/MMM/YYYY	2014 FEB 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: 1002

Form: Product use diary (28)

Data signed: (hcoleman1) 18 Jun 2015 19:27:29

Generated On: 20 Jul 2016 10:56:43

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: 1002

Form: Product use diary (29)

Data signed: (hcoleman1) 18 Jun 2015 19:27:29

Generated On: 20 Jul 2016 10:56:43

Date of Birth	(b) (6)
Date of completion DD/MMM/YYYY	2014 FEB 19
Time of completion hh:mm	20:00
Date the questionnaire was completed for DD/MMM/YYYY	2014 FEB 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?	18
What NRT product did you used today?	Not Applicable <input checked="" type="radio"/>
How many times did you use an inhaler today?	-9
How many times did you use a nasal spray today?	-9
How many gums did you use today?	-9
How many lozenges did you use today?	-9

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1002

Form: Product use diary (29)

Data signed: (hcoleman1) 18 Jun 2015 19:27:29

Generated On: 20 Jul 2016 10:56:43

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: 1002

Form: Product use diary (30)

Data signed: (hcoleman1) 18 Jun 2015 19:27:29

Generated On: 20 Jul 2016 10:56:43

Date of Birth	(b) (6)
Date of completion DD/MMM/YYYY	2014 FEB 20
Time of completion hh:mm	20:00
Date the questionnaire was completed for DD/MMM/YYYY	2014 FEB 20
Assessment Status	Completed <input checked="" type="radio"/>
What tobacco/nicotine product did you use today?	CC <input checked="" type="radio"/>
How many THS 2.2 tobacco sticks did you use today?	-9
How many CC/ roll-your-own did you smoke today?	12
What NRT product did you used today?	Not Applicable <input checked="" type="radio"/>
How many times did you use an inhaler today?	-9
How many times did you use a nasal spray today?	-9
How many gums did you use today?	-9
How many lozenges did you use today?	-9

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Form: Product use diary (30)

Data signed: (hcoleman1) 18 Jun 2015 19:27:29

Generated On: 20 Jul 2016 10:56:43

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: 1002

Form: Product use diary (32)

Data signed: (hcoleman1) 18 Jun 2015 19:27:29

Generated On: 20 Jul 2016 10:56:43

Date of Birth	(b) (6)
Date of completion DD/MMM/YYYY	2014 FEB 21
Time of completion hh:mm	20:00
Date the questionnaire was completed for DD/MMM/YYYY	2014 FEB 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?	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: 1002

Form: Product use diary (32)

Data signed: (hcoleman1) 18 Jun 2015 19:27:29

Generated On: 20 Jul 2016 10:56:43

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: 1002

Form: Product use diary (33)

Data signed: (hcoleman1) 18 Jun 2015 19:27:29

Generated On: 20 Jul 2016 10:56:43

Date of Birth

(b) (6)

Date of completion
DD/MMM/YYYY

2014 FEB 22

Time of completion
hh:mm

19:48

Date the questionnaire was completed for
DD/MMM/YYYY

2014 FEB 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?

18

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: 1002

Form: Product use diary (33)

Data signed: (hcoleman1) 18 Jun 2015 19:27:29

Generated On: 20 Jul 2016 10:56:43

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: 1002

Form: Product use diary (34)

Data signed: (hcoleman1) 18 Jun 2015 19:27:29

Generated On: 20 Jul 2016 10:56:43

Date of Birth

(b) (6)

Date of completion
DD/MMM/YYYY

2014 FEB 23

Time of completion
hh:mm

20:00

Date the questionnaire was completed for
DD/MMM/YYYY

2014 FEB 23

Assessment Status

Completed ☒

What tobacco/nicotine product did you use today?

CC ☒

How many THS 2.2 tobacco sticks did you use today?

-9

How many CC/ roll-your-own did you smoke today?

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: 1002

Form: Product use diary (34)

Data signed: (hcoleman1) 18 Jun 2015 19:27:29

Generated On: 20 Jul 2016 10:56:43

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: 1002

Form: Product use diary (35)

Data signed: (hcoleman1) 18 Jun 2015 19:27:29

Generated On: 20 Jul 2016 10:56:43

Date of Birth

(b) (6)

Date of completion
DD/MMM/YYYY

2014 FEB 24

Time of completion
hh:mm

20:02

Date the questionnaire was completed for
DD/MMM/YYYY

2014 FEB 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?

19

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: 1002

Form: Product use diary (35)

Data signed: (hcoleman1) 18 Jun 2015 19:27:29

Generated On: 20 Jul 2016 10:56:43

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: 1002

Form: Product use diary (36)

Data signed: (hcoleman1) 18 Jun 2015 19:27:29

Generated On: 20 Jul 2016 10:56:43

Date of Birth

(b) (6)

Date of completion
DD/MMM/YYYY

2014 FEB 25

Time of completion
hh:mm

20:00

Date the questionnaire was completed for
DD/MMM/YYYY

2014 FEB 25

Assessment Status

Completed ☒

What tobacco/nicotine product did you use today?

CC ☒

How many THS 2.2 tobacco sticks did you use today?

-9

How many CC/ roll-your-own did you smoke today?

18

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: 1002

Form: Product use diary (36)

Data signed: (hcoleman1) 18 Jun 2015 19:27:29

Generated On: 20 Jul 2016 10:56:43

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: 1002

Form: Product use diary (37)

Data signed: (hcoleman1) 18 Jun 2015 19:27:29

Generated On: 20 Jul 2016 10:56:43

Date of Birth

(b) (6)

Date of completion
DD/MMM/YYYY

2014 FEB 26

Time of completion
hh:mm

20:00

Date the questionnaire was completed for
DD/MMM/YYYY

2014 FEB 26

Assessment Status

Completed ☒

What tobacco/nicotine product did you use today?

CC ☒

How many THS 2.2 tobacco sticks did you use today?

-9

How many CC/ roll-your-own did you smoke today?

20

What NRT product did you used today?

Not Applicable ☒

How many times did you use an inhaler today?

-9

How many times did you use a nasal spray today?

-9

How many gums did you use today?

-9

How many lozenges did you use today?

-9

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1002

Form: Product use diary (37)

Data signed: (hcoleman1) 18 Jun 2015 19:27:29

Generated On: 20 Jul 2016 10:56:43

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: 1002

Form: Product use diary (38)

Data signed: (hcoleman1) 18 Jun 2015 19:27:29

Generated On: 20 Jul 2016 10:56:43

Date of Birth

(b) (6)

Date of completion
DD/MMM/YYYY

2014 FEB 27

Time of completion
hh:mm

20:00

Date the questionnaire was completed for
DD/MMM/YYYY

2014 FEB 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?

20

What NRT product did you used today?

Not Applicable ☒

How many times did you use an inhaler today?

-9

How many times did you use a nasal spray today?

-9

How many gums did you use today?

-9

How many lozenges did you use today?

-9

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1002

Form: Product use diary (38)

Data signed: (hcoleman1) 18 Jun 2015 19:27:29

Generated On: 20 Jul 2016 10:56:43

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: 1002

Form: Product use diary (39)

Data signed: (hcoleman1) 18 Jun 2015 19:27:29

Generated On: 20 Jul 2016 10:56:43

Date of Birth

(b) (6)

Date of completion
DD/MMM/YYYY

2014 FEB 28

Time of completion
hh:mm

18:02

Date the questionnaire was completed for
DD/MMM/YYYY

2014 FEB 28

Assessment Status

Completed ☒

What tobacco/nicotine product did you use today?

CC ☒

How many THS 2.2 tobacco sticks did you use today?

-9

How many CC/ roll-your-own did you smoke today?

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: 1002**

Form: Product use diary (39)

Data signed: (hcoleman1) 18 Jun 2015 19:27:29

Generated On: 20 Jul 2016 10:56:43

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: 1002

Form: Product use diary (40)

Data signed: (hcoleman1) 18 Jun 2015 19:27:29

Generated On: 20 Jul 2016 10:56:43

Date of Birth	(b) (6)
Date of completion DD/MMM/YYYY	2014 MAR 01
Time of completion hh:mm	20:00
Date the questionnaire was completed for DD/MMM/YYYY	2014 MAR 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?	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: 1002

Form: Product use diary (40)

Data signed: (hcoleman1) 18 Jun 2015 19:27:29

Generated On: 20 Jul 2016 10:56:43

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: 1002

Form: Product use diary (41)

Data signed: (hcoleman1) 18 Jun 2015 19:27:29

Generated On: 20 Jul 2016 10:56:43

Date of Birth

(b) (6)

Date of completion
DD/MMM/YYYY

2014 MAR 02

Time of completion
hh:mm

20:01

Date the questionnaire was completed for
DD/MMM/YYYY

2014 MAR 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?

12

What NRT product did you used today?

Not Applicable ☒

How many times did you use an inhaler today?

-9

How many times did you use a nasal spray today?

-9

How many gums did you use today?

-9

How many lozenges did you use today?

-9

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1002

Form: Product use diary (41)

Data signed: (hcoleman1) 18 Jun 2015 19:27:29

Generated On: 20 Jul 2016 10:56:43

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: 1002

Form: Product use diary (42)

Data signed: (hcoleman1) 18 Jun 2015 19:27:29

Generated On: 20 Jul 2016 10:56:43

Date of Birth	(b) (6)
Date of completion DD/MMM/YYYY	2014 MAR 03
Time of completion hh:mm	20:00
Date the questionnaire was completed for DD/MMM/YYYY	2014 MAR 03
Assessment Status	Completed <input checked="" type="radio"/>
What tobacco/nicotine product did you use today?	CC <input checked="" type="radio"/>
How many THS 2.2 tobacco sticks did you use today?	-9
How many CC/ roll-your-own did you smoke today?	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: 1002

Form: Product use diary (42)

Data signed: (hcoleman1) 18 Jun 2015 19:27:29

Generated On: 20 Jul 2016 10:56:43

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: 1002

Form: Product use diary (43)

Data signed: (hcoleman1) 18 Jun 2015 19:27:29

Generated On: 20 Jul 2016 10:56:43

Date of Birth

(b) (6)

Date of completion
DD/MMM/YYYY

2014 MAR 04

Time of completion
hh:mm

20:00

Date the questionnaire was completed for
DD/MMM/YYYY

2014 MAR 04

Assessment Status

Completed ☒

What tobacco/nicotine product did you use today?

CC ☒

How many THS 2.2 tobacco sticks did you use today?

-9

How many CC/ roll-your-own did you smoke today?

12

What NRT product did you used today?

Not Applicable ☒

How many times did you use an inhaler today?

-9

How many times did you use a nasal spray today?

-9

How many gums did you use today?

-9

How many lozenges did you use today?

-9

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Form: Product use diary (43)

Data signed: (hcoleman1) 18 Jun 2015 19:27:29

Generated On: 20 Jul 2016 10:56:43

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: 1002

Form: Product use diary (44)

Data signed: (hcoleman1) 18 Jun 2015 19:27:29

Generated On: 20 Jul 2016 10:56:43

Date of Birth

(b) (6)

Date of completion
DD/MMM/YYYY

2014 MAR 05

Time of completion
hh:mm

20:02

Date the questionnaire was completed for
DD/MMM/YYYY

2014 MAR 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?

13

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: 1002

Form: Product use diary (44)

Data signed: (hcoleman1) 18 Jun 2015 19:27:29

Generated On: 20 Jul 2016 10:56:43

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: 1002

Form: Product use diary (45)

Data signed: (hcoleman1) 18 Jun 2015 19:27:29

Generated On: 20 Jul 2016 10:56:43

Date of Birth	(b) (6)
Date of completion DD/MMM/YYYY	2014 MAR 06
Time of completion hh:mm	21:00
Date the questionnaire was completed for DD/MMM/YYYY	2014 MAR 06
Assessment Status	Completed <input checked="" type="radio"/>
What tobacco/nicotine product did you use today?	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: 1002

Form: Product use diary (45)

Data signed: (hcoleman1) 18 Jun 2015 19:27:29

Generated On: 20 Jul 2016 10:56:43

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: 1002

Form: Product use diary (46)

Data signed: (hcoleman1) 18 Jun 2015 19:27:29

Generated On: 20 Jul 2016 10:56:43

Date of Birth	(b) (6)
Date of completion DD/MMM/YYYY	2014 MAR 07
Time of completion hh:mm	20:00
Date the questionnaire was completed for DD/MMM/YYYY	2014 MAR 07
Assessment Status	Completed <input checked="" type="radio"/>
What tobacco/nicotine product did you use today?	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: 1002

Form: Product use diary (46)

Data signed: (hcoleman1) 18 Jun 2015 19:27:29

Generated On: 20 Jul 2016 10:56:43

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: 1002

Form: Product use diary (47)

Data signed: (hcoleman1) 18 Jun 2015 19:27:29

Generated On: 20 Jul 2016 10:56:43

Date of Birth

(b) (6)

Date of completion
DD/MMM/YYYY

2014 MAR 08

Time of completion
hh:mm

20:42

Date the questionnaire was completed for
DD/MMM/YYYY

2014 MAR 08

Assessment Status

Completed ☒

What tobacco/nicotine product did you use today?

CC ☒

How many THS 2.2 tobacco sticks did you use today?

-9

How many CC/ roll-your-own did you smoke today?

18

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: 1002**

Form: Product use diary (47)

Data signed: (hcoleman1) 18 Jun 2015 19:27:29

Generated On: 20 Jul 2016 10:56:43

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: 1002

Form: Product use diary (48)

Data signed: (hcoleman1) 18 Jun 2015 19:27:29

Generated On: 20 Jul 2016 10:56:43

Date of Birth

(b) (6)

Date of completion
DD/MMM/YYYY

2014 MAR 10

Time of completion
hh:mm

12:01

Date the questionnaire was completed for
DD/MMM/YYYY

2014 MAR 09

Assessment Status

Completed ☒

What tobacco/nicotine product did you use today?

CC ☒

How many THS 2.2 tobacco sticks did you use today?

-9

How many CC/ roll-your-own did you smoke today?

20

What NRT product did you used today?

Not Applicable ☒

How many times did you use an inhaler today?

-9

How many times did you use a nasal spray today?

-9

How many gums did you use today?

-9

How many lozenges did you use today?

-9

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1002

Form: Product use diary (48)

Data signed: (hcoleman1) 18 Jun 2015 19:27:29

Generated On: 20 Jul 2016 10:56:43

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: 1002

Form: Product use diary (49)

Data signed: (hcoleman1) 18 Jun 2015 19:27:29

Generated On: 20 Jul 2016 10:56:43

Date of Birth	(b) (6)
Date of completion DD/MMM/YYYY	2014 MAR 10
Time of completion hh:mm	19:59
Date the questionnaire was completed for DD/MMM/YYYY	2014 MAR 10
Assessment Status	Completed <input checked="" type="radio"/>
What tobacco/nicotine product did you use today?	CC <input checked="" type="radio"/>
How many THS 2.2 tobacco sticks did you use today?	-9
How many CC/ roll-your-own did you smoke today?	18
What NRT product did you used today?	Not Applicable <input checked="" type="radio"/>
How many times did you use an inhaler today?	-9
How many times did you use a nasal spray today?	-9
How many gums did you use today?	-9
How many lozenges did you use today?	-9

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Form: Product use diary (49)

Data signed: (hcoleman1) 18 Jun 2015 19:27:29

Generated On: 20 Jul 2016 10:56:43

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: 1002

Form: Product use diary (50)

Data signed: (hcoleman1) 18 Jun 2015 19:27:29

Generated On: 20 Jul 2016 10:56:43

Date of Birth

(b) (6)

Date of completion
DD/MMM/YYYY

2014 MAR 11

Time of completion
hh:mm

19:57

Date the questionnaire was completed for
DD/MMM/YYYY

2014 MAR 11

Assessment Status

Completed ☒

What tobacco/nicotine product did you use today?

CC ☒

How many THS 2.2 tobacco sticks did you use today?

-9

How many CC/ roll-your-own did you smoke today?

20

What NRT product did you used today?

Not Applicable ☒

How many times did you use an inhaler today?

-9

How many times did you use a nasal spray today?

-9

How many gums did you use today?

-9

How many lozenges did you use today?

-9

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1002

Form: Product use diary (50)

Data signed: (hcoleman1) 18 Jun 2015 19:27:29

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Form: Product use diary (51)

Data signed: (hcoleman1) 18 Jun 2015 19:27:29

Generated On: 20 Jul 2016 10:56:43

Date of Birth	(b) (6)
Date of completion DD/MMM/YYYY	2014 MAR 12
Time of completion hh:mm	20:00
Date the questionnaire was completed for DD/MMM/YYYY	2014 MAR 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?	18
What NRT product did you used today?	Not Applicable <input checked="" type="radio"/>
How many times did you use an inhaler today?	-9
How many times did you use a nasal spray today?	-9
How many gums did you use today?	-9
How many lozenges did you use today?	-9

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1002

Form: Product use diary (51)

Data signed: (hcoleman1) 18 Jun 2015 19:27:29

Generated On: 20 Jul 2016 10:56:43

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: 1002

Form: Product use diary (52)

Data signed: (hcoleman1) 18 Jun 2015 19:27:29

Generated On: 20 Jul 2016 10:56:43

Date of Birth

(b) (6)

Date of completion
DD/MMM/YYYY

2014 MAR 14

Time of completion
hh:mm

19:57

Date the questionnaire was completed for
DD/MMM/YYYY

2014 MAR 14

Assessment Status

Completed ☒

What tobacco/nicotine product did you use today?

CC ☒

How many THS 2.2 tobacco sticks did you use today?

-9

How many CC/ roll-your-own did you smoke today?

18

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: 1002

Form: Product use diary (52)

Data signed: (hcoleman1) 18 Jun 2015 19:27:29

Generated On: 20 Jul 2016 10:56:43

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: 1002

Form: Product use diary (53)

Data signed: (hcoleman1) 18 Jun 2015 19:27:29

Generated On: 20 Jul 2016 10:56:43

Date of Birth	(b) (6)
Date of completion DD/MMM/YYYY	2014 MAR 15
Time of completion hh:mm	20:00
Date the questionnaire was completed for DD/MMM/YYYY	2014 MAR 15
Assessment Status	Completed <input checked="" type="radio"/>
What tobacco/nicotine product did you use today?	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: 1002

Form: Product use diary (53)

Data signed: (hcoleman1) 18 Jun 2015 19:27:29

Generated On: 20 Jul 2016 10:56:43

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: 1002

Form: Product use diary (54)

Data signed: (hcoleman1) 18 Jun 2015 19:27:29

Generated On: 20 Jul 2016 10:56:43

Date of Birth	(b) (6)
Date of completion DD/MMM/YYYY	2014 MAR 16
Time of completion hh:mm	20:00
Date the questionnaire was completed for DD/MMM/YYYY	2014 MAR 16
Assessment Status	Completed <input checked="" type="radio"/>
What tobacco/nicotine product did you use today?	CC <input checked="" type="radio"/>
How many THS 2.2 tobacco sticks did you use today?	-9
How many CC/ roll-your-own did you smoke today?	18
What NRT product did you used today?	Not Applicable <input checked="" type="radio"/>
How many times did you use an inhaler today?	-9
How many times did you use a nasal spray today?	-9
How many gums did you use today?	-9
How many lozenges did you use today?	-9

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Form: Product use diary (54)

Data signed: (hcoleman1) 18 Jun 2015 19:27:29

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Form: Product use diary (55)

Data signed: (hcoleman1) 18 Jun 2015 19:27:29

Generated On: 20 Jul 2016 10:56:43

Date of Birth

(b) (6)

Date of completion
DD/MMM/YYYY

2014 MAR 17

Time of completion
hh:mm

20:00

Date the questionnaire was completed for
DD/MMM/YYYY

2014 MAR 17

Assessment Status

Completed ☒

What tobacco/nicotine product did you use today?

CC ☒

How many THS 2.2 tobacco sticks did you use today?

-9

How many CC/ roll-your-own did you smoke today?

18

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: 1002

Form: Product use diary (55)

Data signed: (hcoleman1) 18 Jun 2015 19:27:29

Generated On: 20 Jul 2016 10:56:43

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: 1002

Form: Product use diary (56)

Data signed: (hcoleman1) 18 Jun 2015 19:27:29

Generated On: 20 Jul 2016 10:56:43

Date of Birth

(b) (6)

Date of completion
DD/MMM/YYYY

2014 MAR 18

Time of completion
hh:mm

20:01

Date the questionnaire was completed for
DD/MMM/YYYY

2014 MAR 18

Assessment Status

Completed ☒

What tobacco/nicotine product did you use today?

CC ☒

How many THS 2.2 tobacco sticks did you use today?

-9

How many CC/ roll-your-own did you smoke today?

12

What NRT product did you used today?

Not Applicable ☒

How many times did you use an inhaler today?

-9

How many times did you use a nasal spray today?

-9

How many gums did you use today?

-9

How many lozenges did you use today?

-9

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1002

Form: Product use diary (56)

Data signed: (hcoleman1) 18 Jun 2015 19:27:29

Generated On: 20 Jul 2016 10:56:43

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: 1002

Form: Product use diary (57)

Data signed: (hcoleman1) 18 Jun 2015 19:27:29

Generated On: 20 Jul 2016 10:56:43

Date of Birth

(b) (6)

Date of completion
DD/MMM/YYYY

2014 MAR 19

Time of completion
hh:mm

20:00

Date the questionnaire was completed for
DD/MMM/YYYY

2014 MAR 19

Assessment Status

Completed ☒

What tobacco/nicotine product did you use today?

CC ☒

How many THS 2.2 tobacco sticks did you use today?

-9

How many CC/ roll-your-own did you smoke today?

18

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: 1002

Form: Product use diary (57)

Data signed: (hcoleman1) 18 Jun 2015 19:27:29

Generated On: 20 Jul 2016 10:56:43

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: 1002

Form: Product use diary (58)

Data signed: (hcoleman1) 18 Jun 2015 19:27:29

Generated On: 20 Jul 2016 10:56:43

Date of Birth

(b) (6)

Date of completion
DD/MMM/YYYY

2014 MAR 20

Time of completion
hh:mm

20:00

Date the questionnaire was completed for
DD/MMM/YYYY

2014 MAR 20

Assessment Status

Completed ☒

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: 1002

Form: Product use diary (58)

Data signed: (hcoleman1) 18 Jun 2015 19:27:29

Generated On: 20 Jul 2016 10:56:43

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: 1002

Form: Product use diary (59)

Data signed: (hcoleman1) 18 Jun 2015 19:27:29

Generated On: 20 Jul 2016 10:56:43

Date of Birth

(b) (6)

Date of completion
DD/MMM/YYYY

2014 MAR 21

Time of completion
hh:mm

20:00

Date the questionnaire was completed for
DD/MMM/YYYY

2014 MAR 21

Assessment Status

Completed ☒

What tobacco/nicotine product did you use today?

CC ☒

How many THS 2.2 tobacco sticks did you use today?

-9

How many CC/ roll-your-own did you smoke today?

12

What NRT product did you used today?

Not Applicable ☒

How many times did you use an inhaler today?

-9

How many times did you use a nasal spray today?

-9

How many gums did you use today?

-9

How many lozenges did you use today?

-9

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1002

Form: Product use diary (59)

Data signed: (hcoleman1) 18 Jun 2015 19:27:29

Generated On: 20 Jul 2016 10:56:43

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: 1002

Form: Product use diary (60)

Data signed: (hcoleman1) 18 Jun 2015 19:27:29

Generated On: 20 Jul 2016 10:56:43

Date of Birth

(b) (6)

Date of completion
DD/MMM/YYYY

2014 MAR 22

Time of completion
hh:mm

21:00

Date the questionnaire was completed for
DD/MMM/YYYY

2014 MAR 22

Assessment Status

Completed ☒

What tobacco/nicotine product did you use today?

CC ☒

How many THS 2.2 tobacco sticks did you use today?

-9

How many CC/ roll-your-own did you smoke today?

14

What NRT product did you used today?

Not Applicable ☒

How many times did you use an inhaler today?

-9

How many times did you use a nasal spray today?

-9

How many gums did you use today?

-9

How many lozenges did you use today?

-9

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1002

Form: Product use diary (60)

Data signed: (hcoleman1) 18 Jun 2015 19:27:29

Generated On: 20 Jul 2016 10:56:43

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: 1002

Form: Product use diary (61)

Data signed: (hcoleman1) 18 Jun 2015 19:27:29

Generated On: 20 Jul 2016 10:56:43

Date of Birth

(b) (6)

Date of completion
DD/MMM/YYYY

2014 MAR 23

Time of completion
hh:mm

20:00

Date the questionnaire was completed for
DD/MMM/YYYY

2014 MAR 23

Assessment Status

Completed ☒

What tobacco/nicotine product did you use today?

CC ☒

How many THS 2.2 tobacco sticks did you use today?

-9

How many CC/ roll-your-own did you smoke today?

12

What NRT product did you used today?

Not Applicable ☒

How many times did you use an inhaler today?

-9

How many times did you use a nasal spray today?

-9

How many gums did you use today?

-9

How many lozenges did you use today?

-9

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1002

Form: Product use diary (61)

Data signed: (hcoleman1) 18 Jun 2015 19:27:29

Generated On: 20 Jul 2016 10:56:43

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: 1002

Form: Product use diary (62)

Data signed: (hcoleman1) 18 Jun 2015 19:27:29

Generated On: 20 Jul 2016 10:56:43

Date of Birth

(b) (6)

Date of completion
DD/MMM/YYYY

2014 MAR 24

Time of completion
hh:mm

20:00

Date the questionnaire was completed for
DD/MMM/YYYY

2014 MAR 24

Assessment Status

Completed ☒

What tobacco/nicotine product did you use today?

CC ☒

How many THS 2.2 tobacco sticks did you use today?

-9

How many CC/ roll-your-own did you smoke today?

18

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: 1002**

Form: Product use diary (62)

Data signed: (hcoleman1) 18 Jun 2015 19:27:29

Generated On: 20 Jul 2016 10:56:43

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: 1002

Form: Product use diary (63)

Data signed: (hcoleman1) 18 Jun 2015 19:27:29

Generated On: 20 Jul 2016 10:56:43

Date of Birth

(b) (6)

Date of completion
DD/MMM/YYYY

2014 MAR 25

Time of completion
hh:mm

20:00

Date the questionnaire was completed for
DD/MMM/YYYY

2014 MAR 25

Assessment Status

Completed ☒

What tobacco/nicotine product did you use today?

CC ☒

How many THS 2.2 tobacco sticks did you use today?

-9

How many CC/ roll-your-own did you smoke today?

18

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: 1002

Form: Product use diary (63)

Data signed: (hcoleman1) 18 Jun 2015 19:27:29

Generated On: 20 Jul 2016 10:56:43

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: 1002

Form: Product use diary (64)

Data signed: (hcoleman1) 18 Jun 2015 19:27:29

Generated On: 20 Jul 2016 10:56:43

Date of Birth

(b) (6)

Date of completion
DD/MMM/YYYY

2014 MAR 26

Time of completion
hh:mm

20:00

Date the questionnaire was completed for
DD/MMM/YYYY

2014 MAR 26

Assessment Status

Completed ☒

What tobacco/nicotine product did you use today?

CC ☒

How many THS 2.2 tobacco sticks did you use today?

-9

How many CC/ roll-your-own did you smoke today?

18

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: 1002

Form: Product use diary (64)

Data signed: (hcoleman1) 18 Jun 2015 19:27:29

Generated On: 20 Jul 2016 10:56:43

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: 1002

Form: Product use diary (65)

Data signed: (hcoleman1) 18 Jun 2015 19:27:29

Generated On: 20 Jul 2016 10:56:43

Date of Birth

(b) (6)

Date of completion
DD/MMM/YYYY

2014 MAR 27

Time of completion
hh:mm

22:00

Date the questionnaire was completed for
DD/MMM/YYYY

2014 MAR 27

Assessment Status

Completed ☒

What tobacco/nicotine product did you use today?

CC ☒

How many THS 2.2 tobacco sticks did you use today?

-9

How many CC/ roll-your-own did you smoke today?

20

What NRT product did you used today?

Not Applicable ☒

How many times did you use an inhaler today?

-9

How many times did you use a nasal spray today?

-9

How many gums did you use today?

-9

How many lozenges did you use today?

-9

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Form: Product use diary (65)

Data signed: (hcoleman1) 18 Jun 2015 19:27:29

Generated On: 20 Jul 2016 10:56:43

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: 1002

Form: Product use diary (66)

Data signed: (hcoleman1) 18 Jun 2015 19:27:29

Generated On: 20 Jul 2016 10:56:43

Date of Birth

(b) (6)

Date of completion
DD/MMM/YYYY

2014 MAR 28

Time of completion
hh:mm

20:00

Date the questionnaire was completed for
DD/MMM/YYYY

2014 MAR 28

Assessment Status

Completed ☒

What tobacco/nicotine product did you use today?

CC ☒

How many THS 2.2 tobacco sticks did you use today?

-9

How many CC/ roll-your-own did you smoke today?

20

What NRT product did you used today?

Not Applicable ☒

How many times did you use an inhaler today?

-9

How many times did you use a nasal spray today?

-9

How many gums did you use today?

-9

How many lozenges did you use today?

-9

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1002

Form: Product use diary (66)

Data signed: (hcoleman1) 18 Jun 2015 19:27:29

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Form: Product use diary (67)

Data signed: (hcoleman1) 18 Jun 2015 19:27:29

Generated On: 20 Jul 2016 10:56:43

Date of Birth	(b) (6)
Date of completion DD/MMM/YYYY	2014 MAR 29
Time of completion hh:mm	20:00
Date the questionnaire was completed for DD/MMM/YYYY	2014 MAR 29
Assessment Status	Completed <input checked="" type="radio"/>
What tobacco/nicotine product did you use today?	CC <input checked="" type="radio"/>
How many THS 2.2 tobacco sticks did you use today?	-9
How many CC/ roll-your-own did you smoke today?	18
What NRT product did you used today?	Not Applicable <input checked="" type="radio"/>
How many times did you use an inhaler today?	-9
How many times did you use a nasal spray today?	-9
How many gums did you use today?	-9
How many lozenges did you use today?	-9

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1002

Form: Product use diary (67)

Data signed: (hcoleman1) 18 Jun 2015 19:27:29

Generated On: 20 Jul 2016 10:56:43

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: 1002

Form: Product use diary (68)

Data signed: (hcoleman1) 18 Jun 2015 19:27:29

Generated On: 20 Jul 2016 10:56:43

Date of Birth

(b) (6)

Date of completion
DD/MMM/YYYY

2014 MAR 30

Time of completion
hh:mm

20:00

Date the questionnaire was completed for
DD/MMM/YYYY

2014 MAR 30

Assessment Status

Completed ☒

What tobacco/nicotine product did you use today?

CC ☒

How many THS 2.2 tobacco sticks did you use today?

-9

How many CC/ roll-your-own did you smoke today?

18

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: 1002**

Form: Product use diary (68)

Data signed: (hcoleman1) 18 Jun 2015 19:27:29

Generated On: 20 Jul 2016 10:56:43

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: 1002

Form: Product use diary (69)

Data signed: (hcoleman1) 18 Jun 2015 19:27:29

Generated On: 20 Jul 2016 10:56:43

Date of Birth

(b) (6)

Date of completion
DD/MMM/YYYY

2014 APR 01

Time of completion
hh:mm

10:00

Date the questionnaire was completed for
DD/MMM/YYYY

2014 MAR 31

Assessment Status

Completed ☒

What tobacco/nicotine product did you use today?

CC ☒

How many THS 2.2 tobacco sticks did you use today?

-9

How many CC/ roll-your-own did you smoke today?

20

What NRT product did you used today?

Not Applicable ☒

How many times did you use an inhaler today?

-9

How many times did you use a nasal spray today?

-9

How many gums did you use today?

-9

How many lozenges did you use today?

-9

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Form: Product use diary (69)

Data signed: (hcoleman1) 18 Jun 2015 19:27:29

Generated On: 20 Jul 2016 10:56:43

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: 1002

Form: Product use diary (70)

Data signed: (hcoleman1) 18 Jun 2015 19:27:29

Generated On: 20 Jul 2016 10:56:43

Date of Birth

(b) (6)

Date of completion
DD/MMM/YYYY

2014 APR 01

Time of completion
hh:mm

22:01

Date the questionnaire was completed for
DD/MMM/YYYY

2014 APR 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?

20

What NRT product did you used today?

Not Applicable ☒

How many times did you use an inhaler today?

-9

How many times did you use a nasal spray today?

-9

How many gums did you use today?

-9

How many lozenges did you use today?

-9

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1002

Form: Product use diary (70)

Data signed: (hcoleman1) 18 Jun 2015 19:27:29

Generated On: 20 Jul 2016 10:56:43

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: 1002

Form: Product use diary (71)

Data signed: (hcoleman1) 18 Jun 2015 19:27:29

Generated On: 20 Jul 2016 10:56:43

Date of Birth	(b) (6)
Date of completion DD/MMM/YYYY	2014 APR 02
Time of completion hh:mm	20:00
Date the questionnaire was completed for DD/MMM/YYYY	2014 APR 02
Assessment Status	Completed <input checked="" type="radio"/>
What tobacco/nicotine product did you use today?	CC <input checked="" type="radio"/>
How many THS 2.2 tobacco sticks did you use today?	-9
How many CC/ roll-your-own did you smoke today?	18
What NRT product did you used today?	Not Applicable <input checked="" type="radio"/>
How many times did you use an inhaler today?	-9
How many times did you use a nasal spray today?	-9
How many gums did you use today?	-9
How many lozenges did you use today?	-9

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1002**

Form: Product use diary (71)

Data signed: (hcoleman1) 18 Jun 2015 19:27:29

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Form: End of study

Data signed: (hcoleman1) 18 Jun 2015 19:27:28

Generated On: 20 Jul 2016 10:56:43

End of study date

30 APR 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: 1002**

Form: Consent Withdrawal

Data signed: (hfarmer1) 26 Mar 2015 13:37:06

Generated On: 20 Jul 2016 10:56:43

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: 1002**

Form: Withdrawal

Data signed: (hfarmer1) 26 Mar 2015 13:37:06

Generated On: 20 Jul 2016 10:56:43

Date of withdrawal	02 APR 2014 DD/MMM/YYYY
--------------------	-------------------------

Did the subject withdraw it's consent from the main study?	Yes <input checked="" type="radio"/>
--	--------------------------------------

If available, please provide details	SUBJECT WITHDREW CONSENT DUE TO MOVING OUT OF STATE
--------------------------------------	---

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 checked="" type="radio"/>
--	--------------------------------------
