

Subject Case Report Forms

1202 (Prod: Covance Clinical Development Services, Daytona Beach, Florida)

Generated On: 20 Jul 2016 20:43:03

All time stamps listed in this document are displayed in GMT

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Form: Subject

Data signed: (hfarmer1) 27 Mar 2015 14:49:35

Generated On: 20 Jul 2016 20:43:03

Screening number	1202
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Site number	DAY
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Subject Status

Form: Subject Status

Data signed: (hfarmer1) 27 Mar 2015 14:50:00

Generated On: 20 Jul 2016 20:43:03

Date of 'Screen Failed' Event

Date of 'Discontinued From
Enrollment' Event

Randomization Date

13 MAR 2014
DD/MMM/YYYY

Randomization Time

14:40
hour:min 24-hour clock

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Screening

Form: Date of Visit

Data signed: (hfarmer1) 27 Mar 2015 14:50:12

Generated On: 20 Jul 2016 20:43:03

Date of Visit

27 FEB 2014
DD/MMM/YYYY

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Screening

Form: Additional Informed Consent

Data signed: (hfarmer1) 27 Mar 2015 14:50:01

Generated On: 20 Jul 2016 20:43:03

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

Yes ☒

Consent Date

27 FEB 2014
DD/MMM/YYYY

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

Yes ☒

Consent Date

27 FEB 2014
DD/MMM/YYYY

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Screening

Form: Inclusion Criteria

Data signed: (hfarmer1) 27 Mar 2015 14:50:06

Generated On: 20 Jul 2016 20:43:03

*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: 1202**

Folder: Screening

Form: Inclusion Criteria (1)

Data signed: (hfarmer1) 27 Mar 2015 14:50:06

Generated On: 20 Jul 2016 20:43:03

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: 1202**

Folder: Screening

Form: Inclusion Criteria (2)

Data signed: (hfarmer1) 27 Mar 2015 14:50:06

Generated On: 20 Jul 2016 20:43:03

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: 1202

Folder: Screening

Form: Inclusion Criteria (3)

Data signed: (hfarmer1) 27 Mar 2015 14:50:06

Generated On: 20 Jul 2016 20:43:03

Inclusion Criterion Number	3
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Inclusion Criterion	Smoking, apparently healthy subject as judged by the Investigator based on all available assessments from the Screening period/Day of Admission (e.g., safety laboratory, spirometry, vital signs, physical examination, ECG, chest X-ray, and medical history).
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Result	Yes
--------	-----

*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: 1202

Folder: Screening

Form: Inclusion Criteria (4)

Data signed: (hfarmer1) 27 Mar 2015 14:50:06

Generated On: 20 Jul 2016 20:43:03

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: 1202**

Folder: Screening

Form: Inclusion Criteria (5)

Data signed: (hfarmer1) 27 Mar 2015 14:50:06

Generated On: 20 Jul 2016 20:43:03

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: 1202**

Folder: Screening

Form: Inclusion Criteria (6)

Data signed: (hfarmer1) 27 Mar 2015 14:50:06

Generated On: 20 Jul 2016 20:43:03

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Screening

Form: Exclusion Criteria

Data signed: (hfarmer1) 27 Mar 2015 14:50:03

Generated On: 20 Jul 2016 20:43:03

*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: 1202**

Folder: Screening

Form: Exclusion Criteria (1)

Data signed: (hfarmer1) 27 Mar 2015 14:50:03

Generated On: 20 Jul 2016 20:43:03

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: 1202

Folder: Screening

Form: Exclusion Criteria (2)

Data signed: (hfarmer1) 27 Mar 2015 14:50:03

Generated On: 20 Jul 2016 20:43:03

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

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

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

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1202

Folder: Screening

Form: Exclusion Criteria (3)

Data signed: (hfarmer1) 27 Mar 2015 14:50:03

Generated On: 20 Jul 2016 20:43:03

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: 1202**

Folder: Screening

Form: Exclusion Criteria (4)

Data signed: (hfarmer1) 27 Mar 2015 14:50:03

Generated On: 20 Jul 2016 20:43:03

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: 1202**

Folder: Screening

Form: Exclusion Criteria (5)

Data signed: (hfarmer1) 27 Mar 2015 14:50:03

Generated On: 20 Jul 2016 20:43:03

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: 1202**

Folder: Screening

Form: Exclusion Criteria (6)

Data signed: (hfarmer1) 27 Mar 2015 14:50:03

Generated On: 20 Jul 2016 20:43:03

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: 1202**

Folder: Screening

Form: Exclusion Criteria (7)

Data signed: (hfarmer1) 27 Mar 2015 14:50:03

Generated On: 20 Jul 2016 20:43:03

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: 1202

Folder: Screening

Form: Exclusion Criteria (8)

Data signed: (hfarmer1) 27 Mar 2015 14:50:03

Generated On: 20 Jul 2016 20:43:03

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: 1202**

Folder: Screening

Form: Exclusion Criteria (9)

Data signed: (hfarmer1) 27 Mar 2015 14:50:03

Generated On: 20 Jul 2016 20:43:03

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

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1202

Folder: Screening

Form: Exclusion Criteria (10)

Data signed: (hfarmer1) 27 Mar 2015 14:50:03

Generated On: 20 Jul 2016 20:43:03

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: 1202**

Folder: Screening

Form: Exclusion Criteria (11)

Data signed: (hfarmer1) 27 Mar 2015 14:50:03

Generated On: 20 Jul 2016 20:43:03

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: 1202**

Folder: Screening

Form: Exclusion Criteria (12)

Data signed: (hfarmer1) 27 Mar 2015 14:50:03

Generated On: 20 Jul 2016 20:43:03

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: 1202

Folder: Screening

Form: Exclusion Criteria (13)

Data signed: (hfarmer1) 27 Mar 2015 14:50:03

Generated On: 20 Jul 2016 20:43:03

Exclusion Criterion Number	14
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Exclusion Criterion	The subject has a positive alcohol test and/or the subject has a history of alcohol abuse that could interfere with the subject's participation in the study.
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Result	No <input checked="" type="radio"/>
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*If any has been answered Yes, subject must not be included in the study.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Screening

Form: Exclusion Criteria (14)

Data signed: (hfarmer1) 27 Mar 2015 14:50:03

Generated On: 20 Jul 2016 20:43:03

Exclusion Criterion Number	15
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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: 1202**

Folder: Screening

Form: Exclusion Criteria (15)

Data signed: (hfarmer1) 27 Mar 2015 14:50:03

Generated On: 20 Jul 2016 20:43:03

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Screening

Form: Exclusion Criteria (16)

Data signed: (hfarmer1) 27 Mar 2015 14:50:03

Generated On: 20 Jul 2016 20:43:03

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

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: 1202**

Folder: Screening

Form: Exclusion Criteria (17)

Data signed: (hfarmer1) 27 Mar 2015 14:50:03

Generated On: 20 Jul 2016 20:43:03

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: 1202

Folder: Screening

Form: Exclusion Criteria (18)

Data signed: (hfarmer1) 27 Mar 2015 14:50:03

Generated On: 20 Jul 2016 20:43:03

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: 1202**

Folder: Screening

Form: Exclusion Criteria (19)

Data signed: (hfarmer1) 27 Mar 2015 14:50:03

Generated On: 20 Jul 2016 20:43:03

Exclusion Criterion Number	20
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Exclusion Criterion	The subject has participated in a clinical study within 3 months prior to the Screening Visit.
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Result	No
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*If any has been answered Yes, subject must not be included in the study.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Screening

Form: Exclusion Criteria (20)

Data signed: (hfarmer1) 27 Mar 2015 14:50:03

Generated On: 20 Jul 2016 20:43:03

Exclusion Criterion Number	21
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Exclusion Criterion	For women only: Subject is pregnant (does not have negative pregnancy tests at Screening and at Admission) or is breast feeding.
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Result	NA
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*If any has been answered Yes, subject must not be included in the study.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Screening

Form: Exclusion Criteria (21)

Data signed: (hfarmer1) 27 Mar 2015 14:50:03

Generated On: 20 Jul 2016 20:43:03

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

Result	NA
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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: 1202**

Folder: Screening

Form: Demographics

Data signed: (hfarmer1) 27 Mar 2015 14:50:00

Generated On: 20 Jul 2016 20:43:03

Date of Birth	(b) (6)
Sex	Male <input checked="" type="radio"/>
Race	White <input checked="" type="radio"/>
Other, specify	
Ethnicity	Hispanic <input checked="" type="radio"/>
Date the Subject signed the Informed Consent	27 FEB 2014 DD/MMM/YYYY
Time the Subject signed the Informed Consent	08:57 hour:min 24-hour clock
Age(Derived)	35

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Screening

Form: Medical History/Concomitant Disease

Data signed: (hfarmer1) 27 Mar 2015 14:50:08

Generated On: 20 Jul 2016 20:43:03

Date of collection

27 FEB 2014
DD/MMM/YYYY

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

Yes ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Screening

Form: Medical History/Concomitant Disease (1)

Data signed: (hfarmer1) 27 Mar 2015 14:50:08

Generated On: 20 Jul 2016 20:43:03

Date of collection	27 FEB 2014 DD/MMM/YYYY
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Has the subject experienced any past and/ or concomitant diseases?	Yes <input checked="" type="radio"/>
---	--------------------------------------

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

Diagnosis Description	ACNE
-----------------------	------

Onset Date DD/MMM/YYYY	UN UNK 1991
---------------------------	-------------

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

Ongoing?	True
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Screening

Form: Medical History/Concomitant Disease (2)

Data signed: (hfarmer1) 27 Mar 2015 14:50:08

Generated On: 20 Jul 2016 20:43:03

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

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

Number	2
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Diagnosis Description	AMOEBIASIS
-----------------------	------------

Onset Date DD/MMM/YYYY	UN UNK 1998
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Stop Date DD/MMM/YYYY	UN UNK 1998
--------------------------	-------------

Ongoing?	False
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Screening

Form: Vital Signs<Screening/<

Data signed: (hfarmer1) 27 Mar 2015 14:50:12

Generated On: 20 Jul 2016 20:43:03

Were Vitals Signs assessed? Yes ☒

If No, please specify the reason: _____

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

Date of assessment 27 FEB 2014
DD/MMM/YYYY

Time of assessment 09:55
hour:min 24-hour clock

Pulse rate 55
beats per minute

Respiratory rate 16
breaths per minute

Blood Pressure (systolic) 122
mmHg

Blood Pressure (diastolic) 73
mmHg

Vital Signs Position of Subject Supine ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Screening

Form: Physical Examination

Data signed: (hfarmer1) 27 Mar 2015 14:50:08

Generated On: 20 Jul 2016 20:43:03

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

27 FEB 2014
DD/MMM/YYYY

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Screening

Form: Physical Examination (1)

Data signed: (hfarmer1) 27 Mar 2015 14:50:08

Generated On: 20 Jul 2016 20:43:03

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of assessment 27 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: 1202**

Folder: Screening

Form: Physical Examination (2)

Data signed: (hfarmer1) 27 Mar 2015 14:50:08

Generated On: 20 Jul 2016 20:43:03

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

27 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: 1202**

Folder: Screening

Form: Physical Examination (3)

Data signed: (hfarmer1) 27 Mar 2015 14:50:08

Generated On: 20 Jul 2016 20:43:03

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of assessment 27 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: 1202**

Folder: Screening

Form: Physical Examination (4)

Data signed: (hfarmer1) 27 Mar 2015 14:50:08

Generated On: 20 Jul 2016 20:43:03

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of assessment 27 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: 1202**

Folder: Screening

Form: Physical Examination (5)

Data signed: (hfarmer1) 27 Mar 2015 14:50:08

Generated On: 20 Jul 2016 20:43:03

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

27 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: 1202**

Folder: Screening

Form: Physical Examination (6)

Data signed: (hfarmer1) 27 Mar 2015 14:50:08

Generated On: 20 Jul 2016 20:43:03

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of assessment 27 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: 1202**

Folder: Screening

Form: Physical Examination (7)

Data signed: (hfarmer1) 27 Mar 2015 14:50:08

Generated On: 20 Jul 2016 20:43:03

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of assessment 27 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: 1202**

Folder: Screening

Form: Physical Examination (8)

Data signed: (hfarmer1) 27 Mar 2015 14:50:08

Generated On: 20 Jul 2016 20:43:03

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of assessment 27 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: 1202**

Folder: Screening

Form: Physical Examination (9)

Data signed: (hfarmer1) 27 Mar 2015 14:50:08

Generated On: 20 Jul 2016 20:43:03

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of assessment 27 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: 1202**

Folder: Screening

Form: Physical Examination (10)

Data signed: (hfarmer1) 27 Mar 2015 14:50:08

Generated On: 20 Jul 2016 20:43:03

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of assessment 27 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: 1202**

Folder: Screening

Form: Physical Examination (11)

Data signed: (hfarmer1) 27 Mar 2015 14:50:08

Generated On: 20 Jul 2016 20:43:03

Was the physical examination performed? Yes ☐

If No, please specify the reason: _____

Date of assessment 27 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: 1202**

Folder: Screening

Form: Physical Examination (12)

Data signed: (hfarmer1) 27 Mar 2015 14:50:08

Generated On: 20 Jul 2016 20:43:03

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of assessment 27 FEB 2014
DD/MMM/YYYY

System Musculoskeletal ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Screening

Form: Physical Examination (13)

Data signed: (hfarmer1) 27 Mar 2015 14:50:08

Generated On: 20 Jul 2016 20:43:03

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of assessment 27 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: 1202**

Folder: Screening

Form: Physical Examination (14)

Data signed: (hfarmer1) 27 Mar 2015 14:50:08

Generated On: 20 Jul 2016 20:43:03

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

27 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: 1202**

Folder: Screening

Form: Physical Examination (15)

Data signed: (hfarmer1) 27 Mar 2015 14:50:08

Generated On: 20 Jul 2016 20:43:03

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

27 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: 1202**

Folder: Screening

Form: Physical Examination (16)

Data signed: (hfarmer1) 27 Mar 2015 14:50:08

Generated On: 20 Jul 2016 20:43:03

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

27 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: 1202**

Folder: Screening

Form: Physical Examination (17)

Data signed: (hfarmer1) 27 Mar 2015 14:50:08

Generated On: 20 Jul 2016 20:43:03

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

27 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: 1202**

Folder: Screening

Form: Physical Examination (18)

Data signed: (hfarmer1) 27 Mar 2015 14:50:08

Generated On: 20 Jul 2016 20:43:03

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

27 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: 1202**

Folder: Screening

Form: Physical Examination (19)

Data signed: (hfarmer1) 27 Mar 2015 14:50:08

Generated On: 20 Jul 2016 20:43:03

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

27 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: 1202**

Folder: Screening

Form: Advice on the risk of smoking and debriefing

Data signed: (hfarmer1) 27 Mar 2015 14:50:12

Generated On: 20 Jul 2016 20:43:03

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: 1202**

Folder: Screening

Form: Identification of Current Cigarette Brand

Data signed: (hfarmer1) 27 Mar 2015 14:50:11

Generated On: 20 Jul 2016 20:43:03

Date

27 FEB 2014
DD/MMM/YYYY

Brand name

MARLBORO MENTHOL GOLD

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Screening

Form: THS 2.2 menthol product demonstration

Data signed: (hfarmer1) 27 Mar 2015 14:50:12

Generated On: 20 Jul 2016 20:43:03

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: 1202

Folder: Screening

Form: Smoking History

Data signed: (hfarmer1) 27 Mar 2015 14:50:12

Generated On: 20 Jul 2016 20:43:03

Date of Assessment

27 FEB 2014
DD/MMM/YYYY

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

No ☐

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

Yes ☐

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

10 to 19 ☐

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

Yes ☐

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

No ☐

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Screening

Form: Weight and Height

Data signed: (hfarmer1) 27 Mar 2015 14:50:12

Generated On: 20 Jul 2016 20:43:03

Measurement(s) assessed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

27 FEB 2014
DD/MMM/YYYY

Weight

72.2
kg

Height

174
cm

BMI (Derived)

23.8
kg/m2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Screening

Form: ECG (12-Lead Standard)

Data signed: (hfarmer1) 27 Mar 2015 14:50:00

Generated On: 20 Jul 2016 20:43:03

Was the ECG performed? Yes ☒

If No, please specify the reason: _____

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

Position Supine ☒

Heart Rate 50
beats per minute

QRS Interval 102
msec

QT Interval 435
msec

QTcB Interval 399
msec

QTcF Interval 410
msec

PR Interval 159
msec

Interpretation Normal ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Screening

Form: ECG (12-Lead Standard)

Data signed: (hfarmer1) 27 Mar 2015 14:50:00

Generated On: 20 Jul 2016 20:43:03

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: 1202**

Folder: Screening

Form: Spirometry (1)

Data signed: (hfarmer1) 27 Mar 2015 14:50:10

Generated On: 20 Jul 2016 20:43:03

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 27 FEB 2014
DD/MMM/YYYY

Time of assessment 10:37

Predicted FVC value 5.10
L

Best measured FVC value 4.97
L

Percent of predicted FVC value 97
%

Best measured FEV1 value 3.74
L

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Screening

Form: Spirometry (1)

Data signed: (hfarmer1) 27 Mar 2015 14:50:10

Generated On: 20 Jul 2016 20:43:03

Predicted FEV1 value	4.18 L
----------------------	-----------

Percent of predicted FEV1 value	90 %
---------------------------------	---------

Calculated ratio between FEV1/FVC	0.75
-----------------------------------	------

MEF 25/75 value	2.96 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: 1202**

Folder: Screening

Form: Spirometry (2)

Data signed: (hfarmer1) 27 Mar 2015 14:50:10

Generated On: 20 Jul 2016 20:43:03

Was the spirometry performed? Yes ☒

If No, please specify the reason: _____

Category With short-acting bronchodilator ☒

Position SITTING

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

Date of assessment DD/MMM/YYYY 27 FEB 2014

Time of assessment 10:59

Name of bronchodilator ALBUTEROL SULFATE

Dose 180 MCG

Predicted FVC value 5.10 L

Best measured FVC value 5.31 L

Percent of predicted FVC value 104 %

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Screening

Form: Spirometry (2)

Data signed: (hfarmer1) 27 Mar 2015 14:50:10

Generated On: 20 Jul 2016 20:43:03

Best measured FEV1 value	4.10 L
--------------------------	-----------

Predicted FEV1 value	4.18 L
----------------------	-----------

Percent of predicted FEV1 value	98 %
---------------------------------	---------

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

MEF 25/75 value	3.49 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: 1202**

Folder: Screening

Form: Chest X-Ray

Data signed: (hfarmer1) 27 Mar 2015 14:50:13

Generated On: 20 Jul 2016 20:43:03

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

Yes ☒

If No, please specify the reason: _____

Date of assessment

10 MAR 2014
DD/MMM/YYYY

System

Chest ☒

Interpretation

Normal ☒

Clinically significant _____

Abnormal, please specify: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Screening

Form: Haematology

Data signed: (hfarmer1) 27 Mar 2015 14:50:08

Generated On: 20 Jul 2016 20:43:03

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: 1202**

Folder: Screening

Form: Clinical Chemistry

Data signed: (hfarmer1) 27 Mar 2015 14:50:07

Generated On: 20 Jul 2016 20:43:03

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: 1202**

Folder: Screening

Form: Urine analysis

Data signed: (hfarmer1) 27 Mar 2015 14:50:08

Generated On: 20 Jul 2016 20:43:03

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: 1202**

Folder: Screening

Form: Serology for HIV and Hepatitis B and C

Data signed: (hfarmer1) 27 Mar 2015 14:50:08

Generated On: 20 Jul 2016 20:43:03

Category

Serology ☒

Not Done

False

If Not Done, please specify the reason:

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1202

Folder: Screening

Form: Urine Drug Screen

Data signed: (hfarmer1) 27 Mar 2015 14:50:07

Generated On: 20 Jul 2016 20:43:03

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

If Not Done, please specify the reason: _____

Date of sample collection	27 FEB 2014 DD/MMM/YYYY
---------------------------	----------------------------

Time of sample collection	09:43 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: 1202

Folder: Screening

Form: Urine Drug Screen (4)

Data signed: (hfarmer1) 27 Mar 2015 14:50:07

Generated On: 20 Jul 2016 20:43:03

Drug type	Result
Cannabinoids	Negative
Cocaine	Negative
Opiates	Negative

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Screening

Form: Alcohol Test

Data signed: (hfarmer1) 27 Mar 2015 14:50:07

Generated On: 20 Jul 2016 20:43:03

Was the alcohol test performed? Yes ☒

If No, please specify the reason: _____

Method used Breath test ☒

Date of assessment 27 FEB 2014
DD/MMM/YYYY

Time of assessment 09:47
hour:min 24-hour clock

Result Negative ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Screening

Form: Urine Cotinine Test

Data signed: (hfarmer1) 27 Mar 2015 14:50:07

Generated On: 20 Jul 2016 20:43:03

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

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

If Not Done, please specify the reason: _____

Date of Sample Collection	27 FEB 2014 DD/MMM/YYYY
---------------------------	----------------------------

Time of Sample Collection	09:43 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: 1202**

Folder: Screening

Form: Lab-BU-LabCorp CHEMISTRY(27 FEB 2014)

Data signed: (hfarmer1) 27 Mar 2015 14:50:13

Generated On: 20 Jul 2016 20:43:03

Experiment Type

CHEMISTRY

Date of Sample Collection
YYYY/MM/DD

27 FEB 2014

Please document clinically relevant abnormalities in the AE form

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Screening

Form: Lab-BU-LabCorp CHEMISTRY(27 FEB 2014)

Data signed: (hfarmer1) 27 Mar 2015 14:50:13

Generated On: 20 Jul 2016 20:43:03

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

Date of Sample Collection YYYY/MM/DD	27 FEB 2014
---	-------------

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

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

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

Time of Sample Collection	10:28
---------------------------	-------

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

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

Result	92
--------	----

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

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

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

Flag	
------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Screening

Form: Lab-BU-LabCorp CHEMISTRY(27 FEB 2014)

Data signed: (hfarmer1) 27 Mar 2015 14:50:13

Generated On: 20 Jul 2016 20:43:03

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

05857100010

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Screening

Form: Lab-BU-LabCorp (2)

Data signed: (hfarmer1) 27 Mar 2015 14:50:13

Generated On: 20 Jul 2016 20:43:03

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

Date of Sample Collection YYYY/MM/DD	27 FEB 2014
---	-------------

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

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

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

Time of Sample Collection	10:28
---------------------------	-------

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

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

Result	12
--------	----

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

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

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

Flag	
------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Screening

Form: Lab-BU-LabCorp (2)

Data signed: (hfarmer1) 27 Mar 2015 14:50:13

Generated On: 20 Jul 2016 20:43:03

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

05857100010

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Screening

Form: Lab-BU-LabCorp (3)

Data signed: (hfarmer1) 27 Mar 2015 14:50:13

Generated On: 20 Jul 2016 20:43:03

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

Date of Sample Collection YYYY/MM/DD	27 FEB 2014
---	-------------

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

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

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

Time of Sample Collection	10:28
---------------------------	-------

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

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

Result	192
--------	-----

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

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

Upper limit	199
-------------	-----

Flag	
------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Screening

Form: Lab-BU-LabCorp (3)

Data signed: (hfarmer1) 27 Mar 2015 14:50:13

Generated On: 20 Jul 2016 20:43:03

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

05857100010

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Screening

Form: Lab-BU-LabCorp (4)

Data signed: (hfarmer1) 27 Mar 2015 14:50:13

Generated On: 20 Jul 2016 20:43:03

Experiment Type

CHEMISTRY

Date of Sample Collection
YYYY/MM/DD

27 FEB 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male ☒

Time of Sample Collection

10:28

Analyte Name

PROTEIN, TOTAL, SERUM

Code

001073

Result

7.5

Unit

G/DL

Lower limit

6.0

Upper limit

8.5

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Screening

Form: Lab-BU-LabCorp (4)

Data signed: (hfarmer1) 27 Mar 2015 14:50:13

Generated On: 20 Jul 2016 20:43:03

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

05857100010

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Screening

Form: Lab-BU-LabCorp (5)

Data signed: (hfarmer1) 27 Mar 2015 14:50:13

Generated On: 20 Jul 2016 20:43:03

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

Date of Sample Collection YYYY/MM/DD	27 FEB 2014
---	-------------

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

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

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

Time of Sample Collection	10:28
---------------------------	-------

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

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

Result	4.7
--------	-----

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

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

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

Flag	
------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Screening

Form: Lab-BU-LabCorp (5)

Data signed: (hfarmer1) 27 Mar 2015 14:50:13

Generated On: 20 Jul 2016 20:43:03

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

05857100010

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Screening

Form: Lab-BU-LabCorp (6)

Data signed: (hfarmer1) 27 Mar 2015 14:50:13

Generated On: 20 Jul 2016 20:43:03

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

Date of Sample Collection YYYY/MM/DD	27 FEB 2014
---	-------------

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

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

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

Time of Sample Collection	10:28
---------------------------	-------

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

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

Result	0.6
--------	-----

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

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

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

Flag	
------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Screening

Form: Lab-BU-LabCorp (6)

Data signed: (hfarmer1) 27 Mar 2015 14:50:13

Generated On: 20 Jul 2016 20:43:03

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

05857100010

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Screening

Form: Lab-BU-LabCorp (7)

Data signed: (hfarmer1) 27 Mar 2015 14:50:13

Generated On: 20 Jul 2016 20:43:03

Experiment Type

CHEMISTRY

Date of Sample Collection
YYYY/MM/DD

27 FEB 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male ☒

Time of Sample Collection

10:28

Analyte Name

ALKALINE PHOSPHATASE, S

Code

001107

Result

70

Unit

IU/L

Lower limit

39

Upper limit

117

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Screening

Form: Lab-BU-LabCorp (7)

Data signed: (hfarmer1) 27 Mar 2015 14:50:13

Generated On: 20 Jul 2016 20:43:03

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

05857100010

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Screening

Form: Lab-BU-LabCorp (8)

Data signed: (hfarmer1) 27 Mar 2015 14:50:13

Generated On: 20 Jul 2016 20:43:03

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

Date of Sample Collection YYYY/MM/DD	27 FEB 2014
---	-------------

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

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

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

Time of Sample Collection	10:28
---------------------------	-------

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

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

Result	121
--------	-----

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

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

Upper limit	225
-------------	-----

Flag	
------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Screening

Form: Lab-BU-LabCorp (8)

Data signed: (hfarmer1) 27 Mar 2015 14:50:13

Generated On: 20 Jul 2016 20:43:03

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

05857100010

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Screening

Form: Lab-BU-LabCorp (9)

Data signed: (hfarmer1) 27 Mar 2015 14:50:13

Generated On: 20 Jul 2016 20:43:03

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

Date of Sample Collection YYYY/MM/DD	27 FEB 2014
---	-------------

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

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

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

Time of Sample Collection	10:28
---------------------------	-------

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

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

Result	16
--------	----

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

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

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

Flag	
------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Screening

Form: Lab-BU-LabCorp (9)

Data signed: (hfarmer1) 27 Mar 2015 14:50:13

Generated On: 20 Jul 2016 20:43:03

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

05857100010

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Screening

Form: Lab-BU-LabCorp (10)

Data signed: (hfarmer1) 27 Mar 2015 14:50:13

Generated On: 20 Jul 2016 20:43:03

Experiment Type

CHEMISTRY

Date of Sample Collection
YYYY/MM/DD

27 FEB 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male ☒

Time of Sample Collection

10:28

Analyte Name

TRIGLYCERIDES

Code

001172

Result

71

Unit

MG/DL

Lower limit

0

Upper limit

149

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Screening

Form: Lab-BU-LabCorp (10)

Data signed: (hfarmer1) 27 Mar 2015 14:50:13

Generated On: 20 Jul 2016 20:43:03

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

05857100010

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Screening

Form: Lab-BU-LabCorp (11)

Data signed: (hfarmer1) 27 Mar 2015 14:50:13

Generated On: 20 Jul 2016 20:43:03

Experiment Type

CHEMISTRY

Date of Sample Collection
YYYY/MM/DD

27 FEB 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male ☒

Time of Sample Collection

10:28

Analyte Name

POTASSIUM, SERUM

Code

001180

Result

4.1

Unit

MMOL/L

Lower limit

3.5

Upper limit

5.2

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Screening

Form: Lab-BU-LabCorp (11)

Data signed: (hfarmer1) 27 Mar 2015 14:50:13

Generated On: 20 Jul 2016 20:43:03

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

05857100010

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Screening

Form: Lab-BU-LabCorp (12)

Data signed: (hfarmer1) 27 Mar 2015 14:50:13

Generated On: 20 Jul 2016 20:43:03

Experiment Type	CHEMISTRY
Date of Sample Collection YYYY/MM/DD	27 FEB 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Male <input checked="" type="radio"/>
Time of Sample Collection	10:28
Analyte Name	SODIUM, SERUM
Code	001198
Result	142
Unit	MMOL/L
Lower limit	134
Upper limit	144
Flag	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Screening

Form: Lab-BU-LabCorp (12)

Data signed: (hfarmer1) 27 Mar 2015 14:50:13

Generated On: 20 Jul 2016 20:43:03

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

05857100010

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Screening

Form: Lab-BU-LabCorp (13)

Data signed: (hfarmer1) 27 Mar 2015 14:50:13

Generated On: 20 Jul 2016 20:43:03

Experiment Type	CHEMISTRY
Date of Sample Collection YYYY/MM/DD	27 FEB 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Male <input checked="" type="radio"/>
Time of Sample Collection	10:28
Analyte Name	BILIRUBIN, DIRECT
Code	001222
Result	0.20
Unit	MG/DL
Lower limit	0.00
Upper limit	0.40
Flag	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Screening

Form: Lab-BU-LabCorp (13)

Data signed: (hfarmer1) 27 Mar 2015 14:50:13

Generated On: 20 Jul 2016 20:43:03

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

05857100010

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Screening

Form: Lab-BU-LabCorp (14)

Data signed: (hfarmer1) 27 Mar 2015 14:50:13

Generated On: 20 Jul 2016 20:43:03

Experiment Type

CHEMISTRY

Date of Sample Collection
YYYY/MM/DD

27 FEB 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male ☒

Time of Sample Collection

10:28

Analyte Name

CREATININE, SERUM

Code

001370

Result

0.86

Unit

MG/DL

Lower limit

0.76

Upper limit

1.27

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Screening

Form: Lab-BU-LabCorp (14)

Data signed: (hfarmer1) 27 Mar 2015 14:50:13

Generated On: 20 Jul 2016 20:43:03

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

05857100010

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Screening

Form: Lab-BU-LabCorp (15)

Data signed: (hfarmer1) 27 Mar 2015 14:50:13

Generated On: 20 Jul 2016 20:43:03

Experiment Type

CHEMISTRY

Date of Sample Collection
YYYY/MM/DD

27 FEB 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male ☒

Time of Sample Collection

10:28

Analyte Name

ALT (SGPT)

Code

001545

Result

14

Unit

IU/L

Lower limit

0

Upper limit

44

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Screening

Form: Lab-BU-LabCorp (15)

Data signed: (hfarmer1) 27 Mar 2015 14:50:13

Generated On: 20 Jul 2016 20:43:03

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

05857100010

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Screening

Form: Lab-BU-LabCorp (16)

Data signed: (hfarmer1) 27 Mar 2015 14:50:13

Generated On: 20 Jul 2016 20:43:03

Experiment Type

CHEMISTRY

Date of Sample Collection
YYYY/MM/DD

27 FEB 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male ☒

Time of Sample Collection

10:28

Analyte Name

GGT

Code

001958

Result

22

Unit

IU/L

Lower limit

0

Upper limit

65

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Screening

Form: Lab-BU-LabCorp (16)

Data signed: (hfarmer1) 27 Mar 2015 14:50:13

Generated On: 20 Jul 2016 20:43:03

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

05857100010

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Screening

Form: Lab-BU-LabCorp (17)

Data signed: (hfarmer1) 27 Mar 2015 14:50:13

Generated On: 20 Jul 2016 20:43:03

Experiment Type

CHEMISTRY

Date of Sample Collection
YYYY/MM/DD

27 FEB 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male ☒

Time of Sample Collection

10:28

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: 1202**

Folder: Screening

Form: Lab-BU-LabCorp (17)

Data signed: (hfarmer1) 27 Mar 2015 14:50:13

Generated On: 20 Jul 2016 20:43:03

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

05857100010

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Screening

Form: Lab-BU-LabCorp SEROLOGY(27 FEB 2014)

Data signed: (hfarmer1) 27 Mar 2015 14:50:15

Generated On: 20 Jul 2016 20:43:03

Experiment Type

SEROLOGY

Date of Sample Collection
YYYY/MM/DD

27 FEB 2014

Please document clinically relevant abnormalities in the AE form

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Screening

Form: Lab-BU-LabCorp SEROLOGY(27 FEB 2014)

Data signed: (hfarmer1) 27 Mar 2015 14:50:15

Generated On: 20 Jul 2016 20:43:03

Experiment Type

SEROLOGY

Date of Sample Collection
YYYY/MM/DD

27 FEB 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male ☒

Time of Sample Collection

10:28

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: 1202**

Folder: Screening

Form: Lab-BU-LabCorp SEROLOGY(27 FEB 2014)

Data signed: (hfarmer1) 27 Mar 2015 14:50:15

Generated On: 20 Jul 2016 20:43:03

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

05857100010

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Screening

Form: Lab-BU-LabCorp (2)

Data signed: (hfarmer1) 27 Mar 2015 14:50:15

Generated On: 20 Jul 2016 20:43:03

Experiment Type

SEROLOGY

Date of Sample Collection
YYYY/MM/DD

27 FEB 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male ☒

Time of Sample Collection

10:28

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: 1202**

Folder: Screening

Form: Lab-BU-LabCorp (2)

Data signed: (hfarmer1) 27 Mar 2015 14:50:15

Generated On: 20 Jul 2016 20:43:03

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

05857100010

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Screening

Form: Lab-BU-LabCorp (3)

Data signed: (hfarmer1) 27 Mar 2015 14:50:15

Generated On: 20 Jul 2016 20:43:03

Experiment Type

SEROLOGY

Date of Sample Collection
YYYY/MM/DD

27 FEB 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male ☒

Time of Sample Collection

10:28

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: 1202**

Folder: Screening

Form: Lab-BU-LabCorp (3)

Data signed: (hfarmer1) 27 Mar 2015 14:50:15

Generated On: 20 Jul 2016 20:43:03

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

05857100010

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Screening

Form: Lab-BU-LabCorp HEMATOLOGY(27 FEB 2014)

Data signed: (hfarmer1) 27 Mar 2015 14:50:16

Generated On: 20 Jul 2016 20:43:03

Experiment Type

HEMATOLOGY

Date of Sample Collection
YYYY/MM/DD

27 FEB 2014

Please document clinically relevant abnormalities in the AE form

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Screening

Form: Lab-BU-LabCorp HEMATOLOGY(27 FEB 2014)

Data signed: (hfarmer1) 27 Mar 2015 14:50:16

Generated On: 20 Jul 2016 20:43:03

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

Date of Sample Collection YYYY/MM/DD	27 FEB 2014
---	-------------

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

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

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

Time of Sample Collection	10:28
---------------------------	-------

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

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

Result	7.6
--------	-----

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

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

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

Flag	
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Screening

Form: Lab-BU-LabCorp HEMATOLOGY(27 FEB 2014)

Data signed: (hfarmer1) 27 Mar 2015 14:50:16

Generated On: 20 Jul 2016 20:43:03

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

05857100010

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Screening

Form: Lab-BU-LabCorp (2)

Data signed: (hfarmer1) 27 Mar 2015 14:50:16

Generated On: 20 Jul 2016 20:43:03

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

Date of Sample Collection YYYY/MM/DD	27 FEB 2014
---	-------------

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

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

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

Time of Sample Collection	10:28
---------------------------	-------

Analyte Name	RBC
--------------	-----

Code	005033
------	--------

Result	5.30
--------	------

Unit	X10E6/UL
------	----------

Lower limit	4.14
-------------	------

Upper limit	5.80
-------------	------

Flag	
------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Screening

Form: Lab-BU-LabCorp (2)

Data signed: (hfarmer1) 27 Mar 2015 14:50:16

Generated On: 20 Jul 2016 20:43:03

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

05857100010

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Screening

Form: Lab-BU-LabCorp (3)

Data signed: (hfarmer1) 27 Mar 2015 14:50:16

Generated On: 20 Jul 2016 20:43:03

Experiment Type

HEMATOLOGY

Date of Sample Collection
YYYY/MM/DD

27 FEB 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male ☒

Time of Sample Collection

10:28

Analyte Name

HEMOGLOBIN

Code

005041

Result

14.2

Unit

G/DL

Lower limit

12.6

Upper limit

17.7

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Screening

Form: Lab-BU-LabCorp (3)

Data signed: (hfarmer1) 27 Mar 2015 14:50:16

Generated On: 20 Jul 2016 20:43:03

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

05857100010

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Screening

Form: Lab-BU-LabCorp (4)

Data signed: (hfarmer1) 27 Mar 2015 14:50:16

Generated On: 20 Jul 2016 20:43:03

Experiment Type

HEMATOLOGY

Date of Sample Collection
YYYY/MM/DD

27 FEB 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male ☒

Time of Sample Collection

10:28

Analyte Name

HEMATOCRIT

Code

005058

Result

43.0

Unit

%

Lower limit

37.5

Upper limit

51.0

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Screening

Form: Lab-BU-LabCorp (4)

Data signed: (hfarmer1) 27 Mar 2015 14:50:16

Generated On: 20 Jul 2016 20:43:03

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

05857100010

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Screening

Form: Lab-BU-LabCorp (5)

Data signed: (hfarmer1) 27 Mar 2015 14:50:16

Generated On: 20 Jul 2016 20:43:03

Experiment Type	HEMATOLOGY
Date of Sample Collection YYYY/MM/DD	27 FEB 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Male <input checked="" type="radio"/>
Time of Sample Collection	10:28
Analyte Name	MCV
Code	015065
Result	81
Unit	FL
Lower limit	79
Upper limit	97
Flag	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Screening

Form: Lab-BU-LabCorp (5)

Data signed: (hfarmer1) 27 Mar 2015 14:50:16

Generated On: 20 Jul 2016 20:43:03

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

05857100010

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Screening

Form: Lab-BU-LabCorp (6)

Data signed: (hfarmer1) 27 Mar 2015 14:50:16

Generated On: 20 Jul 2016 20:43:03

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

Date of Sample Collection YYYY/MM/DD	27 FEB 2014
---	-------------

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

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

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

Time of Sample Collection	10:28
---------------------------	-------

Analyte Name	MCH
--------------	-----

Code	015073
------	--------

Result	26.8
--------	------

Unit	PG
------	----

Lower limit	26.6
-------------	------

Upper limit	33.0
-------------	------

Flag	
------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Screening

Form: Lab-BU-LabCorp (6)

Data signed: (hfarmer1) 27 Mar 2015 14:50:16

Generated On: 20 Jul 2016 20:43:03

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

05857100010

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Screening

Form: Lab-BU-LabCorp (7)

Data signed: (hfarmer1) 27 Mar 2015 14:50:16

Generated On: 20 Jul 2016 20:43:03

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

Date of Sample Collection YYYY/MM/DD	27 FEB 2014
---	-------------

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

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

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

Time of Sample Collection	10:28
---------------------------	-------

Analyte Name	MCHC
--------------	------

Code	015081
------	--------

Result	33.0
--------	------

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

Lower limit	31.5
-------------	------

Upper limit	35.7
-------------	------

Flag	
------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Screening

Form: Lab-BU-LabCorp (7)

Data signed: (hfarmer1) 27 Mar 2015 14:50:16

Generated On: 20 Jul 2016 20:43:03

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

05857100010

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Screening

Form: Lab-BU-LabCorp (8)

Data signed: (hfarmer1) 27 Mar 2015 14:50:16

Generated On: 20 Jul 2016 20:43:03

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

Date of Sample Collection YYYY/MM/DD	27 FEB 2014
---	-------------

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

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

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

Time of Sample Collection	10:28
---------------------------	-------

Analyte Name	NEUTROPHILS
--------------	-------------

Code	015107
------	--------

Result	51
--------	----

Unit	%
------	---

Lower limit	40
-------------	----

Upper limit	74
-------------	----

Flag	
------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Screening

Form: Lab-BU-LabCorp (8)

Data signed: (hfarmer1) 27 Mar 2015 14:50:16

Generated On: 20 Jul 2016 20:43:03

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

05857100010

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Screening

Form: Lab-BU-LabCorp (9)

Data signed: (hfarmer1) 27 Mar 2015 14:50:16

Generated On: 20 Jul 2016 20:43:03

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

Date of Sample Collection YYYY/MM/DD	27 FEB 2014
---	-------------

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

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

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

Time of Sample Collection	10:28
---------------------------	-------

Analyte Name	LYMPHS
--------------	--------

Code	015123
------	--------

Result	37
--------	----

Unit	%
------	---

Lower limit	14
-------------	----

Upper limit	46
-------------	----

Flag	
------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Screening

Form: Lab-BU-LabCorp (9)

Data signed: (hfarmer1) 27 Mar 2015 14:50:16

Generated On: 20 Jul 2016 20:43:03

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

05857100010

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Screening

Form: Lab-BU-LabCorp (10)

Data signed: (hfarmer1) 27 Mar 2015 14:50:16

Generated On: 20 Jul 2016 20:43:03

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

Date of Sample Collection YYYY/MM/DD	27 FEB 2014
---	-------------

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

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

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

Time of Sample Collection	10:28
---------------------------	-------

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

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

Result	10
--------	----

Unit	%
------	---

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

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

Flag	
------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Screening

Form: Lab-BU-LabCorp (10)

Data signed: (hfarmer1) 27 Mar 2015 14:50:16

Generated On: 20 Jul 2016 20:43:03

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

05857100010

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Screening

Form: Lab-BU-LabCorp (11)

Data signed: (hfarmer1) 27 Mar 2015 14:50:16

Generated On: 20 Jul 2016 20:43:03

Experiment Type

HEMATOLOGY

Date of Sample Collection
YYYY/MM/DD

27 FEB 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male ☒

Time of Sample Collection

10:28

Analyte Name

EOS

Code

015149

Result

1

Unit

%

Lower limit

0

Upper limit

5

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Screening

Form: Lab-BU-LabCorp (11)

Data signed: (hfarmer1) 27 Mar 2015 14:50:16

Generated On: 20 Jul 2016 20:43:03

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

05857100010

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1202

Folder: Screening

Form: Lab-BU-LabCorp (12)

Data signed: (hfarmer1) 27 Mar 2015 14:50:16

Generated On: 20 Jul 2016 20:43:03

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

Date of Sample Collection YYYY/MM/DD	27 FEB 2014
---	-------------

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

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

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

Time of Sample Collection	10:28
---------------------------	-------

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: 1202**

Folder: Screening

Form: Lab-BU-LabCorp (12)

Data signed: (hfarmer1) 27 Mar 2015 14:50:16

Generated On: 20 Jul 2016 20:43:03

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

05857100010

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Screening

Form: Lab-BU-LabCorp (13)

Data signed: (hfarmer1) 27 Mar 2015 14:50:16

Generated On: 20 Jul 2016 20:43:03

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

Date of Sample Collection YYYY/MM/DD	27 FEB 2014
---	-------------

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

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

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

Time of Sample Collection	10:28
---------------------------	-------

Analyte Name	PLATELETS
--------------	-----------

Code	015172
------	--------

Result	293
--------	-----

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

Lower limit	155
-------------	-----

Upper limit	379
-------------	-----

Flag	
------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Screening

Form: Lab-BU-LabCorp (13)

Data signed: (hfarmer1) 27 Mar 2015 14:50:16

Generated On: 20 Jul 2016 20:43:03

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

05857100010

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Screening

Form: Lab-BU-LabCorp (14)

Data signed: (hfarmer1) 27 Mar 2015 14:50:16

Generated On: 20 Jul 2016 20:43:03

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

Date of Sample Collection YYYY/MM/DD	27 FEB 2014
---	-------------

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

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

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

Time of Sample Collection	10:28
---------------------------	-------

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

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

Result	3.9
--------	-----

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

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

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

Flag	
------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Screening

Form: Lab-BU-LabCorp (14)

Data signed: (hfarmer1) 27 Mar 2015 14:50:16

Generated On: 20 Jul 2016 20:43:03

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

05857100010

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Screening

Form: Lab-BU-LabCorp (15)

Data signed: (hfarmer1) 27 Mar 2015 14:50:16

Generated On: 20 Jul 2016 20:43:03

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

Date of Sample Collection YYYY/MM/DD	27 FEB 2014
---	-------------

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

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

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

Time of Sample Collection	10:28
---------------------------	-------

Analyte Name	LYMPHS (ABSOLUTE)
--------------	-------------------

Code	015917
------	--------

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

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

Lower limit	0.7
-------------	-----

Upper limit	3.1
-------------	-----

Flag	
------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Screening

Form: Lab-BU-LabCorp (15)

Data signed: (hfarmer1) 27 Mar 2015 14:50:16

Generated On: 20 Jul 2016 20:43:03

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

05857100010

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Screening

Form: Lab-BU-LabCorp (16)

Data signed: (hfarmer1) 27 Mar 2015 14:50:16

Generated On: 20 Jul 2016 20:43:03

Experiment Type

HEMATOLOGY

Date of Sample Collection
YYYY/MM/DD

27 FEB 2014

Subject Number

(b) (6)

Date of Birth

Gender

Male ☒

Time of Sample Collection

10:28

Analyte Name

MONOCYTES(ABSOLUTE)

Code

015925

Result

0.7

Unit

X10E3/UL

Lower limit

0.1

Upper limit

0.9

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Screening

Form: Lab-BU-LabCorp (16)

Data signed: (hfarmer1) 27 Mar 2015 14:50:16

Generated On: 20 Jul 2016 20:43:03

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

05857100010

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Screening

Form: Lab-BU-LabCorp (17)

Data signed: (hfarmer1) 27 Mar 2015 14:50:16

Generated On: 20 Jul 2016 20:43:03

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

Date of Sample Collection YYYY/MM/DD	27 FEB 2014
---	-------------

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

(b) (6)

Date of Birth	
---------------	--

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

Time of Sample Collection	10:28
---------------------------	-------

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

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

Result	0.1
--------	-----

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

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

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

Flag	
------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Screening

Form: Lab-BU-LabCorp (17)

Data signed: (hfarmer1) 27 Mar 2015 14:50:16

Generated On: 20 Jul 2016 20:43:03

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

05857100010

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Screening

Form: Lab-BU-LabCorp (18)

Data signed: (hfarmer1) 27 Mar 2015 14:50:16

Generated On: 20 Jul 2016 20:43:03

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

Date of Sample Collection YYYY/MM/DD	27 FEB 2014
---	-------------

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

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

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

Time of Sample Collection	10:28
---------------------------	-------

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: 1202**

Folder: Screening

Form: Lab-BU-LabCorp (18)

Data signed: (hfarmer1) 27 Mar 2015 14:50:16

Generated On: 20 Jul 2016 20:43:03

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

05857100010

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Screening

Form: Lab-BU-LabCorp URINALYSIS(27 FEB 2014)

Data signed: (hfarmer1) 27 Mar 2015 14:50:18

Generated On: 20 Jul 2016 20:43:03

Experiment Type

URINALYSIS

Date of Sample Collection
YYYY/MM/DD

27 FEB 2014

Please document clinically relevant abnormalities in the AE form

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Screening

Form: Lab-BU-LabCorp URINALYSIS(27 FEB 2014)

Data signed: (hfarmer1) 27 Mar 2015 14:50:18

Generated On: 20 Jul 2016 20:43:03

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

Date of Sample Collection YYYY/MM/DD	27 FEB 2014
---	-------------

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

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

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

Time of Sample Collection	09:55
---------------------------	-------

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

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

Result	1.005
--------	-------

Unit	
------	--

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

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

Flag	
------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Screening

Form: Lab-BU-LabCorp URINALYSIS(27 FEB 2014)

Data signed: (hfarmer1) 27 Mar 2015 14:50:18

Generated On: 20 Jul 2016 20:43:03

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: 1202**

Folder: Screening

Form: Lab-BU-LabCorp (2)

Data signed: (hfarmer1) 27 Mar 2015 14:50:18

Generated On: 20 Jul 2016 20:43:03

Experiment Type

URINALYSIS

Date of Sample Collection
YYYY/MM/DD

27 FEB 2014

Subject Number

(b) (6)

Date of Birth

Gender

Male ☒

Time of Sample Collection

09:55

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: 1202**

Folder: Screening

Form: Lab-BU-LabCorp (2)

Data signed: (hfarmer1) 27 Mar 2015 14:50:18

Generated On: 20 Jul 2016 20:43:03

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: 1202**

Folder: Screening

Form: Lab-BU-LabCorp (3)

Data signed: (hfarmer1) 27 Mar 2015 14:50:18

Generated On: 20 Jul 2016 20:43:03

Experiment Type

URINALYSIS

Date of Sample Collection
YYYY/MM/DD

27 FEB 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male ☒

Time of Sample Collection

09:55

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: 1202**

Folder: Screening

Form: Lab-BU-LabCorp (3)

Data signed: (hfarmer1) 27 Mar 2015 14:50:18

Generated On: 20 Jul 2016 20:43:03

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: 1202**

Folder: Screening

Form: Lab-BU-LabCorp (4)

Data signed: (hfarmer1) 27 Mar 2015 14:50:18

Generated On: 20 Jul 2016 20:43:03

Experiment Type

URINALYSIS

Date of Sample Collection
YYYY/MM/DD

27 FEB 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male ☒

Time of Sample Collection

09:55

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: 1202**

Folder: Screening

Form: Lab-BU-LabCorp (4)

Data signed: (hfarmer1) 27 Mar 2015 14:50:18

Generated On: 20 Jul 2016 20:43:03

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: 1202**

Folder: Screening

Form: Lab-BU-LabCorp (5)

Data signed: (hfarmer1) 27 Mar 2015 14:50:18

Generated On: 20 Jul 2016 20:43:03

Experiment Type

URINALYSIS

Date of Sample Collection
YYYY/MM/DD

27 FEB 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male ☒

Time of Sample Collection

09:55

Analyte Name

OCCULT BLOOD

Code

13102

Result

NEGATIVE

Unit

Lower limit

NEGATIVE

Upper limit

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Screening

Form: Lab-BU-LabCorp (5)

Data signed: (hfarmer1) 27 Mar 2015 14:50:18

Generated On: 20 Jul 2016 20:43:03

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: 1202**

Folder: Screening

Form: Lab-BU-LabCorp (6)

Data signed: (hfarmer1) 27 Mar 2015 14:50:18

Generated On: 20 Jul 2016 20:43:03

Experiment Type

URINALYSIS

Date of Sample Collection
YYYY/MM/DD

27 FEB 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male ☒

Time of Sample Collection

09:55

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: 1202**

Folder: Screening

Form: Lab-BU-LabCorp (6)

Data signed: (hfarmer1) 27 Mar 2015 14:50:18

Generated On: 20 Jul 2016 20:43:03

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: 1202**

Folder: Screening

Form: Lab-BU-LabCorp (7)

Data signed: (hfarmer1) 27 Mar 2015 14:50:18

Generated On: 20 Jul 2016 20:43:03

Experiment Type

URINALYSIS

Date of Sample Collection
YYYY/MM/DD

27 FEB 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male ☒

Time of Sample Collection

09:55

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: 1202**

Folder: Screening

Form: Lab-BU-LabCorp (7)

Data signed: (hfarmer1) 27 Mar 2015 14:50:18

Generated On: 20 Jul 2016 20:43:03

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: 1202**

Folder: Screening

Form: FTND Questionnaire

Generated On: 20 Jul 2016 20:43:03

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

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

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

Time of assessment	11:09
	hour:min 24-hour clock

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

1. How soon after you wake up do you smoke your first cigarette?	After 60 minutes <input checked="" type="radio"/>
--	---

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

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

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

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

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Screening

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

Data signed: (hfarmer1) 27 Mar 2015 14:50:11

Generated On: 20 Jul 2016 20:43:03

Was paper questionnaire used? Yes ☒

Reason not done _____

Type PROCHASKA STAGE OF
CHANGE QUESTIONNAIRE:
INTENTION TO QUIT
SMOKING

Date of assessment 27 FEB 2014
DD/MMM/YYYY

Time of assessment 09:06
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: 1202**

Folder: Admission (Day -2)

Form: Date of Visit

Data signed: (hfarmer1) 27 Mar 2015 14:50:25

Generated On: 20 Jul 2016 20:43:03

Date of Visit

11 MAR 2014
DD/MMM/YYYY

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Admission (Day -2)

Form: Inclusion Criteria

Data signed: (hfarmer1) 27 Mar 2015 14:50:20

Generated On: 20 Jul 2016 20:43:03

*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: 1202

Folder: Admission (Day -2)

Form: Inclusion Criteria (1)

Data signed: (hfarmer1) 27 Mar 2015 14:50:20

Generated On: 20 Jul 2016 20:43:03

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: 1202

Folder: Admission (Day -2)

Form: Inclusion Criteria (2)

Data signed: (hfarmer1) 27 Mar 2015 14:50:20

Generated On: 20 Jul 2016 20:43:03

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: 1202

Folder: Admission (Day -2)

Form: Inclusion Criteria (3)

Data signed: (hfarmer1) 27 Mar 2015 14:50:20

Generated On: 20 Jul 2016 20:43:03

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: 1202

Folder: Admission (Day -2)

Form: Inclusion Criteria (4)

Data signed: (hfarmer1) 27 Mar 2015 14:50:20

Generated On: 20 Jul 2016 20:43:03

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

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

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

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Admission (Day -2)

Form: Exclusion Criteria

Data signed: (hfarmer1) 27 Mar 2015 14:50:19

Generated On: 20 Jul 2016 20:43:03

*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: 1202**

Folder: Admission (Day -2)

Form: Exclusion Criteria (1)

Data signed: (hfarmer1) 27 Mar 2015 14:50:19

Generated On: 20 Jul 2016 20:43:03

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: 1202

Folder: Admission (Day -2)

Form: Exclusion Criteria (2)

Data signed: (hfarmer1) 27 Mar 2015 14:50:19

Generated On: 20 Jul 2016 20:43:03

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: 1202**

Folder: Admission (Day -2)

Form: Exclusion Criteria (3)

Data signed: (hfarmer1) 27 Mar 2015 14:50:19

Generated On: 20 Jul 2016 20:43:03

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

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

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

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

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1202

Folder: Admission (Day -2)

Form: Exclusion Criteria (4)

Data signed: (hfarmer1) 27 Mar 2015 14:50:19

Generated On: 20 Jul 2016 20:43:03

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: 1202

Folder: Admission (Day -2)

Form: Exclusion Criteria (5)

Data signed: (hfarmer1) 27 Mar 2015 14:50:19

Generated On: 20 Jul 2016 20:43:03

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: 1202

Folder: Admission (Day -2)

Form: Exclusion Criteria (6)

Data signed: (hfarmer1) 27 Mar 2015 14:50:19

Generated On: 20 Jul 2016 20:43:03

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: 1202

Folder: Admission (Day -2)

Form: Exclusion Criteria (7)

Data signed: (hfarmer1) 27 Mar 2015 14:50:19

Generated On: 20 Jul 2016 20:43:03

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: 1202

Folder: Admission (Day -2)

Form: Exclusion Criteria (8)

Data signed: (hfarmer1) 27 Mar 2015 14:50:19

Generated On: 20 Jul 2016 20:43:03

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

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

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

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Admission (Day -2)

Form: Exclusion Criteria (9)

Data signed: (hfarmer1) 27 Mar 2015 14:50:19

Generated On: 20 Jul 2016 20:43:03

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: 1202

Folder: Admission (Day -2)

Form: Exclusion Criteria (10)

Data signed: (hfarmer1) 27 Mar 2015 14:50:19

Generated On: 20 Jul 2016 20:43:03

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

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

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

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Admission (Day -2)

Form: Exclusion Criteria (11)

Data signed: (hfarmer1) 27 Mar 2015 14:50:19

Generated On: 20 Jul 2016 20:43:03

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: 1202**

Folder: Admission (Day -2)

Form: Exclusion Criteria (12)

Data signed: (hfarmer1) 27 Mar 2015 14:50:19

Generated On: 20 Jul 2016 20:43:03

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: 1202**

Folder: Admission (Day -2)

Form: Exclusion Criteria (13)

Data signed: (hfarmer1) 27 Mar 2015 14:50:19

Generated On: 20 Jul 2016 20:43:03

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

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

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

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

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1202

Folder: Admission (Day -2)

Form: Exclusion Criteria (14)

Data signed: (hfarmer1) 27 Mar 2015 14:50:19

Generated On: 20 Jul 2016 20:43:03

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

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

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

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Admission (Day -2)

Form: Vital Signs

Data signed: (hfarmer1) 27 Mar 2015 14:50:25

Generated On: 20 Jul 2016 20:43:03

Were Vitals Signs assessed? Yes ☒

If No, please specify the reason: _____

Has the subject smoked within 15 minutes prior to assessment Yes ☒

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

Pulse rate 53
beats per minute

Respiratory rate 16
breaths per minute

Blood Pressure (systolic) 117
mmHg

Blood Pressure (diastolic) 63
mmHg

Vital Signs Position of Subject Supine ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Admission (Day -2)

Form: Product preference

Data signed: (hfarmer1) 27 Mar 2015 14:50:24

Generated On: 20 Jul 2016 20:43:03

Which Product Arm would you prefer to be randomized
to:

mCC 

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Admission (Day -2)

Form: Advice on the risk of smoking and debriefing

Data signed: (hfarmer1) 27 Mar 2015 14:50:25

Generated On: 20 Jul 2016 20:43:03

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: 1202**

Folder: Admission (Day -2)

Form: Physical Examination

Data signed: (hfarmer1) 27 Mar 2015 14:50:21

Generated On: 20 Jul 2016 20:43:03

Was the physical examination performed?

Yes ☒

If No, please specify the reason:

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Admission (Day -2)

Form: Physical Examination (1)

Data signed: (hfarmer1) 27 Mar 2015 14:50:21

Generated On: 20 Jul 2016 20:43:03

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: 1202**

Folder: Admission (Day -2)

Form: Physical Examination (2)

Data signed: (hfarmer1) 27 Mar 2015 14:50:21

Generated On: 20 Jul 2016 20:43:03

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: 1202

Folder: Admission (Day -2)

Form: Physical Examination (3)

Data signed: (hfarmer1) 27 Mar 2015 14:50:21

Generated On: 20 Jul 2016 20:43:03

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: 1202**

Folder: Admission (Day -2)

Form: Physical Examination (4)

Data signed: (hfarmer1) 27 Mar 2015 14:50:21

Generated On: 20 Jul 2016 20:43:03

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: 1202**

Folder: Admission (Day -2)

Form: Physical Examination (5)

Data signed: (hfarmer1) 27 Mar 2015 14:50:21

Generated On: 20 Jul 2016 20:43:03

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: 1202**

Folder: Admission (Day -2)

Form: Physical Examination (6)

Data signed: (hfarmer1) 27 Mar 2015 14:50:21

Generated On: 20 Jul 2016 20:43:03

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: 1202

Folder: Admission (Day -2)

Form: Physical Examination (7)

Data signed: (hfarmer1) 27 Mar 2015 14:50:21

Generated On: 20 Jul 2016 20:43:03

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: 1202**

Folder: Admission (Day -2)

Form: Physical Examination (8)

Data signed: (hfarmer1) 27 Mar 2015 14:50:21

Generated On: 20 Jul 2016 20:43:03

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: 1202**

Folder: Admission (Day -2)

Form: Physical Examination (9)

Data signed: (hfarmer1) 27 Mar 2015 14:50:21

Generated On: 20 Jul 2016 20:43:03

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: 1202**

Folder: Admission (Day -2)

Form: Physical Examination (10)

Data signed: (hfarmer1) 27 Mar 2015 14:50:21

Generated On: 20 Jul 2016 20:43:03

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: 1202**

Folder: Admission (Day -2)

Form: Physical Examination (11)

Data signed: (hfarmer1) 27 Mar 2015 14:50:21

Generated On: 20 Jul 2016 20:43:03

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: 1202

Folder: Admission (Day -2)

Form: Physical Examination (12)

Data signed: (hfarmer1) 27 Mar 2015 14:50:21

Generated On: 20 Jul 2016 20:43:03

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

System Musculoskeletal ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Admission (Day -2)

Form: Physical Examination (13)

Data signed: (hfarmer1) 27 Mar 2015 14:50:21

Generated On: 20 Jul 2016 20:43:03

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: 1202**

Folder: Admission (Day -2)

Form: Physical Examination (14)

Data signed: (hfarmer1) 27 Mar 2015 14:50:21

Generated On: 20 Jul 2016 20:43:03

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: 1202**

Folder: Admission (Day -2)

Form: Physical Examination (15)

Data signed: (hfarmer1) 27 Mar 2015 14:50:21

Generated On: 20 Jul 2016 20:43:03

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: 1202**

Folder: Admission (Day -2)

Form: Physical Examination (16)

Data signed: (hfarmer1) 27 Mar 2015 14:50:21

Generated On: 20 Jul 2016 20:43:03

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: 1202**

Folder: Admission (Day -2)

Form: Physical Examination (17)

Data signed: (hfarmer1) 27 Mar 2015 14:50:21

Generated On: 20 Jul 2016 20:43:03

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: 1202**

Folder: Admission (Day -2)

Form: Physical Examination (18)

Data signed: (hfarmer1) 27 Mar 2015 14:50:21

Generated On: 20 Jul 2016 20:43:03

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: 1202**

Folder: Admission (Day -2)

Form: Physical Examination (19)

Data signed: (hfarmer1) 27 Mar 2015 14:50:21

Generated On: 20 Jul 2016 20:43:03

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: 1202**

Folder: Admission (Day -2)

Form: Identification of Current Cigarette Brand

Data signed: (hfarmer1) 27 Mar 2015 14:50:24

Generated On: 20 Jul 2016 20:43:03

Brand name

MARLBORO MENTHOL GOLD

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1202

Folder: Admission (Day -2)

Form: THS 2.2 menthol product test

Data signed: (hfarmer1) 27 Mar 2015 14:50:25

Generated On: 20 Jul 2016 20:43:03

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: 1202

Folder: Admission (Day -2)

Form: Smoking History

Data signed: (hfarmer1) 27 Mar 2015 14:50:25

Generated On: 20 Jul 2016 20:43:03

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: 1202**

Folder: Admission (Day -2)

Form: Weight

Data signed: (hfarmer1) 27 Mar 2015 14:50:25

Generated On: 20 Jul 2016 20:43:03

Measurement(s) assessed?

Yes ☒

If No, please specify the reason: _____

Time of assessment

12:58
hour:min 24-hour clock

Weight

72.4
kg

Waist circumference

92
cm

BMI

23.9

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1202

Folder: Admission (Day -2)

Form: Urine Drug Screen

Data signed: (hfarmer1) 27 Mar 2015 14:50:21

Generated On: 20 Jul 2016 20:43:03

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

If Not Done, please specify the reason: _____

Time of sample collection	12:42 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: 1202

Folder: Admission (Day -2)

Form: Urine Drug Screen (6)

Data signed: (hfarmer1) 27 Mar 2015 14:50:21

Generated On: 20 Jul 2016 20:43:03

Drug type	Result
Opiates	Negative

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Admission (Day -2)

Form: Alcohol Test

Data signed: (hfarmer1) 27 Mar 2015 14:50:20

Generated On: 20 Jul 2016 20:43:03

Was the alcohol test performed? Yes ☒

If No, please specify the reason: _____

Method used Breath test ☒

Time of assessment 12:45
hour:min 24-hour clock

Result Negative ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Admission (Day -2)

Form: CO Breath Test

Data signed: (hfarmer1) 27 Mar 2015 14:50:19

Generated On: 20 Jul 2016 20:43:03

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

If Not Done, please specify the reason: _____

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

Result	0
	ppm

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Admission (Day -2)

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

Data signed: (hfarmer1) 27 Mar 2015 14:50:24

Generated On: 20 Jul 2016 20:43:03

Was paper questionnaire used? Yes ☒

Reason not done _____

Type PROCHASKA STAGE OF
CHANGE QUESTIONNAIRE:
INTENTION TO QUIT
SMOKING

Date of assessment 11 MAR 2014
DD/MMM/YYYY

Time of assessment 13:28
hour:min 24-hour clock

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

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

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day -1)

Form: Date of Visit

Data signed: (hfarmer1) 27 Mar 2015 14:50:28

Generated On: 20 Jul 2016 20:43:03

Date of Visit

12 MAR 2014
DD/MMM/YYYY

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day -1)

Form: Vital Signs

Data signed: (hcoleman1) 18 Jun 2015 21:10:22

Generated On: 20 Jul 2016 20:43:03

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

09:44
hour:min 24-hour clock

Pulse rate

59
beats per minute

Respiratory rate

20
breaths per minute

Blood Pressure (systolic)

109
mmHg

Blood Pressure (diastolic)

67
mmHg

Vital Signs Position of Subject

Supine ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day -1)

Form: CoHb Blood Sample

Data signed: (hfarmer1) 27 Mar 2015 14:50:25

Generated On: 20 Jul 2016 20:43:03

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

If Not Done, please specify the reason: _____

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

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

Time hour:min 24-hour clock	20:39
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day -1)

Form: CO Breath Test (1)

Data signed: (hfarmer1) 27 Mar 2015 14:50:25

Generated On: 20 Jul 2016 20:43:03

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	07:04
---	-------

Result(ppm)	7
-------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day -1)

Form: CO Breath Test (2)

Data signed: (hfarmer1) 27 Mar 2015 14:50:25

Generated On: 20 Jul 2016 20:43:03

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	12:25
---	-------

Result(ppm)	9
-------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day -1)

Form: CO Breath Test (3)

Data signed: (hfarmer1) 27 Mar 2015 14:50:25

Generated On: 20 Jul 2016 20:43:03

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

If Not Done, please specify the reason: _____

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

Actual Time of Assessment hour:min 24-hour clock	16:29
---	-------

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day -1)

Form: CO Breath Test (4)

Data signed: (hfarmer1) 27 Mar 2015 14:50:25

Generated On: 20 Jul 2016 20:43:03

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

If Not Done, please specify the reason: _____

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

Actual Time of Assessment hour:min 24-hour clock	20:12
---	-------

Result(ppm)	18
-------------	----

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day -1)

Form: 4 hour urine collection

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

Generated On: 20 Jul 2016 20:43:03

Start Time	10:08
	hour:min 24-hour clock

End Time	14:10
	hour:min 24-hour clock

Volume	402
	mL

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day -1)

Form: Sample Urine Collection (4 Hour collection)

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

Generated On: 20 Jul 2016 20:43:03

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: 1202**

Folder: Baseline (Day -1)

Form: Lab_BU_COHB (1)

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

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05115150001409
----------------	----------------

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

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

Result	5.60
--------	------

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

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

Date of Collection	2014-MAR-12
--------------------	-------------

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day -1)

Form: Lab_BU_COHB (1)

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

Generated On: 20 Jul 2016 20:43:03

Start Day (24 hour urine only)

End Day (24 hour Urine Only)

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1202

Folder: Baseline (Day -1)

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)

Data signed: (hfarmer1) 27 Mar 2015 14:50:28

Generated On: 20 Jul 2016 20:43:03

Date of Birth	(b) (6)
Date of assessment DD/MMM/YYYY	2014 MAR 12 DD/MMM/YYYY
Time of assessment	20:04 hour:min 24-hour clock
Assessment Status	Completed <input type="radio"/>
1. Was smoking satisfying?	Quite a lot <input type="radio"/>
2. Did cigarettes taste good?	Quite a lot <input type="radio"/>
3. Did you enjoy the sensation in your throat and chest?	Moderately <input type="radio"/>
4. Did smoking calm you down?	Moderately <input type="radio"/>
5. Did smoking make you feel more awake?	Not at all <input type="radio"/>
6. Did smoking make you feel less irritable?	Little <input type="radio"/>
7. Did smoking help you concentrate?	Not at all <input type="radio"/>
8. Did smoking reduce your hunger for food?	Quite a lot <input type="radio"/>

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day -1)

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)

Data signed: (hfarmer1) 27 Mar 2015 14:50:28

Generated On: 20 Jul 2016 20:43:03

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

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

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

12. Did you enjoy smoking? Extremely ☐

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day -1)

Form: Behavioral Risk Factor Surveillance System Questionnaire

Data signed: (hfarmer1) 27 Mar 2015 14:50:25

Generated On: 20 Jul 2016 20:43:03

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

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

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

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

Time of assessment	20:43 hour:min 24-hour clock
--------------------	---------------------------------

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

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

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

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day -1)

Form: Behavioral Risk Factor Surveillance System Questionnaire

Data signed: (hfarmer1) 27 Mar 2015 14:50:25

Generated On: 20 Jul 2016 20:43:03

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: 1202

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ)

Data signed: (hfarmer1) 27 Mar 2015 14:50:26

Generated On: 20 Jul 2016 20:43:03

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

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

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

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

Time of assessment	20:46 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?	17 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: 1202**

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ)

Data signed: (hfarmer1) 27 Mar 2015 14:50:26

Generated On: 20 Jul 2016 20:43:03

Months

Days

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

Years 00 Years

Months 00 Months

Days 00 Days

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

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1202

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:50:26

Generated On: 20 Jul 2016 20:43:03

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

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

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

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

Time of assessment	20:46 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?	17 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: 1202

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:50:26

Generated On: 20 Jul 2016 20:43:03

Months

Days

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

Years 00 Years

Months 00 Months

Days 00 Days

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

Time Currently (last 3 months) ☒

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: 1202**

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:50:26

Generated On: 20 Jul 2016 20:43:03

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: 1202

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (2)

Data signed: (hfarmer1) 27 Mar 2015 14:50:26

Generated On: 20 Jul 2016 20:43:03

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

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

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

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

Time of assessment	20:46 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?	17 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: 1202

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (2)

Data signed: (hfarmer1) 27 Mar 2015 14:50:26

Generated On: 20 Jul 2016 20:43:03

Months

Days

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

Years 00 Years

Months 00 Months

Days 00 Days

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

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: 1202**

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (2)

Data signed: (hfarmer1) 27 Mar 2015 14:50:26

Generated On: 20 Jul 2016 20:43:03

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: 1202

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (3)

Data signed: (hfarmer1) 27 Mar 2015 14:50:26

Generated On: 20 Jul 2016 20:43:03

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

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

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

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

Time of assessment	20:46 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?	17 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: 1202

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (3)

Data signed: (hfarmer1) 27 Mar 2015 14:50:26

Generated On: 20 Jul 2016 20:43:03

Months

Days

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

Years

00 Years

Months

00 Months

Days

00 Days

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

Time

5 years ago ☒

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

Manufactured Cigarettes
per day

10

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

None ☒

Hand-rolled Cigarettes
per day

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (3)

Data signed: (hfarmer1) 27 Mar 2015 14:50:26

Generated On: 20 Jul 2016 20:43:03

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: 1202

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (4)

Data signed: (hfarmer1) 27 Mar 2015 14:50:26

Generated On: 20 Jul 2016 20:43:03

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

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

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

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

Time of assessment	20:46 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?	17 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: 1202

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (4)

Data signed: (hfarmer1) 27 Mar 2015 14:50:26

Generated On: 20 Jul 2016 20:43:03

Months

Days

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

Years 00 Years

Months 00 Months

Days 00 Days

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

Time 10 years ago ☒

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

Manufactured Cigarettes per day 10

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

Hand-rolled Cigarettes per day

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (4)

Data signed: (hfarmer1) 27 Mar 2015 14:50:26

Generated On: 20 Jul 2016 20:43:03

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: 1202

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (5)

Data signed: (hfarmer1) 27 Mar 2015 14:50:26

Generated On: 20 Jul 2016 20:43:03

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

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

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

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

Time of assessment	20:46 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?	17 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: 1202**

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (5)

Data signed: (hfarmer1) 27 Mar 2015 14:50:26

Generated On: 20 Jul 2016 20:43:03

Months

Days

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

Years 00 Years

Months 00 Months

Days 00 Days

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

Time 15 years ago ☒

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

Manufactured Cigarettes 5
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: 1202**

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (5)

Data signed: (hfarmer1) 27 Mar 2015 14:50:26

Generated On: 20 Jul 2016 20:43:03

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: 1202

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (6)

Data signed: (hfarmer1) 27 Mar 2015 14:50:26

Generated On: 20 Jul 2016 20:43:03

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

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

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

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

Time of assessment	20:46 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?	17 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: 1202

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (6)

Data signed: (hfarmer1) 27 Mar 2015 14:50:26

Generated On: 20 Jul 2016 20:43:03

Months

Days

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

Years

00 Years

Months

00 Months

Days

00 Days

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

Time

20 years ago ☒

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

Manufactured Cigarettes
per day

2

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: 1202**

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (6)

Data signed: (hfarmer1) 27 Mar 2015 14:50:26

Generated On: 20 Jul 2016 20:43:03

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: 1202

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (7)

Data signed: (hfarmer1) 27 Mar 2015 14:50:26

Generated On: 20 Jul 2016 20:43:03

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

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

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

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

Time of assessment	20:46 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?	17 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: 1202

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (7)

Data signed: (hfarmer1) 27 Mar 2015 14:50:26

Generated On: 20 Jul 2016 20:43:03

Months

Days

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

Years 00 Years

Months 00 Months

Days 00 Days

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

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: 1202**

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (7)

Data signed: (hfarmer1) 27 Mar 2015 14:50:26

Generated On: 20 Jul 2016 20:43:03

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: 1202**

Folder: Baseline (Day -1)

Form: Supplemental Questions

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

Generated On: 20 Jul 2016 20:43:03

Was paper questionnaire used? Yes ☐

Reason not done _____

Date of Assessment 12 MAR 2014
DD/MMM/YYYY

Time of assessment 20:47

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: 1202

Folder: Baseline (Day -1)

Form: Supplemental Questions (1)

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

Generated On: 20 Jul 2016 20:43:03

Was paper questionnaire used? Yes ☐

Reason not done _____

Date of Assessment 12 MAR 2014
DD/MMM/YYYY

Time of assessment 20:47

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 Yes ☐

Comments (open-end) _____

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1202

Folder: Baseline (Day -1)

Form: Supplemental Questions (2)

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

Generated On: 20 Jul 2016 20:43:03

Was paper questionnaire used? Yes ☐

Reason not done _____

Date of Assessment 12 MAR 2014
DD/MMM/YYYY

Time of assessment 20:47

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: 1202**

Folder: Baseline (Day -1)

Form: Supplemental Questions (3)

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

Generated On: 20 Jul 2016 20:43:03

Was paper questionnaire used? Yes ☐

Reason not done _____

Date of Assessment 12 MAR 2014
DD/MMM/YYYY

Time of assessment 20:47

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: 1202

Folder: Baseline (Day -1)

Form: Supplemental Questions (4)

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

Generated On: 20 Jul 2016 20:43:03

Was paper questionnaire used? Yes ☐

Reason not done _____

Date of Assessment 12 MAR 2014
DD/MMM/YYYY

Time of assessment 20:47

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: 1202**

Folder: Baseline (Day -1)

Form: Supplemental Questions (5)

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

Generated On: 20 Jul 2016 20:43:03

Was paper questionnaire used? Yes ☐

Reason not done _____

Date of Assessment 12 MAR 2014
DD/MMM/YYYY

Time of assessment 20:47

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: 1202

Folder: Baseline (Day -1)

Form: Supplemental Questions (6)

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

Generated On: 20 Jul 2016 20:43:03

Was paper questionnaire used? Yes ☐

Reason not done _____

Date of Assessment 12 MAR 2014
DD/MMM/YYYY

Time of assessment 20:47

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: 1202**

Folder: Baseline (Day -1)

Form: Questionnaire on smoking urges (QSU)

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

Generated On: 20 Jul 2016 20:43:03

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

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

Date of assessment	2014 MAR 12
--------------------	-------------

DD/MMM/YYYY

Time of assessment	20:02
--------------------	-------

hour:min 24-hour clock

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

1. I have a desire for a cigarette right now	Do not agree or disagree <input type="radio"/>
--	--

2. Nothing would be better than smoking a cigarette right now	Do not agree or disagree <input type="radio"/>
---	--

3. If it were possible I would probably smoke now	Somewhat agree <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	Do not agree or 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: 1202**

Folder: Baseline (Day -1)

Form: Questionnaire on smoking urges (QSU)

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

Generated On: 20 Jul 2016 20:43:03

7. A cigarette would taste good now Do not agree or disagree ☐

8. I would do almost anything for a cigarette now Do not agree or disagree ☐

9. Smoking would make me less depressed Strongly disagree ☐

10. I am going to smoke as soon as possible Do not agree or disagree ☐

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day -1)

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

Data signed: (hfarmer1) 27 Mar 2015 14:50:30

Generated On: 20 Jul 2016 20:43:03

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day -1)

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

Data signed: (hfarmer1) 27 Mar 2015 14:50:30

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05112450002266
Analyte	HPMA
Sample type	URINE
Result	533
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	-1
Celerion Study Number	AA99128-03
Date of Collection	2014-MAR-12
Timepoint-minutes	
Urine Start Day	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day -1)

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

Data signed: (hfarmer1) 27 Mar 2015 14:50:30

Generated On: 20 Jul 2016 20:43:03

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (CEMA, HPMa, HBMA) (2)

Data signed: (hfarmer1) 27 Mar 2015 14:50:30

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05112450002266
Analyte	CEMA
Sample type	URINE
Result	67.2
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	-1
Celerion Study Number	AA99128-03
Date of Collection	2014-MAR-12
Timepoint-minutes	
Urine Start Day	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (2)

Data signed: (hfarmer1) 27 Mar 2015 14:50:30

Generated On: 20 Jul 2016 20:43:03

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (CEMA, HPMa, HBMA) (3)

Data signed: (hfarmer1) 27 Mar 2015 14:50:30

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05112450002266
Analyte	HBMA
Sample type	URINE
Result	161
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	-1
Celerion Study Number	AA99128-03
Date of Collection	2014-MAR-12
Timepoint-minutes	
Urine Start Day	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (3)

Data signed: (hfarmer1) 27 Mar 2015 14:50:30

Generated On: 20 Jul 2016 20:43:03

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (NNN, NNAL)

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

Generated On: 20 Jul 2016 20:43:03

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (NNN, NNAL) (1)

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

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05112460002691
Analyte	NNAL
Sample type	URINE
Result	.
Result Unit	PG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	-1
Celerion Study Number	AA99128-04
Date of Collection	2014-MAR-12
Timepoint-minutes	
Urine Start Day	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (NNN, NNAL) (1)

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

Generated On: 20 Jul 2016 20:43:03

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (NNN, NNAL) (2)

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

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05112460002691
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Analyte	NNN
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Sample type	URINE
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Result	.
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Result Unit	PG/ML
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Lab Status	OTHER
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Sample comment	ANALYSIS NOT REQUIRED
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Detection method	LC-MS/MS
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Planned time point (Hour)	0
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Day of Visit	-1
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Celerion Study Number	AA99128-04
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Date of Collection	2014-MAR-12
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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: 1202**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (NNN, NNAL) (2)

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

Generated On: 20 Jul 2016 20:43:03

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (HEMA)

Data signed: (hfarmer1) 27 Mar 2015 14:50:30

Generated On: 20 Jul 2016 20:43:03

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (HEMA) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:50:30

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05112470001345
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Analyte	HEMA
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Sample type	URINE
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Result	.
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Result Unit	NG/ML
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Lab Status	OTHER
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Sample comment	ANALYSIS NOT REQUIRED
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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-MAR-12
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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: 1202**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (HEMA) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:50:30

Generated On: 20 Jul 2016 20:43:03

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day -1)

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

Data signed: (hfarmer1) 27 Mar 2015 14:50:31

Generated On: 20 Jul 2016 20:43:03

Sample type

URINE

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1202

Folder: Baseline (Day -1)

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

Data signed: (hfarmer1) 27 Mar 2015 14:50:31

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05112550000254
Analyte	COT
Sample type	URINE
Result	1350
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	-1
Celerion Study Number	AA99128-13
Date of Collection	2014-MAR-12
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day -1)

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

Data signed: (hfarmer1) 27 Mar 2015 14:50:31

Generated On: 20 Jul 2016 20:43:03

Urine Start Day

Urine End Day

-1

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1202

Folder: Baseline (Day -1)

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

Data signed: (hfarmer1) 27 Mar 2015 14:50:31

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05112550000254
Analyte	COT-GLUC
Sample type	URINE
Result	3450
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	-1
Celerion Study Number	AA99128-13
Date of Collection	2014-MAR-12
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day -1)

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

Data signed: (hfarmer1) 27 Mar 2015 14:50:31

Generated On: 20 Jul 2016 20:43:03

Urine Start Day

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day -1)

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(3)**

Data signed: (hfarmer1) 27 Mar 2015 14:50:31

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05112550000254
Analyte	NIC
Sample type	URINE
Result	622
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	-1
Celerion Study Number	AA99128-13
Date of Collection	2014-MAR-12
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day -1)

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(3)**

Data signed: (hfarmer1) 27 Mar 2015 14:50:31

Generated On: 20 Jul 2016 20:43:03

Urine Start Day

Urine End Day

-1

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1202

Folder: Baseline (Day -1)

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

Data signed: (hfarmer1) 27 Mar 2015 14:50:31

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05112550000254
Analyte	NIC-GLUC
Sample type	URINE
Result	510
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	-1
Celerion Study Number	AA99128-13
Date of Collection	2014-MAR-12
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day -1)

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

Data signed: (hfarmer1) 27 Mar 2015 14:50:31

Generated On: 20 Jul 2016 20:43:03

Urine Start Day

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day -1)

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

Data signed: (hfarmer1) 27 Mar 2015 14:50:31

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05112550000254
Analyte	THCOT
Sample type	URINE
Result	1710
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	-1
Celerion Study Number	AA99128-13
Date of Collection	2014-MAR-12
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day -1)

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

Data signed: (hfarmer1) 27 Mar 2015 14:50:31

Generated On: 20 Jul 2016 20:43:03

Urine Start Day

Urine End Day

-1

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1202

Folder: Baseline (Day -1)

Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc) (6)

Data signed: (hfarmer1) 27 Mar 2015 14:50:31

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05112550000254
Analyte	THCOT-GLUC
Sample type	URINE
Result	698
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	-1
Celerion Study Number	AA99128-13
Date of Collection	2014-MAR-12
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day -1)

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(6)**

Data signed: (hfarmer1) 27 Mar 2015 14:50:31

Generated On: 20 Jul 2016 20:43:03

Urine Start Day

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (3-OH BaP)

Data signed: (hfarmer1) 27 Mar 2015 14:50:31

Generated On: 20 Jul 2016 20:43:03

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (3-OH BaP) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:50:31

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05112490001345
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Analyte	3-OH BAP
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Sample type	URINE
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Result	.
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Result Unit	FG/ML
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Lab Status	OTHER
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Sample comment	ANALYSIS NOT REQUIRED
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Detection method	LC-MS/MS
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Planned time point (Hour)	0
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Day of Visit	-1
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Celerion Study Number	AA99128-07
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Date of Collection	2014-MAR-12
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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: 1202**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (3-OH BaP) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:50:31

Generated On: 20 Jul 2016 20:43:03

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP)

Data signed: (hfarmer1) 27 Mar 2015 14:50:31

Generated On: 20 Jul 2016 20:43:03

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:50:31

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05112510001367
Analyte	1-NA
Sample type	URINE
Result	63.3
Result Unit	PG/ML
Lab Status	OTHER
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	-1
Celerion Study Number	AA99128-09
Date of Collection	2014-MAR-12
Timepoint-minutes	
Urine Start Day	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:50:31

Generated On: 20 Jul 2016 20:43:03

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (2)

Data signed: (hfarmer1) 27 Mar 2015 14:50:31

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05112510001367
Analyte	2-NA
Sample type	URINE
Result	15.4
Result Unit	PG/ML
Lab Status	OTHER
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	-1
Celerion Study Number	AA99128-09
Date of Collection	2014-MAR-12
Timepoint-minutes	
Urine Start Day	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (2)

Data signed: (hfarmer1) 27 Mar 2015 14:50:31

Generated On: 20 Jul 2016 20:43:03

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (3)

Data signed: (hfarmer1) 27 Mar 2015 14:50:31

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05112510001367
Analyte	4-ABP
Sample type	URINE
Result	9.42
Result Unit	PG/ML
Lab Status	OTHER
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	-1
Celerion Study Number	AA99128-09
Date of Collection	2014-MAR-12
Timepoint-minutes	
Urine Start Day	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (3)

Data signed: (hfarmer1) 27 Mar 2015 14:50:31

Generated On: 20 Jul 2016 20:43:03

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (4)

Data signed: (hfarmer1) 27 Mar 2015 14:50:31

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05112510001367
Analyte	O-TOL
Sample type	URINE
Result	84.4
Result Unit	PG/ML
Lab Status	OTHER
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	-1
Celerion Study Number	AA99128-09
Date of Collection	2014-MAR-12
Timepoint-minutes	
Urine Start Day	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (4)

Data signed: (hfarmer1) 27 Mar 2015 14:50:31

Generated On: 20 Jul 2016 20:43:03

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (11-dTXb2)

Data signed: (hfarmer1) 27 Mar 2015 14:50:30

Generated On: 20 Jul 2016 20:43:03

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (11-dTXb2) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:50:30

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05112530000428
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Analyte	11-DTXB2
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Sample type	URINE
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Result	.
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Result Unit	PG/ML
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Lab Status	OTHER
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Sample comment	ANALYSIS NOT REQUIRED
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Detection method	LC-MS/MS
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Planned time point (Hour)	0
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Day of Visit	-1
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Celerion Study Number	AA99128-11
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Date of Collection	2014-MAR-12
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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: 1202**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (11-dTXb2) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:50:30

Generated On: 20 Jul 2016 20:43:03

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (iPF2a-III)

Data signed: (hfarmer1) 27 Mar 2015 14:50:30

Generated On: 20 Jul 2016 20:43:03

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (iPF2a-III) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:50:30

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05112540000421
Analyte	IPF2A-III
Sample type	URINE
Result	217
Result Unit	PG/ML
Lab Status	OTHER
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	-1
Celerion Study Number	AA99128-12
Date of Collection	2014-MAR-12
Timepoint-minutes	
Urine Start Day	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (iPF2a-III) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:50:30

Generated On: 20 Jul 2016 20:43:03

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (1-OHP)

Data signed: (hfarmer1) 27 Mar 2015 14:50:31

Generated On: 20 Jul 2016 20:43:03

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (1-OHP) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:50:31

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05115190001607
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Analyte	1-OHP
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Sample type	URINE
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Result	.
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Result Unit	PG/ML
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Lab Status	OTHER
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Sample comment	ANALYSIS NOT REQUIRED
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Detection method	LC-MS/MS
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Planned time point (Hour)	0
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Day of Visit	-1
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Celerion Study Number	AA99598-03
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Date of Collection	2014-MAR-12
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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: 1202**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (1-OHP) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:50:31

Generated On: 20 Jul 2016 20:43:03

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (SPMA, SBMA)

Data signed: (hfarmer1) 27 Mar 2015 14:50:30

Generated On: 20 Jul 2016 20:43:03

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (SPMA, SBMA) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:50:30

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05115170001585
Analyte	SBMA
Sample type	URINE
Result	.
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	-1
Celerion Study Number	AA99598-01
Date of Collection	2014-MAR-12
Timepoint-minutes	
Urine Start Day	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (SPMA, SBMA) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:50:30

Generated On: 20 Jul 2016 20:43:03

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (SPMA, SBMA) (2)

Data signed: (hfarmer1) 27 Mar 2015 14:50:30

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05115170001585
----------------	----------------

Analyte	SPMA
---------	------

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

Result	.
--------	---

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

Lab Status	OTHER
------------	-------

Sample comment	ANALYSIS NOT REQUIRED
----------------	-----------------------

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

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

Celerion Study Number	AA99598-01
-----------------------	------------

Date of Collection	2014-MAR-12
--------------------	-------------

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

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (SPMA, SBMA) (2)

Data signed: (hfarmer1) 27 Mar 2015 14:50:30

Generated On: 20 Jul 2016 20:43:03

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (MHBMA)

Data signed: (hfarmer1) 27 Mar 2015 14:50:30

Generated On: 20 Jul 2016 20:43:03

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (MHBMA) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:50:30

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05115180001607
----------------	----------------

Analyte	MHBMA
---------	-------

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

Result	.
--------	---

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

Lab Status	OTHER
------------	-------

Sample comment	ANALYSIS NOT REQUIRED
----------------	-----------------------

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

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

Celerion Study Number	AA99598-02
-----------------------	------------

Date of Collection	2014-MAR-12
--------------------	-------------

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

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (MHBMA) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:50:30

Generated On: 20 Jul 2016 20:43:03

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (Creatinine)

Data signed: (hfarmer1) 27 Mar 2015 14:50:31

Generated On: 20 Jul 2016 20:43:03

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (Creatinine) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:50:31

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05115160001345
----------------	----------------

Analyte	CREATININE
---------	------------

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

Result	.
--------	---

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

Lab Status	OTHER
------------	-------

Sample comment	ANALYSIS NOT REQUIRED
----------------	-----------------------

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

Planned time point (Hour)	0
---------------------------	---

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

Celerion Study Number	AA99128-14
-----------------------	------------

Date of Collection	2014-MAR-12
--------------------	-------------

Timepoint-minutes	_____
-------------------	-------

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (Creatinine) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:50:31

Generated On: 20 Jul 2016 20:43:03

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day 0)

Form: Date of Visit

Data signed: (hfarmer1) 27 Mar 2015 14:50:33

Generated On: 20 Jul 2016 20:43:03

Date of Visit

13 MAR 2014
DD/MMM/YYYY

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day 0)

Form: Randomization

Data signed: (hfarmer1) 27 Mar 2015 14:50:33

Generated On: 20 Jul 2016 20:43:03

Randomization number (4 digits)	1064
---------------------------------	------

Allocation Arm	SA <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: 1202**

Folder: Baseline (Day 0)

Form: Vital Signs

Data signed: (hfarmer1) 27 Mar 2015 14:50:33

Generated On: 20 Jul 2016 20:43:03

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 09:50
hour:min 24-hour clock

Pulse rate 59
beats per minute

Respiratory rate 18
breaths per minute

Blood Pressure (systolic) 123
mmHg

Blood Pressure (diastolic) 69
mmHg

Vital Signs Position of Subject Supine ☒

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1202

Folder: Baseline (Day 0)

Form: Gas Transfer

Data signed: (hfarmer1) 27 Mar 2015 14:50:32

Generated On: 20 Jul 2016 20:43:03

Was the Gas Transfer performed?

Yes ☒

If No, please specify the reason: _____

Category _____

Position

SITTING

Time of assessment

07:03

DLCO value

28.74
ml/min/mmHg

KCO value

1.58
mmol/min/kPa/L

DLCO/VA value

4.67
mL/min/mmHg/L

Interpretation

Normal ☒

If Abnormal, Clinical Significance _____

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

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1202

Folder: Baseline (Day 0)

Form: Lung Volume Measurements

Data signed: (hfarmer1) 27 Mar 2015 14:50:33

Generated On: 20 Jul 2016 20:43:03

Were the Lung Volume Measurements performed? Yes ☒

If No, please specify the reason: _____

Category _____

Position SITTING

Time of assessment 07:19

VC value 4.92
L

TLC value 6.36
L

IC value 3.16
L

FRC value 3.20
L

Interpretation Normal ☒

If Abnormal, Clinical Significance _____

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

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1202

Folder: Baseline (Day 0)

Form: Spirometry with a short-acting bronchodilator

Data signed: (hcoleman1) 18 Jun 2015 21:10:22

Generated On: 20 Jul 2016 20:43:03

Was the Spirometry with a short-acting bronchodilator performed?

Yes ☒

If No, please specify the reason: _____

Category

With short-acting bronchodilator ☒

Position

SITTING

Time of assessment

07:48

Name of bronchodilator

ALBUTEROL SULFATE

Dose

180 MCG

Predicted FVC value

5.13
L

Best measured FVC value

4.92
L

Percent of predicted FVC value

95
%

Best measured FEV1 value

3.90
L

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day 0)

Form: Spirometry with a short-acting bronchodilator

Data signed: (hcoleman1) 18 Jun 2015 21:10:22

Generated On: 20 Jul 2016 20:43:03

Predicted FEV1 value	4.14 L
----------------------	-----------

Percent of predicted FEV1 value	94 %
---------------------------------	---------

Calculated ratio between FEV1/FVC	_____
-----------------------------------	-------

MEF 25/75 value	3.44 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: 1202**

Folder: Baseline (Day 0)

Form: Haematology

Data signed: (hfarmer1) 27 Mar 2015 14:50:31

Generated On: 20 Jul 2016 20:43:03

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: 1202**

Folder: Baseline (Day 0)

Form: Clinical Chemistry

Data signed: (hfarmer1) 27 Mar 2015 14:50:31

Generated On: 20 Jul 2016 20:43:03

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: 1202**

Folder: Baseline (Day 0)

Form: Urine analysis

Data signed: (hfarmer1) 27 Mar 2015 14:50:31

Generated On: 20 Jul 2016 20:43:03

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: 1202**

Folder: Baseline (Day 0)

Form: Plasma Nicotine Sample

Data signed: (hfarmer1) 27 Mar 2015 14:50:32

Generated On: 20 Jul 2016 20:43:03

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	13 MAR 2014
---------------------	-------------

Time hour:min 24-hour clock	20:48
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day 0)

Form: Plasma Cotinine Sample

Data signed: (hfarmer1) 27 Mar 2015 14:50:32

Generated On: 20 Jul 2016 20:43:03

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	13 MAR 2014
---------------------	-------------

Time hour:min 24-hour clock	20:48
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day 0)

Form: CoHb Blood Sample <D0> (1)

Data signed: (hfarmer1) 27 Mar 2015 14:50:31

Generated On: 20 Jul 2016 20:43:03

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	13 MAR 2014
---------------------	-------------

Timepoint	Prior to gas transfer assessment and prior to product use <input checked="" type="radio"/>
-----------	--

Time hour:min 24-hour clock	06:09
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day 0)

Form: CoHb Blood Sample <D0> (2)

Data signed: (hfarmer1) 27 Mar 2015 14:50:31

Generated On: 20 Jul 2016 20:43:03

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	13 MAR 2014
---------------------	-------------

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

Time hour:min 24-hour clock	20:48
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day 0)

Form: Oxysterols

Data signed: (hfarmer1) 27 Mar 2015 14:50:32

Generated On: 20 Jul 2016 20:43:03

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

If Not Done, please specify the reason: _____

Was the subject fasting for at least 10 hours at time of sample collection?	Yes <input checked="" type="radio"/>
--	--------------------------------------

Date DD/MMM/YYYY	13 MAR 2014
---------------------	-------------

Time hour:min 24-hour clock	06:09
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day 0)

Form: CO Breath Test (1)

Data signed: (hfarmer1) 27 Mar 2015 14:50:31

Generated On: 20 Jul 2016 20:43:03

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	07:55
---	-------

Result(ppm)	18
-------------	----

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day 0)

Form: CO Breath Test (2)

Data signed: (hfarmer1) 27 Mar 2015 14:50:31

Generated On: 20 Jul 2016 20:43:03

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

If Not Done, please specify the reason: _____

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

Actual Time of Assessment hour:min 24-hour clock	12:08
---	-------

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day 0)

Form: CO Breath Test (3)

Data signed: (hfarmer1) 27 Mar 2015 14:50:31

Generated On: 20 Jul 2016 20:43:03

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)	16
-------------	----

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day 0)

Form: CO Breath Test (4)

Data signed: (hfarmer1) 27 Mar 2015 14:50:31

Generated On: 20 Jul 2016 20:43:03

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

If Not Done, please specify the reason: _____

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

Actual Time of Assessment hour:min 24-hour clock	20:08
---	-------

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

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1202

Folder: Baseline (Day 0)

Form: CYP2A6 activity Sample

Data signed: (hfarmer1) 27 Mar 2015 14:50:32

Generated On: 20 Jul 2016 20:43:03

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

If Not Done, please specify the reason: _____

Date of sample collection
DD/MMM/YYYY

Time of sample collection
hour:min 24-hour clock

Parameter

13 MAR 2014

06:09

trans-3'-hydroxyc
otinine

13 MAR 2014

06:09

cotinine

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1202

Folder: Baseline (Day 0)

Form: CYP1A2 activity Sample

Data signed: (hfarmer1) 27 Mar 2015 14:50:32

Generated On: 20 Jul 2016 20:43:03

Time of caffeine tablet intake	10:58
	hour:min 24-hour clock

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

If Not Done, please specify the reason: _____

Date of sample collection DD/MMM/YYYY	Time of sample collection hour:min 24-hour clock	Parameter
13 MAR 2014	16:53	Caffeine
13 MAR 2014	16:53	Paraxanthine

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day 0)

**Form: Risk Marker: hs-CRP, fibrinogen, homocysteine, LDL, HDL,
sICAM-1, HbA1c, Apo A1, Apo B**

Data signed: (hfarmer1) 27 Mar 2015 14:50:32

Generated On: 20 Jul 2016 20:43:03

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	13 MAR 2014
---------------------	-------------

Time hour:min 24-hour clock	06:09
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day 0)

Form: 24 hour urine collections

Data signed: (hfarmer1) 27 Mar 2015 14:50:33

Generated On: 20 Jul 2016 20:43:03

Start Date	13 MAR 2014 DD/MMM/YYYY
------------	----------------------------

Start Time	06:26 hour:min 24-hour clock
------------	---------------------------------

End Date	14 MAR 2014 DD/MMM/YYYY
----------	----------------------------

End Time	06:08 hour:min 24-hour clock
----------	---------------------------------

Volume	2674 mL
--------	------------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day 0)

Form: Sample Urine Collection

Data signed: (hfarmer1) 27 Mar 2015 14:50:33

Generated On: 20 Jul 2016 20:43:03

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: 1202

Folder: Baseline (Day 0)

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Data signed: (hfarmer1) 27 Mar 2015 14:50:56

Generated On: 20 Jul 2016 20:43:03

Date of Birth

(b) (6)

Date of assessment
DD/MMM/YYYY

2014 MAR 13
DD/MMM/YYYY

Time of assessment

06:18
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: 1202

Folder: Baseline (Day 0)

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Data signed: (hfarmer1) 27 Mar 2015 14:50:56

Generated On: 20 Jul 2016 20:43:03

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

5. Difficulty concentrating

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

6. Increased appetite, hungry, weight gain

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

7. Insomnia, sleep problems, awakening at night

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

8. Restless

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

9. Impatient

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

10. Constipation

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

11. Dizziness

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

12. Coughing

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day 0)

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Data signed: (hfarmer1) 27 Mar 2015 14:50:56

Generated On: 20 Jul 2016 20:43:03

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: 1202

Folder: Baseline (Day 0)

Form: Cough Assessment

Data signed: (hfarmer1) 27 Mar 2015 14:50:55

Generated On: 20 Jul 2016 20:43:03

Date of Birth	(b) (6)
Date of assessment DD/MMM/YYYY	2014 MAR 13 DD/MMM/YYYY
Time of assessment	06:17 hour:min 24-hour clock
Assessment Status	Completed <input checked="" type="radio"/>
Have you experienced a regular need to cough e.g. coughing several times in the last 24 hrs?	No <input checked="" type="radio"/>
If YES, please answer the following questions:	
First Question: Cough Impact Scale How much is your cough bothering you?	-9
Second Question: Cough Intensity Scale: How intense is your cough?	Not Applicable <input checked="" type="radio"/>
Third Question: Cough Frequency Scale: How frequently do you normally have to cough each day?	Not Applicable <input checked="" type="radio"/>
Fourth Question: Sputum Production To what extent do you produce sputum when coughing?	Not Applicable <input checked="" type="radio"/>

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day 0)

Form: Bio-banking (Transcriptomics)

Data signed: (hfarmer1) 27 Mar 2015 14:50:55

Generated On: 20 Jul 2016 20:43:03

Was a Bio-banking sample for transcriptomics taken?

Yes ☒

Time of Sample Collection

06:09
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: 1202**

Folder: Baseline (Day 0)

Form: Bio-banking (Biomarkers of exposure and risk markers)

Data signed: (hfarmer1) 27 Mar 2015 14:50:55

Generated On: 20 Jul 2016 20:43:03

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

Yes ☒

Time of Sample Collection

06:09
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: 1202**

Folder: Baseline (Day 0)

Form: Bio-banking (nasal epithelial collection/buccal collection)

Data signed: (hfarmer1) 27 Mar 2015 14:50:55

Generated On: 20 Jul 2016 20:43:03

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

Yes ☒

Time of Buccal Collection

15:07
hour:min 24-hour clock

Time of Nasal Epithelial Collection

15:04
hour:min 24-hour clock

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

Yes ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (1)

Data signed: (hfarmer1) 27 Mar 2015 14:50:33

Generated On: 20 Jul 2016 20:43:03

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	<hr/>
----------------------	-------

Subject Sex	M
-------------	---

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

Visit Name	<hr/>
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	W098753
--------------	---------

Actual Collection Date	2014 03 13
------------------------	------------

Actual Collection Time	06:09
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	RC1029
------------	--------

Battery Name	TRIGLYCERIDES
--------------	---------------

Lab Test ID	RCT19
-------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (1)

Data signed: (hfarmer1) 27 Mar 2015 14:50:33

Generated On: 20 Jul 2016 20:43:03

Lab Test Name	TRIGLYCERIDES (GPO)
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	119
Reported Numeric Result	119
Reference Range low	50
Reference Range high	321
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: 1202**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (1)

Data signed: (hfarmer1) 27 Mar 2015 14:50:33

Generated On: 20 Jul 2016 20:43:03

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (2)

Data signed: (hfarmer1) 27 Mar 2015 14:50:33

Generated On: 20 Jul 2016 20:43:03

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6) 

Visit Name _____

Visit Type Scheduled ☒

Accession ID W098753

Actual Collection Date 2014 03 13

Actual Collection Time 06:09

Specimen Condition _____

Battery ID RC1092

Battery Name FASTING GLUCOSE

Lab Test ID RCT142

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1202

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (2)

Data signed: (hfarmer1) 27 Mar 2015 14:50:33

Generated On: 20 Jul 2016 20:43:03

Lab Test Name	FASTING GLUCOSE
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	92
Reported Numeric Result	92
Reference Range low	70
Reference Range high	100
Range Units	MG/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (2)

Data signed: (hfarmer1) 27 Mar 2015 14:50:33

Generated On: 20 Jul 2016 20:43:03

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (3)

Data signed: (hfarmer1) 27 Mar 2015 14:50:33

Generated On: 20 Jul 2016 20:43:03

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6) 

Visit Name _____

Visit Type Scheduled ☒

Accession ID W098753

Actual Collection Date 2014 03 13

Actual Collection Time 06:09

Specimen Condition _____

Battery ID RC272

Battery Name TOTAL CHOLESTEROL

Lab Test ID RCT20

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (3)

Data signed: (hfarmer1) 27 Mar 2015 14:50:33


Generated On: 20 Jul 2016 20:43:03

Lab Test Name

CHOLESTEROL (HIGH
PERFORMANCE)

Test ID

Test Status

Done 

Reported Text Result

211

Reported Numeric Result

211

Reference Range low

150

Reference Range high

264

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: 1202**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (3)

Data signed: (hfarmer1) 27 Mar 2015 14:50:33

Generated On: 20 Jul 2016 20:43:03

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: 1202**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (4)

Data signed: (hfarmer1) 27 Mar 2015 14:50:33

Generated On: 20 Jul 2016 20:43:03

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6) 

Visit Name _____

Visit Type Scheduled ☒

Accession ID W098753

Actual Collection Date 2014 03 13

Actual Collection Time 06:09

Specimen Condition _____

Battery ID RC9255

Battery Name CHEMISTRY PANEL

Lab Test ID RCT1

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1202

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (4)

Data signed: (hfarmer1) 27 Mar 2015 14:50:33

Generated On: 20 Jul 2016 20:43:03

Lab Test Name	TOTAL BILIRUBIN
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	0.9
Reported Numeric Result	0.9
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: 1202**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (4)

Data signed: (hfarmer1) 27 Mar 2015 14:50:33

Generated On: 20 Jul 2016 20:43:03

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (5)

Data signed: (hfarmer1) 27 Mar 2015 14:50:33

Generated On: 20 Jul 2016 20:43:03

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	M
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Subject Date of Birth	(b) (6)
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	W098753
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Actual Collection Date	2014 03 13
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Actual Collection Time	06:09
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Specimen Condition	<hr/>
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Battery ID	RC9255
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Battery Name	CHEMISTRY PANEL
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Lab Test ID	RCT12
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1202

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (5)

Data signed: (hfarmer1) 27 Mar 2015 14:50:33

Generated On: 20 Jul 2016 20:43:03

Lab Test Name	TOTAL PROTEIN
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	7.1
Reported Numeric Result	7.1
Reference Range low	6.1
Reference Range high	8.4
Range Units	G/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (5)

Data signed: (hfarmer1) 27 Mar 2015 14:50:33

Generated On: 20 Jul 2016 20:43:03

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (6)

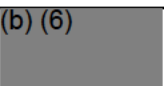
Data signed: (hfarmer1) 27 Mar 2015 14:50:33

Generated On: 20 Jul 2016 20:43:03

Transmission Type Cumulative ☒

Subject ID or Number

Subject Sex M

Subject Date of Birth (b) (6) 

Visit Name

Visit Type Scheduled ☒

Accession ID W098753

Actual Collection Date 2014 03 13

Actual Collection Time 06:09

Specimen Condition

Battery ID RC9255

Battery Name CHEMISTRY PANEL

Lab Test ID RCT13

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (6)

Data signed: (hfarmer1) 27 Mar 2015 14:50:33

Generated On: 20 Jul 2016 20:43:03

Lab Test Name	ALBUMIN
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	4.0
Reported Numeric Result	4.0
Reference Range low	3.3
Reference Range high	4.9
Range Units	G/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (6)

Data signed: (hfarmer1) 27 Mar 2015 14:50:33

Generated On: 20 Jul 2016 20:43:03

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (7)

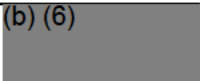
Data signed: (hfarmer1) 27 Mar 2015 14:50:33

Generated On: 20 Jul 2016 20:43:03

Transmission Type Cumulative ☐

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6) 

Visit Name _____

Visit Type Scheduled ☐

Accession ID W098753

Actual Collection Date 2014 03 13

Actual Collection Time 06:09

Specimen Condition _____

Battery ID RC9255

Battery Name CHEMISTRY PANEL

Lab Test ID RCT1407

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1202

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (7)

Data signed: (hfarmer1) 27 Mar 2015 14:50:33

Generated On: 20 Jul 2016 20:43:03

Lab Test Name	ALKALINE PHOSPHATASE
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	73
Reported Numeric Result	73
Reference Range low	31
Reference Range high	129
Range Units	U/L
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (7)

Data signed: (hfarmer1) 27 Mar 2015 14:50:33

Generated On: 20 Jul 2016 20:43:03

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (8)

Data signed: (hfarmer1) 27 Mar 2015 14:50:33

Generated On: 20 Jul 2016 20:43:03

Transmission Type Cumulative ☐

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6) 

Visit Name _____

Visit Type Scheduled ☐

Accession ID W098753

Actual Collection Date 2014 03 13

Actual Collection Time 06:09

Specimen Condition _____

Battery ID RC9255

Battery Name CHEMISTRY PANEL

Lab Test ID RCT1408

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1202

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (8)

Data signed: (hfarmer1) 27 Mar 2015 14:50:33

Generated On: 20 Jul 2016 20:43:03

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: 1202**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (8)

Data signed: (hfarmer1) 27 Mar 2015 14:50:33

Generated On: 20 Jul 2016 20:43:03

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (9)

Data signed: (hfarmer1) 27 Mar 2015 14:50:33

Generated On: 20 Jul 2016 20:43:03

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6) 

Visit Name _____

Visit Type Scheduled ☒

Accession ID W098753

Actual Collection Date 2014 03 13

Actual Collection Time 06:09

Specimen Condition _____

Battery ID RC9255

Battery Name CHEMISTRY PANEL

Lab Test ID RCT15

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1202

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (9)

Data signed: (hfarmer1) 27 Mar 2015 14:50:33

Generated On: 20 Jul 2016 20:43:03

Lab Test Name	SERUM SODIUM
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	140
Reported Numeric Result	140
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: 1202**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (9)

Data signed: (hfarmer1) 27 Mar 2015 14:50:33

Generated On: 20 Jul 2016 20:43:03

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (10)

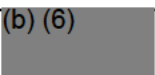
Data signed: (hfarmer1) 27 Mar 2015 14:50:33

Generated On: 20 Jul 2016 20:43:03

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	M
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Subject Date of Birth	(b) (6) 
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	W098753
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Actual Collection Date	2014 03 13
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Actual Collection Time	06:09
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Specimen Condition	<hr/>
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Battery ID	RC9255
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Battery Name	CHEMISTRY PANEL
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Lab Test ID	RCT16
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1202

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (10)

Data signed: (hfarmer1) 27 Mar 2015 14:50:33

Generated On: 20 Jul 2016 20:43:03

Lab Test Name	SERUM POTASSIUM
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	3.8
Reported Numeric Result	3.8
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: 1202**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (10)

Data signed: (hfarmer1) 27 Mar 2015 14:50:33

Generated On: 20 Jul 2016 20:43:03

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (11)

Data signed: (hfarmer1) 27 Mar 2015 14:50:33

Generated On: 20 Jul 2016 20:43:03

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6) 

Visit Name _____

Visit Type Scheduled ☒

Accession ID W098753

Actual Collection Date 2014 03 13

Actual Collection Time 06:09

Specimen Condition _____

Battery ID RC9255

Battery Name CHEMISTRY PANEL

Lab Test ID RCT29

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1202

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (11)

Data signed: (hfarmer1) 27 Mar 2015 14:50:33

Generated On: 20 Jul 2016 20:43:03

Lab Test Name	DIRECT BILIRUBIN
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	0.2
Reported Numeric Result	0.2
Reference Range low	0.0
Reference Range high	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: 1202**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (11)

Data signed: (hfarmer1) 27 Mar 2015 14:50:33

Generated On: 20 Jul 2016 20:43:03

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (12)

Data signed: (hfarmer1) 27 Mar 2015 14:50:33

Generated On: 20 Jul 2016 20:43:03

Transmission Type Cumulative ☐

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6) 

Visit Name _____

Visit Type Scheduled ☐

Accession ID W098753

Actual Collection Date 2014 03 13

Actual Collection Time 06:09

Specimen Condition _____

Battery ID RC9255

Battery Name CHEMISTRY PANEL

Lab Test ID RCT3

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1202

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (12)

Data signed: (hfarmer1) 27 Mar 2015 14:50:33

Generated On: 20 Jul 2016 20:43:03

Lab Test Name	GGT
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	25
Reported Numeric Result	25
Reference Range low	10
Reference Range high	61
Range Units	U/L
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (12)

Data signed: (hfarmer1) 27 Mar 2015 14:50:33

Generated On: 20 Jul 2016 20:43:03

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (13)

Data signed: (hfarmer1) 27 Mar 2015 14:50:33

Generated On: 20 Jul 2016 20:43:03

Transmission Type Cumulative ☒

Subject ID or Number

Subject Sex M

Subject Date of Birth (b) (6) 

Visit Name

Visit Type Scheduled ☒

Accession ID W098753

Actual Collection Date 2014 03 13

Actual Collection Time 06:09

Specimen Condition

Battery ID RC9255

Battery Name CHEMISTRY PANEL

Lab Test ID RCT392

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (13)

Data signed: (hfarmer1) 27 Mar 2015 14:50:33

Generated On: 20 Jul 2016 20:43:03

Lab Test Name	CREATININE (RATE BLANKED)
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Test ID	<hr/>
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Test Status	Done <input checked="" type="radio"/>
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Reported Text Result	1.0
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Reported Numeric Result	1.0
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Reference Range low	0.5
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Reference Range high	1.2
----------------------	-----

Range Units	MG/DL
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Conventional Text Result	<hr/>
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Conventional Numeric Result	<hr/>
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Conventional Reference Range Low	<hr/>
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Conventional Reference Range High	<hr/>
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Conventional Units	<hr/>
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SI Text Result	<hr/>
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (13)

Data signed: (hfarmer1) 27 Mar 2015 14:50:33

Generated On: 20 Jul 2016 20:43:03

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (14)

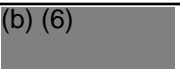
Data signed: (hfarmer1) 27 Mar 2015 14:50:33

Generated On: 20 Jul 2016 20:43:03

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6) 

Visit Name _____

Visit Type Scheduled ☒

Accession ID W098753

Actual Collection Date 2014 03 13

Actual Collection Time 06:09

Specimen Condition _____

Battery ID RC9255

Battery Name CHEMISTRY PANEL

Lab Test ID RCT4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (14)

Data signed: (hfarmer1) 27 Mar 2015 14:50:33

Generated On: 20 Jul 2016 20:43:03

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	43
Range Units	U/L
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (14)

Data signed: (hfarmer1) 27 Mar 2015 14:50:33

Generated On: 20 Jul 2016 20:43:03

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (15)


Data signed: (hfarmer1) 27 Mar 2015 14:50:33

Generated On: 20 Jul 2016 20:43:03

Transmission Type Cumulative ☐

Subject ID or Number

Subject Sex M

Subject Date of Birth (b) (6) 

Visit Name

Visit Type Scheduled ☐

Accession ID W098753

Actual Collection Date 2014 03 13

Actual Collection Time 06:09

Specimen Condition

Battery ID RC9255

Battery Name CHEMISTRY PANEL

Lab Test ID RCT5

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1202

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (15)

Data signed: (hfarmer1) 27 Mar 2015 14:50:33

Generated On: 20 Jul 2016 20:43:03

Lab Test Name	AST (SGOT)
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	18
Reported Numeric Result	18
Reference Range low	11
Reference Range high	36
Range Units	U/L
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (15)

Data signed: (hfarmer1) 27 Mar 2015 14:50:33

Generated On: 20 Jul 2016 20:43:03

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (16)

Data signed: (hfarmer1) 27 Mar 2015 14:50:33

Generated On: 20 Jul 2016 20:43:03

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6) 

Visit Name _____

Visit Type Scheduled ☒

Accession ID W098753

Actual Collection Date 2014 03 13

Actual Collection Time 06:09

Specimen Condition _____

Battery ID RC9255

Battery Name CHEMISTRY PANEL

Lab Test ID RCT6

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (16)

Data signed: (hfarmer1) 27 Mar 2015 14:50:33

Generated On: 20 Jul 2016 20:43:03

Lab Test Name	UREA NITROGEN
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	15
Reported Numeric Result	15
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: 1202**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (16)

Data signed: (hfarmer1) 27 Mar 2015 14:50:33

Generated On: 20 Jul 2016 20:43:03

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (17)

Data signed: (hfarmer1) 27 Mar 2015 14:50:33

Generated On: 20 Jul 2016 20:43:03

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	M
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Subject Date of Birth	(b) (6) 
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	W098753
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Actual Collection Date	2014 03 13
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Actual Collection Time	06:09
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Specimen Condition	<hr/>
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Battery ID	HM1604
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Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
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Lab Test ID	HMT10
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (17)

Data signed: (hfarmer1) 27 Mar 2015 14:50:33

Generated On: 20 Jul 2016 20:43:03

Lab Test Name	MONOCYTES
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	0.66
Reported Numeric Result	0.66
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: 1202**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (17)

Data signed: (hfarmer1) 27 Mar 2015 14:50:33

Generated On: 20 Jul 2016 20:43:03

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (18)

Data signed: (hfarmer1) 27 Mar 2015 14:50:33

Generated On: 20 Jul 2016 20:43:03

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	M
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Subject Date of Birth	(b) (6) 
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	W098753
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Actual Collection Date	2014 03 13
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Actual Collection Time	06:09
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Specimen Condition	<hr/>
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Battery ID	HM1604
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Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
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Lab Test ID	HMT100
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1202

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (18)

Data signed: (hfarmer1) 27 Mar 2015 14:50:33

Generated On: 20 Jul 2016 20:43:03

Lab Test Name	MCH
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	26
Reported Numeric Result	26
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: 1202**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (18)

Data signed: (hfarmer1) 27 Mar 2015 14:50:33

Generated On: 20 Jul 2016 20:43:03

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (19)

Data signed: (hfarmer1) 27 Mar 2015 14:50:33

Generated On: 20 Jul 2016 20:43:03

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6) 

Visit Name _____

Visit Type Scheduled ☒

Accession ID W098753

Actual Collection Date 2014 03 13

Actual Collection Time 06:09

Specimen Condition _____

Battery ID HM1604

Battery Name HEMATOLOGY
&DIFFERENTIAL PANEL

Lab Test ID HMT102

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1202

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (19)

Data signed: (hfarmer1) 27 Mar 2015 14:50:33

Generated On: 20 Jul 2016 20:43:03

Lab Test Name	MCHC
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	32
Reported Numeric Result	32
Reference Range low	31
Reference Range high	38
Range Units	G/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (19)

Data signed: (hfarmer1) 27 Mar 2015 14:50:33

Generated On: 20 Jul 2016 20:43:03

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (20)

Data signed: (hfarmer1) 27 Mar 2015 14:50:33

Generated On: 20 Jul 2016 20:43:03

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6) 

Visit Name _____

Visit Type Scheduled ☒

Accession ID W098753

Actual Collection Date 2014 03 13

Actual Collection Time 06:09

Specimen Condition _____

Battery ID HM1604

Battery Name HEMATOLOGY
&DIFFERENTIAL PANEL

Lab Test ID HMT11

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (20)

Data signed: (hfarmer1) 27 Mar 2015 14:50:33

Generated On: 20 Jul 2016 20:43:03

Lab Test Name	EOSINOPHILS
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	0.11
Reported Numeric Result	0.11
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: 1202**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (20)

Data signed: (hfarmer1) 27 Mar 2015 14:50:33

Generated On: 20 Jul 2016 20:43:03

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (21)

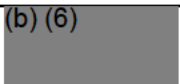
Data signed: (hfarmer1) 27 Mar 2015 14:50:33

Generated On: 20 Jul 2016 20:43:03

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6) 

Visit Name _____

Visit Type Scheduled ☒

Accession ID W098753

Actual Collection Date 2014 03 13

Actual Collection Time 06:09

Specimen Condition _____

Battery ID HM1604

Battery Name HEMATOLOGY
&DIFFERENTIAL PANEL

Lab Test ID HMT12

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1202

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (21)

Data signed: (hfarmer1) 27 Mar 2015 14:50:33

Generated On: 20 Jul 2016 20:43:03

Lab Test Name	BASOPHILS
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	0.03
Reported Numeric Result	0.03
Reference Range low	0.00
Reference Range high	0.20
Range Units	X10^3/UL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (21)

Data signed: (hfarmer1) 27 Mar 2015 14:50:33

Generated On: 20 Jul 2016 20:43:03

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (22)

Data signed: (hfarmer1) 27 Mar 2015 14:50:33

Generated On: 20 Jul 2016 20:43:03

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6) 

Visit Name _____

Visit Type Scheduled ☒

Accession ID W098753

Actual Collection Date 2014 03 13

Actual Collection Time 06:09

Specimen Condition _____

Battery ID HM1604

Battery Name HEMATOLOGY
&DIFFERENTIAL PANEL

Lab Test ID HMT13

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1202

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (22)

Data signed: (hfarmer1) 27 Mar 2015 14:50:33

Generated On: 20 Jul 2016 20:43:03

Lab Test Name	PLATELETS
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	277
Reported Numeric Result	277
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: 1202**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (22)

Data signed: (hfarmer1) 27 Mar 2015 14:50:33

Generated On: 20 Jul 2016 20:43:03

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1202

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (23)

Data signed: (hfarmer1) 27 Mar 2015 14:50:33

Generated On: 20 Jul 2016 20:43:03

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6) 

Visit Name _____

Visit Type Scheduled ☒

Accession ID W098753

Actual Collection Date 2014 03 13

Actual Collection Time 06:09

Specimen Condition _____

Battery ID HM1604

Battery Name HEMATOLOGY
&DIFFERENTIAL PANEL

Lab Test ID HMT15

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1202

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (23)

Data signed: (hfarmer1) 27 Mar 2015 14:50:33

Generated On: 20 Jul 2016 20:43:03

Lab Test Name	NEUTROPHILS (%)
Test ID	
Test Status	Done <input checked="" type="checkbox"/>
Reported Text Result	46.4
Reported Numeric Result	46.4
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: 1202**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (23)

Data signed: (hfarmer1) 27 Mar 2015 14:50:33

Generated On: 20 Jul 2016 20:43:03

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1202

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (24)

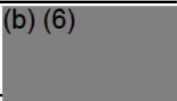
Data signed: (hfarmer1) 27 Mar 2015 14:50:33

Generated On: 20 Jul 2016 20:43:03

Transmission Type Cumulative ☐

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6) 

Visit Name _____

Visit Type Scheduled ☐

Accession ID W098753

Actual Collection Date 2014 03 13

Actual Collection Time 06:09

Specimen Condition _____

Battery ID HM1604

Battery Name HEMATOLOGY
&DIFFERENTIAL PANEL

Lab Test ID HMT16

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1202

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (24)

Data signed: (hfarmer1) 27 Mar 2015 14:50:33

Generated On: 20 Jul 2016 20:43:03

Lab Test Name	LYMPHOCYTES (%)
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	42.8
Reported Numeric Result	42.8
Reference Range low	15.4
Reference Range high	48.5
Range Units	%
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (24)

Data signed: (hfarmer1) 27 Mar 2015 14:50:33

Generated On: 20 Jul 2016 20:43:03

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (25)

Data signed: (hfarmer1) 27 Mar 2015 14:50:33

Generated On: 20 Jul 2016 20:43:03

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6)

Visit Name _____

Visit Type Scheduled ☒

Accession ID W098753

Actual Collection Date 2014 03 13

Actual Collection Time 06:09

Specimen Condition _____

Battery ID HM1604

Battery Name HEMATOLOGY
&DIFFERENTIAL PANEL

Lab Test ID HMT17

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1202

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (25)

Data signed: (hfarmer1) 27 Mar 2015 14:50:33

Generated On: 20 Jul 2016 20:43:03

Lab Test Name	MONOCYTES (%)
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	8.8
Reported Numeric Result	8.8
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: 1202**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (25)

Data signed: (hfarmer1) 27 Mar 2015 14:50:33

Generated On: 20 Jul 2016 20:43:03

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (26)

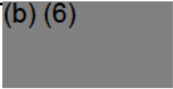
Data signed: (hfarmer1) 27 Mar 2015 14:50:33

Generated On: 20 Jul 2016 20:43:03

Transmission Type Cumulative ☐

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6) 

Visit Name _____

Visit Type Scheduled ☐

Accession ID W098753

Actual Collection Date 2014 03 13

Actual Collection Time 06:09

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: 1202**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (26)

Data signed: (hfarmer1) 27 Mar 2015 14:50:33

Generated On: 20 Jul 2016 20:43:03

Lab Test Name	EOSINOPHILS (%)
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	1.5
Reported Numeric Result	1.5
Reference Range low	0.0
Reference Range high	6.8
Range Units	%
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (26)

Data signed: (hfarmer1) 27 Mar 2015 14:50:33

Generated On: 20 Jul 2016 20:43:03

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1202

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (27)

Data signed: (hfarmer1) 27 Mar 2015 14:50:33

Generated On: 20 Jul 2016 20:43:03

Transmission Type Cumulative ☐

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6)

Visit Name _____

Visit Type Scheduled ☐

Accession ID W098753

Actual Collection Date 2014 03 13

Actual Collection Time 06:09

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: 1202

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (27)

Data signed: (hfarmer1) 27 Mar 2015 14:50:33

Generated On: 20 Jul 2016 20:43:03

Lab Test Name	BASOPHILS (%)
Test ID	
Test Status	Done <input type="checkbox"/>
Reported Text Result	0.4
Reported Numeric Result	0.4
Reference Range low	0.0
Reference Range high	2.0
Range Units	%
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (27)

Data signed: (hfarmer1) 27 Mar 2015 14:50:33

Generated On: 20 Jul 2016 20:43:03

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (28)

Data signed: (hfarmer1) 27 Mar 2015 14:50:33

Generated On: 20 Jul 2016 20:43:03

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6) 

Visit Name _____

Visit Type Scheduled ☒

Accession ID W098753

Actual Collection Date 2014 03 13

Actual Collection Time 06:09

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: 1202

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (28)

Data signed: (hfarmer1) 27 Mar 2015 14:50:33

Generated On: 20 Jul 2016 20:43:03

Lab Test Name	HEMATOCRIT
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	45
Reported Numeric Result	45
Reference Range low	39
Reference Range high	54
Range Units	%
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (28)

Data signed: (hfarmer1) 27 Mar 2015 14:50:33

Generated On: 20 Jul 2016 20:43:03

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (29)

Data signed: (hfarmer1) 27 Mar 2015 14:50:33

Generated On: 20 Jul 2016 20:43:03

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	M
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Subject Date of Birth	(b) (6)
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	W098753
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Actual Collection Date	2014 03 13
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Actual Collection Time	06:09
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Specimen Condition	<hr/>
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Battery ID	HM1604
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Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
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Lab Test ID	HMT3
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (29)

Data signed: (hfarmer1) 27 Mar 2015 14:50:33

Generated On: 20 Jul 2016 20:43:03

Lab Test Name	RBC
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	5.5
Reported Numeric Result	5.5
Reference Range low	4.5
Reference Range high	6.4
Range Units	X10^6/UL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (29)

Data signed: (hfarmer1) 27 Mar 2015 14:50:33

Generated On: 20 Jul 2016 20:43:03

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1202

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (30)

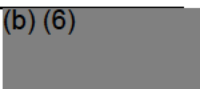
Data signed: (hfarmer1) 27 Mar 2015 14:50:33

Generated On: 20 Jul 2016 20:43:03

Transmission Type Cumulative ☐

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6) 

Visit Name _____

Visit Type Scheduled ☐

Accession ID W098753

Actual Collection Date 2014 03 13

Actual Collection Time 06:09

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: 1202

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (30)

Data signed: (hfarmer1) 27 Mar 2015 14:50:33

Generated On: 20 Jul 2016 20:43:03

Lab Test Name	MCV
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	82
Reported Numeric Result	82
Reference Range low	79
Reference Range high	96
Range Units	FL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (30)

Data signed: (hfarmer1) 27 Mar 2015 14:50:33

Generated On: 20 Jul 2016 20:43:03

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (31)

Data signed: (hfarmer1) 27 Mar 2015 14:50:33

Generated On: 20 Jul 2016 20:43:03

Transmission Type Cumulative ☐

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6)

Visit Name _____

Visit Type Scheduled ☐

Accession ID W098753

Actual Collection Date 2014 03 13

Actual Collection Time 06:09

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: 1202

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (31)

Data signed: (hfarmer1) 27 Mar 2015 14:50:33

Generated On: 20 Jul 2016 20:43:03

Lab Test Name	HEMOGLOBIN
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	14.4
Reported Numeric Result	14.4
Reference Range low	12.7
Reference Range high	18.1
Range Units	G/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (31)

Data signed: (hfarmer1) 27 Mar 2015 14:50:33

Generated On: 20 Jul 2016 20:43:03

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (32)

Data signed: (hfarmer1) 27 Mar 2015 14:50:33

Generated On: 20 Jul 2016 20:43:03

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6) _____

Visit Name _____

Visit Type Scheduled ☒

Accession ID W098753

Actual Collection Date 2014 03 13

Actual Collection Time 06:09

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: 1202**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (32)

Data signed: (hfarmer1) 27 Mar 2015 14:50:33

Generated On: 20 Jul 2016 20:43:03

Lab Test Name	WBC
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	7.43
Reported Numeric Result	7.43
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: 1202**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (32)

Data signed: (hfarmer1) 27 Mar 2015 14:50:33

Generated On: 20 Jul 2016 20:43:03

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (33)


Data signed: (hfarmer1) 27 Mar 2015 14:50:33

Generated On: 20 Jul 2016 20:43:03

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	M
-------------	---

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

Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	W098753
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Actual Collection Date	2014 03 13
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Actual Collection Time	06:09
------------------------	-------

Specimen Condition	<hr/>
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Battery ID	HM1604
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Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
--------------	-----------------------------------

Lab Test ID	HMT71
-------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (33)

Data signed: (hfarmer1) 27 Mar 2015 14:50:33


Generated On: 20 Jul 2016 20:43:03

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: 1202**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (33)

Data signed: (hfarmer1) 27 Mar 2015 14:50:33

Generated On: 20 Jul 2016 20:43:03

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (34)

Data signed: (hfarmer1) 27 Mar 2015 14:50:33

Generated On: 20 Jul 2016 20:43:03

Transmission Type Cumulative ☐

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6)

Visit Name _____

Visit Type Scheduled ☐

Accession ID W098753

Actual Collection Date 2014 03 13

Actual Collection Time 06:09

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: 1202

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (34)

Data signed: (hfarmer1) 27 Mar 2015 14:50:33

Generated On: 20 Jul 2016 20:43:03

Lab Test Name	NEUTROPHILS
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	3.45
Reported Numeric Result	3.45
Reference Range low	1.96
Reference Range high	7.23
Range Units	X10^3/UL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (34)

Data signed: (hfarmer1) 27 Mar 2015 14:50:33

Generated On: 20 Jul 2016 20:43:03

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (35)

Data signed: (hfarmer1) 27 Mar 2015 14:50:33

Generated On: 20 Jul 2016 20:43:03

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	M
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Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	W098753
--------------	---------

Actual Collection Date	2014 03 13
------------------------	------------

Actual Collection Time	06:09
------------------------	-------

Specimen Condition	<hr/>
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Battery ID	HM1604
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Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
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Lab Test ID	HMT9
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (35)

Data signed: (hfarmer1) 27 Mar 2015 14:50:33

Generated On: 20 Jul 2016 20:43:03

Lab Test Name	LYMPHOCYTES
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	3.18
Reported Numeric Result	3.18
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: 1202**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (35)

Data signed: (hfarmer1) 27 Mar 2015 14:50:33

Generated On: 20 Jul 2016 20:43:03

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (36)

Data signed: (hfarmer1) 27 Mar 2015 14:50:33

Generated On: 20 Jul 2016 20:43:03

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
----------------------	-------

Subject Sex	M
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Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	W098753
--------------	---------

Actual Collection Date	2014 03 13
------------------------	------------

Actual Collection Time	06:09
------------------------	-------

Specimen Condition	<hr/>
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Battery ID	UA1538
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Battery Name	URINE MACRO PANEL
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Lab Test ID	UAT10
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (36)

Data signed: (hfarmer1) 27 Mar 2015 14:50:33


Generated On: 20 Jul 2016 20:43:03

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: 1202**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (36)

Data signed: (hfarmer1) 27 Mar 2015 14:50:33

Generated On: 20 Jul 2016 20:43:03

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (37)

Data signed: (hfarmer1) 27 Mar 2015 14:50:33

Generated On: 20 Jul 2016 20:43:03

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
----------------------	-------

Subject Sex	M
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Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	W098753
--------------	---------

Actual Collection Date	2014 03 13
------------------------	------------

Actual Collection Time	06:09
------------------------	-------

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: 1202

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (37)

Data signed: (hfarmer1) 27 Mar 2015 14:50:33

Generated On: 20 Jul 2016 20:43:03

Lab Test Name	UR SPECIFIC GRAVITY
Test ID	
Test Status	Done <input type="checkbox"/>
Reported Text Result	1.018
Reported Numeric Result	1.018
Reference Range low	1.003
Reference Range high	1.035
Range Units	
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (37)

Data signed: (hfarmer1) 27 Mar 2015 14:50:33

Generated On: 20 Jul 2016 20:43:03

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (38)

Data signed: (hfarmer1) 27 Mar 2015 14:50:33

Generated On: 20 Jul 2016 20:43:03

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	M
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Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	W098753
--------------	---------

Actual Collection Date	2014 03 13
------------------------	------------

Actual Collection Time	06:09
------------------------	-------

Specimen Condition	<hr/>
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Battery ID	UA1538
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Battery Name	URINE MACRO PANEL
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Lab Test ID	UAT3
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (38)

Data signed: (hfarmer1) 27 Mar 2015 14:50:33

Generated On: 20 Jul 2016 20:43:03

Lab Test Name	UR PH
Test ID	
Test Status	Done <input type="checkbox"/>
Reported Text Result	5.5
Reported Numeric Result	5.5
Reference Range low	5.0
Reference Range high	8.0
Range Units	
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (38)

Data signed: (hfarmer1) 27 Mar 2015 14:50:33

Generated On: 20 Jul 2016 20:43:03

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (39)

Data signed: (hfarmer1) 27 Mar 2015 14:50:33

Generated On: 20 Jul 2016 20:43:03

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	M
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Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	W098753
--------------	---------

Actual Collection Date	2014 03 13
------------------------	------------

Actual Collection Time	06:09
------------------------	-------

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: 1202

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (39)

Data signed: (hfarmer1) 27 Mar 2015 14:50:33


Generated On: 20 Jul 2016 20:43:03

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: 1202**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (39)

Data signed: (hfarmer1) 27 Mar 2015 14:50:33

Generated On: 20 Jul 2016 20:43:03

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (40)

Data signed: (hfarmer1) 27 Mar 2015 14:50:33

Generated On: 20 Jul 2016 20:43:03

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	M
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Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	W098753
--------------	---------

Actual Collection Date	2014 03 13
------------------------	------------

Actual Collection Time	06:09
------------------------	-------

Specimen Condition	<hr/>
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Battery ID	UA1538
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Battery Name	URINE MACRO PANEL
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Lab Test ID	UAT49
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (40)

Data signed: (hfarmer1) 27 Mar 2015 14:50:33

Generated On: 20 Jul 2016 20:43:03

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: 1202**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (40)

Data signed: (hfarmer1) 27 Mar 2015 14:50:33

Generated On: 20 Jul 2016 20:43:03

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (41)

Data signed: (hfarmer1) 27 Mar 2015 14:50:33

Generated On: 20 Jul 2016 20:43:03

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	<hr/>
----------------------	-------

Subject Sex	M
-------------	---

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

Visit Name	<hr/>
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	W098753
--------------	---------

Actual Collection Date	2014 03 13
------------------------	------------

Actual Collection Time	06:09
------------------------	-------

Specimen Condition	<hr/>
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Battery ID	UA1538
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Battery Name	URINE MACRO PANEL
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Lab Test ID	UAT5
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (41)

Data signed: (hfarmer1) 27 Mar 2015 14:50:33


Generated On: 20 Jul 2016 20:43:03

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: 1202**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (41)

Data signed: (hfarmer1) 27 Mar 2015 14:50:33

Generated On: 20 Jul 2016 20:43:03

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (42)

Data signed: (hfarmer1) 27 Mar 2015 14:50:33

Generated On: 20 Jul 2016 20:43:03

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	<hr/>
----------------------	-------

Subject Sex	M
-------------	---

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

Visit Name	<hr/>
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	W098753
--------------	---------

Actual Collection Date	2014 03 13
------------------------	------------

Actual Collection Time	06:09
------------------------	-------

Specimen Condition	<hr/>
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Battery ID	UA1538
------------	--------

Battery Name	URINE MACRO PANEL
--------------	-------------------

Lab Test ID	UAT7
-------------	------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (42)

Data signed: (hfarmer1) 27 Mar 2015 14:50:33


Generated On: 20 Jul 2016 20:43:03

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: 1202**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (42)

Data signed: (hfarmer1) 27 Mar 2015 14:50:33

Generated On: 20 Jul 2016 20:43:03

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day 0)

Form: Oxysterol results (1)

Generated On: 20 Jul 2016 20:43:03

Sample Accession number	3209875339
-------------------------	------------

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: 1202**

Folder: Baseline (Day 0)

Form: Oxysterol results (2)

Generated On: 20 Jul 2016 20:43:03

Sample Accession number	3209875339
-------------------------	------------

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: 1202**

Folder: Baseline (Day 0)

Form: Oxysterol results (3)

Generated On: 20 Jul 2016 20:43:03

Sample Accession number	3209875339
-------------------------	------------

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: 1202**

Folder: Baseline (Day 0)

Form: Oxysterol results (4)

Generated On: 20 Jul 2016 20:43:03

Sample Accession number	3209875339
-------------------------	------------

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: 1202**

Folder: Baseline (Day 0)

Form: Oxysterol results (5)

Generated On: 20 Jul 2016 20:43:03

Sample Accession number	3209875339
-------------------------	------------

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: 1202**

Folder: Baseline (Day 0)

Form: Oxysterol results (6)

Generated On: 20 Jul 2016 20:43:03

Sample Accession number	3209875339
-------------------------	------------

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: 1202**

Folder: Baseline (Day 0)

Form: Oxysterol results (7)

Generated On: 20 Jul 2016 20:43:03

Sample Accession number	3209875339
-------------------------	------------

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: 1202**

Folder: Baseline (Day 0)

Form: Oxysterol results (8)

Generated On: 20 Jul 2016 20:43:03

Sample Accession number	3209875339
-------------------------	------------

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: 1202**

Folder: Baseline (Day 0)

Form: Oxysterol results (9)

Generated On: 20 Jul 2016 20:43:03

Sample Accession number	3209875339
-------------------------	------------

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: 1202**

Folder: Baseline (Day 0)

Form: Oxysterol results (10)

Generated On: 20 Jul 2016 20:43:03

Sample Accession number	3209875339
-------------------------	------------

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: 1202**

Folder: Baseline (Day 0)

Form: Oxysterol results (11)

Generated On: 20 Jul 2016 20:43:03

Sample Accession number	3209875339
-------------------------	------------

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: 1202**

Folder: Baseline (Day 0)

Form: Oxysterol results (12)

Generated On: 20 Jul 2016 20:43:03

Sample Accession number	3209875339
-------------------------	------------

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: 1202**

Folder: Baseline (Day 0)

Form: Lab_BU_COHB (1)

Data signed: (hfarmer1) 27 Mar 2015 14:51:02

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05115150001410
Analyte	CARBOXYHEMOGLOBIN
Sample type	BLOOD
Result	3.60
Result Unit	%
Lab Status	OK
Sample comment	
Detection method	SPECTROPHOTOMETRIC
Lower limit of quantification	0.500
Planned time point (Hour)	6
Day of Visit	0
Celerion Study Number	AA99128-16
Date of Collection	2014-MAR-13
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day 0)

Form: Lab_BU_COHB (1)

Data signed: (hfarmer1) 27 Mar 2015 14:51:02

Generated On: 20 Jul 2016 20:43:03

Start Day (24 hour urine only) _____

End Day (24 hour Urine Only) _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day 0)

Form: Lab_BU_COHB (2)

Data signed: (hfarmer1) 27 Mar 2015 14:51:02

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05115150001411
----------------	----------------

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

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

Result	5.30
--------	------

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

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

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

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

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

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

Day of Visit	0
--------------	---

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

Date of Collection	2014-MAR-13
--------------------	-------------

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day 0)

Form: Lab_BU_COHB (2)

Data signed: (hfarmer1) 27 Mar 2015 14:51:02

Generated On: 20 Jul 2016 20:43:03

Start Day (24 hour urine only)

End Day (24 hour Urine Only)

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day 0)

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)

Data signed: (hfarmer1) 27 Mar 2015 14:50:55

Generated On: 20 Jul 2016 20:43:03

Date of Birth

(b) (6)

Date of assessment

2014 MAR 13

DD/MMM/YYYY

DD/MMM/YYYY

Time of assessment

20:03

hour:min 24-hour clock

Assessment Status

Completed ☒

1. Was smoking satisfying?

Extremely ☒

2. Did cigarettes taste good?

Extremely ☒

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

Quite a lot ☒

4. Did smoking calm you down?

Moderately ☒

5. Did smoking make you feel more awake?

Little ☒

6. Did smoking make you feel less irritable?

Not at all ☒

7. Did smoking help you concentrate?

Moderately ☒

8. Did smoking reduce your hunger for food?

Quite a lot ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day 0)

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)

Data signed: (hfarmer1) 27 Mar 2015 14:50:55

Generated On: 20 Jul 2016 20:43:03

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

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

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

12. Did you enjoy smoking? A lot ☐

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1202

Folder: Baseline (Day 0)

Form: Human Smoking Topography Questionnaire

Data signed: (hfarmer1) 27 Mar 2015 14:50:33

Generated On: 20 Jul 2016 20:43:03

Type	HUMAN SMOKING TOPOGRAPHY QUESTIONNAIRE
------	--

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

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

Date of assessment	13 MAR 2014 DD/MMM/YYYY
--------------------	----------------------------

Time of assessment	20:18 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.	Disagree <input type="radio"/>
--	--------------------------------

If you agree or strongly agree, please describe :	<hr/>
---	-------

2. You enjoy smoking with the device as much as without it.	Strongly agree <input type="radio"/>
---	--------------------------------------

If you disagree or strongly disagree, please describe :	<hr/>
---	-------

3. The taste of the conventional cigarettes/products is different with the device.	Strongly disagree <input type="radio"/>
--	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day 0)

Form: Human Smoking Topography Questionnaire

Data signed: (hfarmer1) 27 Mar 2015 14:50:33

Generated On: 20 Jul 2016 20:43:03

If you agree or strongly agree, please describe : _____

4. The device is easy to use.

Strongly agree ☒

If you disagree or strongly disagree, please describe : _____

5. Your smoking is disturbed by the device.

Strongly disagree ☒

If you agree or strongly agree, please describe : _____

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1202

Folder: Baseline (Day 0)

Form: Questionnaire on smoking urges (QSU)

Data signed: (hfarmer1) 27 Mar 2015 14:50:56

Generated On: 20 Jul 2016 20:43:03

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

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

Date of assessment	2014 MAR 13
--------------------	-------------

DD/MMM/YYYY

Time of assessment	20:02
--------------------	-------

hour:min 24-hour clock

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

1. I have a desire for a cigarette right now	Do not agree or disagree <input type="radio"/>
--	--

2. Nothing would be better than smoking a cigarette right now	Do not agree or disagree <input type="radio"/>
---	--

3. If it were possible I would probably smoke now	Do not agree or disagree <input type="radio"/>
---	--

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

5. All I want right now is a cigarette	Somewhat agree <input type="radio"/>
--	--------------------------------------

6. I have an urge for a cigarette	Somewhat agree <input type="radio"/>
-----------------------------------	--------------------------------------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day 0)

Form: Questionnaire on smoking urges (QSU)

Data signed: (hfarmer1) 27 Mar 2015 14:50:56

Generated On: 20 Jul 2016 20:43:03

7. A cigarette would taste good now Agree ☐

8. I would do almost anything for a cigarette now Do not agree or disagree ☐

9. Smoking would make me less depressed Strongly disagree ☐

10. I am going to smoke as soon as possible Strongly agree ☐

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1202

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:50:57

Generated On: 20 Jul 2016 20:43:03

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	1202
----------------------	------

Subject Sex	M
-------------	---

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

Visit Name	DAY0
------------	------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	W098753
--------------	---------

Actual Collection Date	2014 03 13
------------------------	------------

Actual Collection Time	06:09
------------------------	-------

Specimen Condition	
--------------------	--

Battery ID	HM1054
------------	--------

Battery Name	HEMOGLOBIN A1C
--------------	----------------

Lab Test ID	HMT370
-------------	--------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:50:57


Generated On: 20 Jul 2016 20:43:03

Lab Test Name

HEMOGLOBIN
A1C,VARIANT(-70)

Test ID

Test Status

Done 

Reported Text Result

5.2

Reported Numeric Result

5.2

Reference Range low

Reference Range high

<6.5

Range Units

%

Conventional Text Result

Conventional Numeric Result

Conventional Reference Range Low

Conventional Reference Range High

Conventional Units

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:50:57

Generated On: 20 Jul 2016 20:43:03

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: 1202**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (2)

Data signed: (hfarmer1) 27 Mar 2015 14:50:57

Generated On: 20 Jul 2016 20:43:03

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	1202
----------------------	------

Subject Sex	M
-------------	---

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

Visit Name	DAY0
------------	------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	W098753
--------------	---------

Actual Collection Date	2014 03 13
------------------------	------------

Actual Collection Time	06:09
------------------------	-------

Specimen Condition	
--------------------	--

Battery ID	RC6871
------------	--------

Battery Name	HDL
--------------	-----

Lab Test ID	RCT1684
-------------	---------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (2)

Data signed: (hfarmer1) 27 Mar 2015 14:50:57

Generated On: 20 Jul 2016 20:43:03

Lab Test Name	DIRECT HDL-C 3RD GENERATION
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	57
Reported Numeric Result	57
Reference Range low	29
Reference Range high	62
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: 1202**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (2)

Data signed: (hfarmer1) 27 Mar 2015 14:50:57

Generated On: 20 Jul 2016 20:43:03

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: 1202

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (3)

Data signed: (hfarmer1) 27 Mar 2015 14:50:57

Generated On: 20 Jul 2016 20:43:03

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	1202
----------------------	------

Subject Sex	M
-------------	---

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

Visit Name	DAY0
------------	------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	W098753
--------------	---------

Actual Collection Date	2014 03 13
------------------------	------------

Actual Collection Time	06:09
------------------------	-------

Specimen Condition	
--------------------	--

Battery ID	SC3249
------------	--------

Battery Name	HS-CRP
--------------	--------

Lab Test ID	SCT1528
-------------	---------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1202

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (3)

Data signed: (hfarmer1) 27 Mar 2015 14:50:57

Generated On: 20 Jul 2016 20:43:03

Lab Test Name	C-REACTIVE PROTEIN (NHS)-QT
---------------	-----------------------------

Test ID	<hr/>
---------	-------

Test Status	Done <input checked="" type="radio"/>
-------------	---------------------------------------

Reported Text Result	0.239
----------------------	-------

Reported Numeric Result	0.239
-------------------------	-------

Reference Range low	<hr/>
---------------------	-------

Reference Range high	<=0.287
----------------------	---------

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/>
--------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (3)

Data signed: (hfarmer1) 27 Mar 2015 14:50:57

Generated On: 20 Jul 2016 20:43:03

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: 1202**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (4)

Data signed: (hfarmer1) 27 Mar 2015 14:50:57

Generated On: 20 Jul 2016 20:43:03

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	1202
----------------------	------

Subject Sex	M
-------------	---

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

Visit Name	DAY0
------------	------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	W098753
--------------	---------

Actual Collection Date	2014 03 13
------------------------	------------

Actual Collection Time	06:09
------------------------	-------

Specimen Condition	
--------------------	--

Battery ID	SC3582
------------	--------

Battery Name	APOLIPOPROTEIN
--------------	----------------

Lab Test ID	SCT3639
-------------	---------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1202

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (4)

Data signed: (hfarmer1) 27 Mar 2015 14:50:57

Generated On: 20 Jul 2016 20:43:03

Lab Test Name	APOLIPOPROTEIN A1, RAND
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	159
Reported Numeric Result	159
Reference Range low	110
Reference Range high	205
Range Units	MG/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (4)

Data signed: (hfarmer1) 27 Mar 2015 14:50:57

Generated On: 20 Jul 2016 20:43:03

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: 1202**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (5)

Data signed: (hfarmer1) 27 Mar 2015 14:50:57

Generated On: 20 Jul 2016 20:43:03

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	1202
----------------------	------

Subject Sex	M
-------------	---

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

Visit Name	DAY0
------------	------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	W098753
--------------	---------

Actual Collection Date	2014 03 13
------------------------	------------

Actual Collection Time	06:09
------------------------	-------

Specimen Condition	
--------------------	--

Battery ID	SC3582
------------	--------

Battery Name	APOLIPOPROTEIN
--------------	----------------

Lab Test ID	SCT3643
-------------	---------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1202

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (5)

Data signed: (hfarmer1) 27 Mar 2015 14:50:57

Generated On: 20 Jul 2016 20:43:03

Lab Test Name	APOLIPOPROTEIN B, RAND
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	100
Reported Numeric Result	100
Reference Range low	55
Reference Range high	140
Range Units	MG/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (5)

Data signed: (hfarmer1) 27 Mar 2015 14:50:57

Generated On: 20 Jul 2016 20:43:03

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: 1202**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (6)

Data signed: (hfarmer1) 27 Mar 2015 14:50:57

Generated On: 20 Jul 2016 20:43:03

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	1202
----------------------	------

Subject Sex	M
-------------	---

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

Visit Name	DAY0
------------	------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	W098753
--------------	---------

Actual Collection Date	2014 03 13
------------------------	------------

Actual Collection Time	06:09
------------------------	-------

Specimen Condition	
--------------------	--

Battery ID	CG267
------------	-------

Battery Name	FIBRINOGEN
--------------	------------

Lab Test ID	CGT285
-------------	--------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1202

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (6)

Data signed: (hfarmer1) 27 Mar 2015 14:50:57

Generated On: 20 Jul 2016 20:43:03

Lab Test Name	FIBRINOGEN
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	302
Reported Numeric Result	302
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: 1202**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (6)

Data signed: (hfarmer1) 27 Mar 2015 14:50:57

Generated On: 20 Jul 2016 20:43:03

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: 1202

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (7)

Data signed: (hfarmer1) 27 Mar 2015 14:50:57

Generated On: 20 Jul 2016 20:43:03

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	1202
----------------------	------

Subject Sex	M
-------------	---

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

Visit Name	DAY0
------------	------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	W098753
--------------	---------

Actual Collection Date	2014 03 13
------------------------	------------

Actual Collection Time	06:09
------------------------	-------

Specimen Condition	
--------------------	--

Battery ID	CN236
------------	-------

Battery Name	HOMOCYSTEINE
--------------	--------------

Lab Test ID	CNT145
-------------	--------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1202

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (7)

Data signed: (hfarmer1) 27 Mar 2015 14:50:57

Generated On: 20 Jul 2016 20:43:03

Lab Test Name	HOMOCYSTEINE, EDTAPL
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	8.53
Reported Numeric Result	8.53
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: 1202**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (7)

Data signed: (hfarmer1) 27 Mar 2015 14:50:57

Generated On: 20 Jul 2016 20:43:03

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: 1202**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (8)

Data signed: (hfarmer1) 27 Mar 2015 14:50:57

Generated On: 20 Jul 2016 20:43:03

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	1202
----------------------	------

Subject Sex	M
-------------	---

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

Visit Name	DAY0
------------	------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	W098753
--------------	---------

Actual Collection Date	2014 03 13
------------------------	------------

Actual Collection Time	06:09
------------------------	-------

Specimen Condition	
--------------------	--

Battery ID	IM2293
------------	--------

Battery Name	SICAM-1
--------------	---------

Lab Test ID	IMT1768
-------------	---------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1202

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (8)

Data signed: (hfarmer1) 27 Mar 2015 14:50:57

Generated On: 20 Jul 2016 20:43:03

Lab Test Name	SICAM-1-RUO
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	154.3
Reported Numeric Result	154.3
Reference Range low	98.8
Reference Range high	320.0
Range Units	NG/ML
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (8)

Data signed: (hfarmer1) 27 Mar 2015 14:50:57

Generated On: 20 Jul 2016 20:43:03

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: 1202

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (9)

Data signed: (hfarmer1) 27 Mar 2015 14:50:57

Generated On: 20 Jul 2016 20:43:03

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	1202
----------------------	------

Subject Sex	M
-------------	---

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

Visit Name	DAY0
------------	------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	W098753
--------------	---------

Actual Collection Date	2014 03 13
------------------------	------------

Actual Collection Time	06:09
------------------------	-------

Specimen Condition	
--------------------	--

Battery ID	RC9267
------------	--------

Battery Name	LDL
--------------	-----

Lab Test ID	RCT2394
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1202

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (9)

Data signed: (hfarmer1) 27 Mar 2015 14:50:57

Generated On: 20 Jul 2016 20:43:03

Lab Test Name	DIRECT LDL-C 2ND GEN (-70)
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Test ID	<hr/>
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Test Status	Done 
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Reported Text Result	139
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Reported Numeric Result	139
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Reference Range low	81
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Reference Range high	189
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Range Units	MG/DL
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Conventional Text Result	<hr/>
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Conventional Numeric Result	<hr/>
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Conventional Reference Range Low	<hr/>
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Conventional Reference Range High	<hr/>
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Conventional Units	<hr/>
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SI Text Result	<hr/>
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (9)

Data signed: (hfarmer1) 27 Mar 2015 14:50:57

Generated On: 20 Jul 2016 20:43:03

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: 1202**

Folder: Baseline (Day 0)

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

Data signed: (hfarmer1) 27 Mar 2015 14:51:03

Generated On: 20 Jul 2016 20:43:03

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day 0)

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

Data signed: (hfarmer1) 27 Mar 2015 14:51:03

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05112450002277
Analyte	HPMA
Sample type	URINE
Result	408
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	0
Celerion Study Number	AA99128-03
Date of Collection	2014-MAR-13
Timepoint-minutes	
Urine Start Day	0

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day 0)

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

Data signed: (hfarmer1) 27 Mar 2015 14:51:03

Generated On: 20 Jul 2016 20:43:03

Urine End Day

1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (CEMA, HPMa, HBMA) (2)

Data signed: (hfarmer1) 27 Mar 2015 14:51:03

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05112450002277
Analyte	CEMA
Sample type	URINE
Result	37.7
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	0
Celerion Study Number	AA99128-03
Date of Collection	2014-MAR-13
Timepoint-minutes	
Urine Start Day	0

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (CEMA, HPMa, HBMA) (2)

Data signed: (hfarmer1) 27 Mar 2015 14:51:03

Generated On: 20 Jul 2016 20:43:03

Urine End Day	1
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (CEMA, HPMa, HBMA) (3)

Data signed: (hfarmer1) 27 Mar 2015 14:51:03

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05112450002277
Analyte	HBMA
Sample type	URINE
Result	159
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	0
Celerion Study Number	AA99128-03
Date of Collection	2014-MAR-13
Timepoint-minutes	
Urine Start Day	0

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (3)

Data signed: (hfarmer1) 27 Mar 2015 14:51:03

Generated On: 20 Jul 2016 20:43:03

Urine End Day	1
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (NNN, NNAL)

Data signed: (hfarmer1) 27 Mar 2015 14:51:02

Generated On: 20 Jul 2016 20:43:03

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (NNN, NNAL) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:51:02

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05112460002720
Analyte	NNAL
Sample type	URINE
Result	.
Result Unit	PG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	0
Celerion Study Number	AA99128-04
Date of Collection	2014-MAR-13
Timepoint-minutes	
Urine Start Day	0

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (NNN, NNAL) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:51:02

Generated On: 20 Jul 2016 20:43:03

Urine End Day	1
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (NNN, NNAL) (2)

Data signed: (hfarmer1) 27 Mar 2015 14:51:02

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05112460002720
Analyte	NNN
Sample type	URINE
Result	.
Result Unit	PG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	0
Celerion Study Number	AA99128-04
Date of Collection	2014-MAR-13
Timepoint-minutes	
Urine Start Day	0

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (NNN, NNAL) (2)

Data signed: (hfarmer1) 27 Mar 2015 14:51:02

Generated On: 20 Jul 2016 20:43:03

Urine End Day

1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (HEMA)

Data signed: (hfarmer1) 27 Mar 2015 14:51:02

Generated On: 20 Jul 2016 20:43:03

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (HEMA) (2)

Data signed: (hfarmer1) 27 Mar 2015 14:51:02

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05112470001347
Analyte	HEMA
Sample type	URINE
Result	1.84
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	0
Celerion Study Number	AA99128-05
Date of Collection	2014-MAR-13
Timepoint-minutes	
Urine Start Day	0

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (HEMA) (2)

Data signed: (hfarmer1) 27 Mar 2015 14:51:02

Generated On: 20 Jul 2016 20:43:03

Urine End Day	1
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day 0)

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

Data signed: (hfarmer1) 27 Mar 2015 14:51:03

Generated On: 20 Jul 2016 20:43:03

Sample type

URINE

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1202

Folder: Baseline (Day 0)

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

Data signed: (hfarmer1) 27 Mar 2015 14:51:03

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05112550000256
Analyte	COT
Sample type	URINE
Result	728
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	0
Celerion Study Number	AA99128-13
Date of Collection	2014-MAR-13
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day 0)

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

Data signed: (hfarmer1) 27 Mar 2015 14:51:03

Generated On: 20 Jul 2016 20:43:03

Urine Start Day	0
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Urine End Day	1
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1202

Folder: Baseline (Day 0)

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

Data signed: (hfarmer1) 27 Mar 2015 14:51:03

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05112550000256
Analyte	COT-GLUC
Sample type	URINE
Result	1550
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	0
Celerion Study Number	AA99128-13
Date of Collection	2014-MAR-13
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day 0)

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

Data signed: (hfarmer1) 27 Mar 2015 14:51:03

Generated On: 20 Jul 2016 20:43:03

Urine Start Day	0
<hr/>	
Urine End Day	1
<hr/>	

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1202

Folder: Baseline (Day 0)

Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc) (3)

Data signed: (hfarmer1) 27 Mar 2015 14:51:03

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05112550000256
Analyte	NIC
Sample type	URINE
Result	363
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	0
Celerion Study Number	AA99128-13
Date of Collection	2014-MAR-13
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day 0)

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(3)**

Data signed: (hfarmer1) 27 Mar 2015 14:51:03

Generated On: 20 Jul 2016 20:43:03

Urine Start Day	0
<hr/>	
Urine End Day	1
<hr/>	

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1202

Folder: Baseline (Day 0)

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

Data signed: (hfarmer1) 27 Mar 2015 14:51:03

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05112550000256
Analyte	NIC-GLUC
Sample type	URINE
Result	379
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	0
Celerion Study Number	AA99128-13
Date of Collection	2014-MAR-13
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day 0)

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

Data signed: (hfarmer1) 27 Mar 2015 14:51:03

Generated On: 20 Jul 2016 20:43:03

Urine Start Day	0
<hr/>	
Urine End Day	1
<hr/>	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day 0)

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

Data signed: (hfarmer1) 27 Mar 2015 14:51:03

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05112550000256
Analyte	THCOT
Sample type	URINE
Result	1510
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	0
Celerion Study Number	AA99128-13
Date of Collection	2014-MAR-13
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day 0)

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

Data signed: (hfarmer1) 27 Mar 2015 14:51:03

Generated On: 20 Jul 2016 20:43:03

Urine Start Day	0
<hr/>	
Urine End Day	1
<hr/>	

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1202

Folder: Baseline (Day 0)

Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc) (6)

Data signed: (hfarmer1) 27 Mar 2015 14:51:03

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05112550000256
Analyte	THCOT-GLUC
Sample type	URINE
Result	686
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	0
Celerion Study Number	AA99128-13
Date of Collection	2014-MAR-13
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day 0)

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(6)**

Data signed: (hfarmer1) 27 Mar 2015 14:51:03

Generated On: 20 Jul 2016 20:43:03

Urine Start Day	0
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Urine End Day	1
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (3-OH BaP)

Data signed: (hfarmer1) 27 Mar 2015 14:51:04

Generated On: 20 Jul 2016 20:43:03

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (3-OH BaP) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:51:04

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05112490001356
Analyte	3-OH BAP
Sample type	URINE
Result	.
Result Unit	FG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	0
Celerion Study Number	AA99128-07
Date of Collection	2014-MAR-13
Timepoint-minutes	
Urine Start Day	0

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (3-OH BaP) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:51:04

Generated On: 20 Jul 2016 20:43:03

Urine End Day

1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day 0)

Form: Biomarker-Plasma (Caffeine, Paraxanthine)

Generated On: 20 Jul 2016 20:43:03

Sample type

PLASMA

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day 0)

Form: Biomarker-Plasma (Caffeine, Paraxanthine) (1)

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05112500000370
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Analyte	CAFFEINE
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Sample type	PLASMA
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Result	1010
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Result Unit	NG/ML
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Lab Status	OTHER
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Sample comment	ANALYZED IN ERROR
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Detection method	LC-MS/MS
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Planned time point (Hour)	6
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Day of Visit	0
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Celerion Study Number	AA99128-08
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Date of Collection	2014-MAR-13
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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: 1202**

Folder: Baseline (Day 0)

Form: Biomarker-Plasma (Caffeine, Paraxanthine) (1)

Generated On: 20 Jul 2016 20:43:03

Urine End Day	0
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day 0)

Form: Biomarker-Plasma (Caffeine, Paraxanthine) (2)

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05112500000370
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Analyte	PARAXANTHINE
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Sample type	PLASMA
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Result	1320
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Result Unit	NG/ML
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Lab Status	OTHER
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Sample comment	ANALYZED IN ERROR
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Detection method	LC-MS/MS
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Planned time point (Hour)	6
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Day of Visit	0
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Celerion Study Number	AA99128-08
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Date of Collection	2014-MAR-13
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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: 1202**

Folder: Baseline (Day 0)

Form: Biomarker-Plasma (Caffeine, Paraxanthine) (2)

Generated On: 20 Jul 2016 20:43:03

Urine End Day	0
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP)

Data signed: (hfarmer1) 27 Mar 2015 14:51:04

Generated On: 20 Jul 2016 20:43:03

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:51:04

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05112510001378
Analyte	1-NA
Sample type	URINE
Result	41.9
Result Unit	PG/ML
Lab Status	OTHER
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	0
Celerion Study Number	AA99128-09
Date of Collection	2014-MAR-13
Timepoint-minutes	
Urine Start Day	0

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:51:04

Generated On: 20 Jul 2016 20:43:03

Urine End Day	1
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (2)

Data signed: (hfarmer1) 27 Mar 2015 14:51:04

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05112510001378
Analyte	2-NA
Sample type	URINE
Result	10.9
Result Unit	PG/ML
Lab Status	OTHER
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	0
Celerion Study Number	AA99128-09
Date of Collection	2014-MAR-13
Timepoint-minutes	
Urine Start Day	0

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (2)

Data signed: (hfarmer1) 27 Mar 2015 14:51:04

Generated On: 20 Jul 2016 20:43:03

Urine End Day	1
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (3)

Data signed: (hfarmer1) 27 Mar 2015 14:51:04

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05112510001378
Analyte	4-ABP
Sample type	URINE
Result	6.71
Result Unit	PG/ML
Lab Status	OTHER
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	0
Celerion Study Number	AA99128-09
Date of Collection	2014-MAR-13
Timepoint-minutes	
Urine Start Day	0

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (3)

Data signed: (hfarmer1) 27 Mar 2015 14:51:04

Generated On: 20 Jul 2016 20:43:03

Urine End Day	1
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (4)

Data signed: (hfarmer1) 27 Mar 2015 14:51:04

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05112510001378
Analyte	O-TOL
Sample type	URINE
Result	56.8
Result Unit	PG/ML
Lab Status	OTHER
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	0
Celerion Study Number	AA99128-09
Date of Collection	2014-MAR-13
Timepoint-minutes	
Urine Start Day	0

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (4)

Data signed: (hfarmer1) 27 Mar 2015 14:51:04

Generated On: 20 Jul 2016 20:43:03

Urine End Day	1
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (11-dTXb2)

Data signed: (hfarmer1) 27 Mar 2015 14:51:02

Generated On: 20 Jul 2016 20:43:03

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (11-dTXb2) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:51:02

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05112530000430
Analyte	11-DTXB2
Sample type	URINE
Result	.
Result Unit	PG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	0
Celerion Study Number	AA99128-11
Date of Collection	2014-MAR-13
Timepoint-minutes	
Urine Start Day	0

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (11-dTXb2) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:51:02

Generated On: 20 Jul 2016 20:43:03

Urine End Day	1
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (iPF2a-III)

Data signed: (hfarmer1) 27 Mar 2015 14:51:02

Generated On: 20 Jul 2016 20:43:03

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (iPF2a-III) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:51:02

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05112540000423
Analyte	IPF2A-III
Sample type	URINE
Result	150
Result Unit	PG/ML
Lab Status	OTHER
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	0
Celerion Study Number	AA99128-12
Date of Collection	2014-MAR-13
Timepoint-minutes	
Urine Start Day	0

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (iPF2a-III) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:51:02

Generated On: 20 Jul 2016 20:43:03

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (Ames)

Data signed: (hfarmer1) 27 Mar 2015 14:51:05

Generated On: 20 Jul 2016 20:43:03

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (Ames) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:51:05

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05113320000139
Analyte	AMES
Sample type	URINE
Result	16.1
Result Unit	REV/ML
Lab Status	OTHER
Sample comment	ANALYZED IN ERROR
Detection method	COUNT
Planned time point (Hour)	0
Day of Visit	0
Celerion Study Number	AA99128-15
Date of Collection	2014-MAR-13
Timepoint-minutes	
Urine Start Day	0

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (Ames) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:51:05

Generated On: 20 Jul 2016 20:43:03

Urine End Day	1
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (1-OHP)

Data signed: (hfarmer1) 27 Mar 2015 14:51:05

Generated On: 20 Jul 2016 20:43:03

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (1-OHP) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:51:05

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05115190001609
Analyte	1-OHP
Sample type	URINE
Result	.
Result Unit	PG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	0
Celerion Study Number	AA99598-03
Date of Collection	2014-MAR-13
Timepoint-minutes	
Urine Start Day	0

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (1-OHP) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:51:05

Generated On: 20 Jul 2016 20:43:03

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (SPMA, SBMA)

Data signed: (hfarmer1) 27 Mar 2015 14:51:02

Generated On: 20 Jul 2016 20:43:03

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (SPMA, SBMA) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:51:02

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05115170001587
Analyte	SBMA
Sample type	URINE
Result	.
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	0
Celerion Study Number	AA99598-01
Date of Collection	2014-MAR-13
Timepoint-minutes	
Urine Start Day	0

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (SPMA, SBMA) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:51:02

Generated On: 20 Jul 2016 20:43:03

Urine End Day

1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (SPMA, SBMA) (2)

Data signed: (hfarmer1) 27 Mar 2015 14:51:02

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05115170001587
Analyte	SPMA
Sample type	URINE
Result	.
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	0
Celerion Study Number	AA99598-01
Date of Collection	2014-MAR-13
Timepoint-minutes	
Urine Start Day	0

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (SPMA, SBMA) (2)

Data signed: (hfarmer1) 27 Mar 2015 14:51:02

Generated On: 20 Jul 2016 20:43:03

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (MHBMA)

Data signed: (hfarmer1) 27 Mar 2015 14:51:03

Generated On: 20 Jul 2016 20:43:03

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (MHBMA) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:51:03

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05115180001609
Analyte	MHBMA
Sample type	URINE
Result	.
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	0
Celerion Study Number	AA99598-02
Date of Collection	2014-MAR-13
Timepoint-minutes	
Urine Start Day	0

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (MHBMA) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:51:03

Generated On: 20 Jul 2016 20:43:03

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (Creatinine)

Data signed: (hfarmer1) 27 Mar 2015 14:51:05

Generated On: 20 Jul 2016 20:43:03

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (Creatinine) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:51:05

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05115160001356
Analyte	CREATININE
Sample type	URINE
Result	.
Result Unit	MG/DL
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	SPECTROPHOTOMETRIC
Planned time point (Hour)	0
Day of Visit	0
Celerion Study Number	AA99128-14
Date of Collection	2014-MAR-13
Timepoint-minutes	
Urine Start Day	0

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (Creatinine) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:51:05

Generated On: 20 Jul 2016 20:43:03

Urine End Day

1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day 0)

Form: Biomarker-Plasma (Nic, Cot, tHCot)

Generated On: 20 Jul 2016 20:43:03

Sample type

PLASMA

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day 0)

Form: Biomarker-Plasma (Nic, Cot, tHCot) (1)

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05112440000231
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Analyte	COT
---------	-----

Sample type	PLASMA
-------------	--------

Result	135
--------	-----

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

Lab Status	OTHER
------------	-------

Sample comment	ANALYZED IN ERROR
----------------	-------------------

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	0
--------------	---

Celerion Study Number	AA99128-02
-----------------------	------------

Date of Collection	2014-MAR-13
--------------------	-------------

Timepoint-minutes	0
-------------------	---

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day 0)

Form: Biomarker-Plasma (Nic, Cot, tHCot) (1)

Generated On: 20 Jul 2016 20:43:03

Urine End Day	0
---------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day 0)

Form: Biomarker-Plasma (Nic, Cot, tHCot) (2)

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05112440000231
----------------	----------------

Analyte	NIC
---------	-----

Sample type	PLASMA
-------------	--------

Result	8.93
--------	------

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

Lab Status	OTHER
------------	-------

Sample comment	ANALYZED IN ERROR
----------------	-------------------

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	0
--------------	---

Celerion Study Number	AA99128-02
-----------------------	------------

Date of Collection	2014-MAR-13
--------------------	-------------

Timepoint-minutes	0
-------------------	---

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day 0)

Form: Biomarker-Plasma (Nic, Cot, tHCot) (2)

Generated On: 20 Jul 2016 20:43:03

Urine End Day	0
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day 0)

Form: Biomarker-Plasma (Nic, Cot, tHCot) (3)

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05112520000370
----------------	----------------

Analyte	COT
---------	-----

Sample type	PLASMA
-------------	--------

Result	118
--------	-----

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

Lab Status	OTHER
------------	-------

Sample comment	ANALYZED IN ERROR
----------------	-------------------

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	0
--------------	---

Celerion Study Number	AA99128-10
-----------------------	------------

Date of Collection	2014-MAR-13
--------------------	-------------

Timepoint-minutes	0
-------------------	---

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day 0)

Form: Biomarker-Plasma (Nic, Cot, tHCot) (3)

Generated On: 20 Jul 2016 20:43:03

Urine End Day	0
---------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day 0)

Form: Biomarker-Plasma (Nic, Cot, tHCot) (4)

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05112520000370
----------------	----------------

Analyte	THCOT
---------	-------

Sample type	PLASMA
-------------	--------

Result	44.2
--------	------

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

Lab Status	OTHER
------------	-------

Sample comment	ANALYZED IN ERROR
----------------	-------------------

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	0
--------------	---

Celerion Study Number	AA99128-10
-----------------------	------------

Date of Collection	2014-MAR-13
--------------------	-------------

Timepoint-minutes	0
-------------------	---

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Baseline (Day 0)

Form: Biomarker-Plasma (Nic, Cot, tHCot) (4)

Generated On: 20 Jul 2016 20:43:03

Urine End Day	0
---------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 1

Form: Date of Visit

Data signed: (hfarmer1) 27 Mar 2015 14:51:05

Generated On: 20 Jul 2016 20:43:03

Date of Visit

14 MAR 2014
DD/MMM/YYYY

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 1

Form: Vital Signs

Data signed: (hcoleman1) 18 Jun 2015 21:10:23

Generated On: 20 Jul 2016 20:43:03

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

09:52
hour:min 24-hour clock

Pulse rate

55
beats per minute

Respiratory rate

16
breaths per minute

Blood Pressure (systolic)

104
mmHg

Blood Pressure (diastolic)

58
mmHg

Vital Signs Position of Subject

Supine ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 1

Form: Plasma Nicotine Sample

Data signed: (hfarmer1) 27 Mar 2015 14:51:05

Generated On: 20 Jul 2016 20:43:03

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	14 MAR 2014
---------------------	-------------

Time hour:min 24-hour clock	21:01
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 1

Form: Plasma Cotinine Sample

Data signed: (hfarmer1) 27 Mar 2015 14:51:05

Generated On: 20 Jul 2016 20:43:03

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	14 MAR 2014
---------------------	-------------

Time hour:min 24-hour clock	21:01
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 1

Form: CoHb Blood Sample

Data signed: (hfarmer1) 27 Mar 2015 14:51:05

Generated On: 20 Jul 2016 20:43:03

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	14 MAR 2014
---------------------	-------------

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

Time hour:min 24-hour clock	21:01
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 1

Form: CO Breath Test <SA arm/> (1)

Data signed: (hfarmer1) 27 Mar 2015 14:51:06

Generated On: 20 Jul 2016 20:43:03

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

If Not Done, please specify the reason: _____

Scheduled Time	08:00 - 09:30 
----------------	---

Actual Time of Assessment hour:min 24-hour clock	08:15
---	-------

Result(ppm)	8
-------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 1

Form: CO Breath Test <SA arm/> (2)

Data signed: (hfarmer1) 27 Mar 2015 14:51:06

Generated On: 20 Jul 2016 20:43:03

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	12:22
---	-------

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 1

Form: CO Breath Test <SA arm/> (3)

Data signed: (hfarmer1) 27 Mar 2015 14:51:06

Generated On: 20 Jul 2016 20:43:03

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

If Not Done, please specify the reason: _____

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

Actual Time of Assessment hour:min 24-hour clock	16:29
---	-------

Result(ppm)	6
-------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 1

Form: CO Breath Test <SA arm/> (4)

Data signed: (hfarmer1) 27 Mar 2015 14:51:06

Generated On: 20 Jul 2016 20:43:03

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	20:28
---	-------

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 1

Form: 24 hour urine collections

Data signed: (hfarmer1) 27 Mar 2015 14:51:05

Generated On: 20 Jul 2016 20:43:03

Start Time	06:08
	hour:min 24-hour clock

End Date	15 MAR 2014
	DD/MMM/YYYY

End Time	06:09
	hour:min 24-hour clock

Volume	1624
	mL

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 1

Form: Sample Urine Collection

Data signed: (hfarmer1) 27 Mar 2015 14:51:05

Generated On: 20 Jul 2016 20:43:03

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: 1202**

Folder: Day 1

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Data signed: (hfarmer1) 27 Mar 2015 14:51:07

Generated On: 20 Jul 2016 20:43:03

Date of Birth

(b) (6)

Date of assessment
DD/MMM/YYYY

2014 MAR 14
DD/MMM/YYYY

Time of assessment

06:25
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?

Mild ☐

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: 1202**

Folder: Day 1

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Data signed: (hfarmer1) 27 Mar 2015 14:51:07

Generated On: 20 Jul 2016 20:43:03

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

5. Difficulty concentrating

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

6. Increased appetite, hungry, weight gain

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

7. Insomnia, sleep problems, awakening at night

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

8. Restless

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

9. Impatient

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

10. Constipation

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

11. Dizziness

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

12. Coughing

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 1

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Data signed: (hfarmer1) 27 Mar 2015 14:51:07

Generated On: 20 Jul 2016 20:43:03

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: 1202**

Folder: Day 1

Form: Cough Assessment

Data signed: (hfarmer1) 27 Mar 2015 14:51:07

Generated On: 20 Jul 2016 20:43:03

Date of Birth

(b) (6)

Date of assessment
DD/MMM/YYYY

2014 MAR 14
DD/MMM/YYYY

Time of assessment

06:24
hour:min 24-hour clock

Assessment Status

Completed ☒

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

No ☒

If YES, please answer the following questions:

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

-9

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

Not Applicable ☒

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

Not Applicable ☒

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

Not Applicable ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 1

Form: Lab_BU_COHB (1)

Data signed: (hfarmer1) 27 Mar 2015 14:51:08

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05115150001412
----------------	----------------

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

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

Result	2.40
--------	------

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

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

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

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

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

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

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

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

Date of Collection	2014-MAR-14
--------------------	-------------

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 1

Form: Lab_BU_COHB (1)

Data signed: (hfarmer1) 27 Mar 2015 14:51:08

Generated On: 20 Jul 2016 20:43:03

Start Day (24 hour urine only)

End Day (24 hour Urine Only)

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 1

Form: Questionnaire on smoking urges (QSU)

Data signed: (hfarmer1) 27 Mar 2015 14:51:08

Generated On: 20 Jul 2016 20:43:03

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

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

Date of assessment	2014 MAR 14
--------------------	-------------

DD/MMM/YYYY

Time of assessment	20:13
--------------------	-------

hour:min 24-hour clock

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

1. I have a desire for a cigarette right now	Somewhat agree <input checked="" type="radio"/>
--	---

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

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

4. I could control things better right now if I could smoke	Do not agree or disagree <input checked="" type="radio"/>
---	---

5. All I want right now is a cigarette	Do not agree or disagree <input checked="" type="radio"/>
--	---

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 1

Form: Questionnaire on smoking urges (QSU)

Data signed: (hfarmer1) 27 Mar 2015 14:51:08

Generated On: 20 Jul 2016 20:43:03

7. A cigarette would taste good now Strongly agree ☐

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: 1202**

Folder: Day 1

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

Data signed: (hfarmer1) 27 Mar 2015 14:51:09

Generated On: 20 Jul 2016 20:43:03

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 1

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

Data signed: (hfarmer1) 27 Mar 2015 14:51:09

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05112450002278
Analyte	HPMA
Sample type	URINE
Result	234
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	1
Celerion Study Number	AA99128-03
Date of Collection	2014-MAR-14
Timepoint-minutes	
Urine Start Day	1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 1

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

Data signed: (hfarmer1) 27 Mar 2015 14:51:09

Generated On: 20 Jul 2016 20:43:03

Urine End Day

2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 1

Form: Biomarker-Urine (CEMA, HPMa, HBMA) (2)

Data signed: (hfarmer1) 27 Mar 2015 14:51:09

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05112450002278
Analyte	CEMA
Sample type	URINE
Result	26.9
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	1
Celerion Study Number	AA99128-03
Date of Collection	2014-MAR-14
Timepoint-minutes	
Urine Start Day	1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 1

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (2)

Data signed: (hfarmer1) 27 Mar 2015 14:51:09

Generated On: 20 Jul 2016 20:43:03

Urine End Day

2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 1

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (3)

Data signed: (hfarmer1) 27 Mar 2015 14:51:09

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05112450002278
Analyte	HBMA
Sample type	URINE
Result	203
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	1
Celerion Study Number	AA99128-03
Date of Collection	2014-MAR-14
Timepoint-minutes	
Urine Start Day	1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 1

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (3)

Data signed: (hfarmer1) 27 Mar 2015 14:51:09

Generated On: 20 Jul 2016 20:43:03

Urine End Day

2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 1

Form: Biomarker-Urine (NNN, NNAL)

Data signed: (hfarmer1) 27 Mar 2015 14:51:08

Generated On: 20 Jul 2016 20:43:03

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 1

Form: Biomarker-Urine (NNN, NNAL) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:51:08

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05112460002721
Analyte	NNAL
Sample type	URINE
Result	.
Result Unit	PG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	1
Celerion Study Number	AA99128-04
Date of Collection	2014-MAR-14
Timepoint-minutes	
Urine Start Day	1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 1

Form: Biomarker-Urine (NNN, NNAL) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:51:08

Generated On: 20 Jul 2016 20:43:03

Urine End Day

2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 1

Form: Biomarker-Urine (NNN, NNAL) (2)

Data signed: (hfarmer1) 27 Mar 2015 14:51:08

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05112460002721
Analyte	NNN
Sample type	URINE
Result	.
Result Unit	PG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	1
Celerion Study Number	AA99128-04
Date of Collection	2014-MAR-14
Timepoint-minutes	
Urine Start Day	1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 1

Form: Biomarker-Urine (NNN, NNAL) (2)

Data signed: (hfarmer1) 27 Mar 2015 14:51:08

Generated On: 20 Jul 2016 20:43:03

Urine End Day

2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 1

Form: Biomarker-Urine (HEMA)

Data signed: (hfarmer1) 27 Mar 2015 14:51:08

Generated On: 20 Jul 2016 20:43:03

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 1

Form: Biomarker-Urine (HEMA) (2)

Data signed: (hfarmer1) 27 Mar 2015 14:51:08

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05112470001348
Analyte	HEMA
Sample type	URINE
Result	1.14
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	1
Celerion Study Number	AA99128-05
Date of Collection	2014-MAR-14
Timepoint-minutes	
Urine Start Day	1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 1

Form: Biomarker-Urine (HEMA) (2)

Data signed: (hfarmer1) 27 Mar 2015 14:51:08

Generated On: 20 Jul 2016 20:43:03

Urine End Day

2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 1

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

Data signed: (hfarmer1) 27 Mar 2015 14:51:09

Generated On: 20 Jul 2016 20:43:03

Sample type

URINE

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1202

Folder: Day 1

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

Data signed: (hfarmer1) 27 Mar 2015 14:51:09

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05112550000257
Analyte	COT
Sample type	URINE
Result	582
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	1
Celerion Study Number	AA99128-13
Date of Collection	2014-MAR-14
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 1

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

Data signed: (hfarmer1) 27 Mar 2015 14:51:09

Generated On: 20 Jul 2016 20:43:03

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: 1202**

Folder: Day 1

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

Data signed: (hfarmer1) 27 Mar 2015 14:51:09

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05112550000257
Analyte	COT-GLUC
Sample type	URINE
Result	1940
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	1
Celerion Study Number	AA99128-13
Date of Collection	2014-MAR-14
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 1

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

Data signed: (hfarmer1) 27 Mar 2015 14:51:09

Generated On: 20 Jul 2016 20:43:03

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: 1202**

Folder: Day 1

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(3)**

Data signed: (hfarmer1) 27 Mar 2015 14:51:09

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05112550000257
Analyte	NIC
Sample type	URINE
Result	21.9
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	1
Celerion Study Number	AA99128-13
Date of Collection	2014-MAR-14
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 1

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(3)**

Data signed: (hfarmer1) 27 Mar 2015 14:51:09

Generated On: 20 Jul 2016 20:43:03

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: 1202**

Folder: Day 1

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

Data signed: (hfarmer1) 27 Mar 2015 14:51:09

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05112550000257
Analyte	NIC-GLUC
Sample type	URINE
Result	96.2
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	1
Celerion Study Number	AA99128-13
Date of Collection	2014-MAR-14
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 1

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

Data signed: (hfarmer1) 27 Mar 2015 14:51:09

Generated On: 20 Jul 2016 20:43:03

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: 1202

Folder: Day 1

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

Data signed: (hfarmer1) 27 Mar 2015 14:51:09

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05112550000257
Analyte	THCOT
Sample type	URINE
Result	2100
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	1
Celerion Study Number	AA99128-13
Date of Collection	2014-MAR-14
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 1

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

Data signed: (hfarmer1) 27 Mar 2015 14:51:09

Generated On: 20 Jul 2016 20:43:03

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: 1202**

Folder: Day 1

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(6)**

Data signed: (hfarmer1) 27 Mar 2015 14:51:09

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05112550000257
Analyte	THCOT-GLUC
Sample type	URINE
Result	1130
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	1
Celerion Study Number	AA99128-13
Date of Collection	2014-MAR-14
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 1

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(6)**

Data signed: (hfarmer1) 27 Mar 2015 14:51:09

Generated On: 20 Jul 2016 20:43:03

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: 1202**

Folder: Day 1

Form: Biomarker-Urine (3-OH BaP)

Data signed: (hfarmer1) 27 Mar 2015 14:51:10

Generated On: 20 Jul 2016 20:43:03

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 1

Form: Biomarker-Urine (3-OH BaP) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:51:10

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05112490001357
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Analyte	3-OH BAP
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Sample type	URINE
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Result	.
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Result Unit	FG/ML
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Lab Status	OTHER
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Sample comment	ANALYSIS NOT REQUIRED
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Detection method	LC-MS/MS
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Planned time point (Hour)	0
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Day of Visit	1
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Celerion Study Number	AA99128-07
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Date of Collection	2014-MAR-14
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Timepoint-minutes	
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Urine Start Day	1
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 1

Form: Biomarker-Urine (3-OH BaP) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:51:10

Generated On: 20 Jul 2016 20:43:03

Urine End Day

2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 1

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP)

Data signed: (hfarmer1) 27 Mar 2015 14:51:10

Generated On: 20 Jul 2016 20:43:03

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 1

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:51:10

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05112510001379
Analyte	1-NA
Sample type	URINE
Result	7.84
Result Unit	PG/ML
Lab Status	OTHER
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	1
Celerion Study Number	AA99128-09
Date of Collection	2014-MAR-14
Timepoint-minutes	
Urine Start Day	1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 1

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:51:10

Generated On: 20 Jul 2016 20:43:03

Urine End Day

2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 1

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (2)

Data signed: (hfarmer1) 27 Mar 2015 14:51:10

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05112510001379
Analyte	2-NA
Sample type	URINE
Result	3.54
Result Unit	PG/ML
Lab Status	OTHER
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	1
Celerion Study Number	AA99128-09
Date of Collection	2014-MAR-14
Timepoint-minutes	
Urine Start Day	1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 1

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (2)

Data signed: (hfarmer1) 27 Mar 2015 14:51:10

Generated On: 20 Jul 2016 20:43:03

Urine End Day

2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 1

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (3)

Data signed: (hfarmer1) 27 Mar 2015 14:51:10

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05112510001379
Analyte	4-ABP
Sample type	URINE
Result	3.07
Result Unit	PG/ML
Lab Status	OTHER
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	1
Celerion Study Number	AA99128-09
Date of Collection	2014-MAR-14
Timepoint-minutes	
Urine Start Day	1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 1

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (3)

Data signed: (hfarmer1) 27 Mar 2015 14:51:10

Generated On: 20 Jul 2016 20:43:03

Urine End Day

2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 1

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (4)

Data signed: (hfarmer1) 27 Mar 2015 14:51:10

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05112510001379
Analyte	O-TOL
Sample type	URINE
Result	BLQ<(50.0)
Result Unit	PG/ML
Lab Status	OTHER
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	1
Celerion Study Number	AA99128-09
Date of Collection	2014-MAR-14
Timepoint-minutes	
Urine Start Day	1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 1

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (4)

Data signed: (hfarmer1) 27 Mar 2015 14:51:10

Generated On: 20 Jul 2016 20:43:03

Urine End Day

2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 1

Form: Biomarker-Urine (1-OHP)

Data signed: (hfarmer1) 27 Mar 2015 14:51:11

Generated On: 20 Jul 2016 20:43:03

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 1

Form: Biomarker-Urine (1-OHP) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:51:11

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05115190001610
Analyte	1-OHP
Sample type	URINE
Result	.
Result Unit	PG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	1
Celerion Study Number	AA99598-03
Date of Collection	2014-MAR-14
Timepoint-minutes	
Urine Start Day	1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 1

Form: Biomarker-Urine (1-OHP) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:51:11

Generated On: 20 Jul 2016 20:43:03

Urine End Day

2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 1

Form: Biomarker-Urine (SPMA, SBMA)

Data signed: (hfarmer1) 27 Mar 2015 14:51:08

Generated On: 20 Jul 2016 20:43:03

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 1

Form: Biomarker-Urine (SPMA, SBMA) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:51:08

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05115170001588
Analyte	SBMA
Sample type	URINE
Result	.
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	1
Celerion Study Number	AA99598-01
Date of Collection	2014-MAR-14
Timepoint-minutes	
Urine Start Day	1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 1

Form: Biomarker-Urine (SPMA, SBMA) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:51:08

Generated On: 20 Jul 2016 20:43:03

Urine End Day

2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 1

Form: Biomarker-Urine (SPMA, SBMA) (2)

Data signed: (hfarmer1) 27 Mar 2015 14:51:08

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05115170001588
Analyte	SPMA
Sample type	URINE
Result	.
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	1
Celerion Study Number	AA99598-01
Date of Collection	2014-MAR-14
Timepoint-minutes	
Urine Start Day	1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 1

Form: Biomarker-Urine (SPMA, SBMA) (2)

Data signed: (hfarmer1) 27 Mar 2015 14:51:08

Generated On: 20 Jul 2016 20:43:03

Urine End Day

2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 1

Form: Biomarker-Urine (MHBMA)

Data signed: (hfarmer1) 27 Mar 2015 14:51:09

Generated On: 20 Jul 2016 20:43:03

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 1

Form: Biomarker-Urine (MHBMA) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:51:09

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05115180001610
Analyte	MHBMA
Sample type	URINE
Result	.
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	1
Celerion Study Number	AA99598-02
Date of Collection	2014-MAR-14
Timepoint-minutes	
Urine Start Day	1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 1

Form: Biomarker-Urine (MHBMA) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:51:09

Generated On: 20 Jul 2016 20:43:03

Urine End Day

2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 1

Form: Biomarker-Urine (Creatinine)

Data signed: (hfarmer1) 27 Mar 2015 14:51:11

Generated On: 20 Jul 2016 20:43:03

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 1

Form: Biomarker-Urine (Creatinine) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:51:11

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05115160001357
Analyte	CREATININE
Sample type	URINE
Result	.
Result Unit	MG/DL
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	SPECTROPHOTOMETRIC
Planned time point (Hour)	0
Day of Visit	1
Celerion Study Number	AA99128-14
Date of Collection	2014-MAR-14
Timepoint-minutes	
Urine Start Day	1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 1

Form: Biomarker-Urine (Creatinine) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:51:11

Generated On: 20 Jul 2016 20:43:03

Urine End Day

2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 1

Form: Biomarker-Plasma (Nic, Cot, tHCot)

Data signed: (hfarmer1) 27 Mar 2015 14:51:09

Generated On: 20 Jul 2016 20:43:03

Sample type

PLASMA

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 1

Form: Biomarker-Plasma (Nic, Cot, tHCot) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:51:09

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05112440000232
Analyte	COT
Sample type	PLASMA
Result	59.7
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	1
Celerion Study Number	AA99128-02
Date of Collection	2014-MAR-14
Timepoint-minutes	0
Urine Start Day	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 1

Form: Biomarker-Plasma (Nic, Cot, tHCot) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:51:09

Generated On: 20 Jul 2016 20:43:03

Urine End Day

1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 1

Form: Biomarker-Plasma (Nic, Cot, tHCot) (2)

Data signed: (hfarmer1) 27 Mar 2015 14:51:09

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05112440000232
Analyte	NIC
Sample type	PLASMA
Result	0.207
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	1
Celerion Study Number	AA99128-02
Date of Collection	2014-MAR-14
Timepoint-minutes	0
Urine Start Day	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 1

Form: Biomarker-Plasma (Nic, Cot, tHCot) (2)

Data signed: (hfarmer1) 27 Mar 2015 14:51:09

Generated On: 20 Jul 2016 20:43:03

Urine End Day

1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 2

Form: Date of Visit

Data signed: (hfarmer1) 27 Mar 2015 14:51:12

Generated On: 20 Jul 2016 20:43:03

Date of Visit

15 MAR 2014
DD/MMM/YYYY

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 2

Form: Vital Signs

Data signed: (hfarmer1) 27 Mar 2015 14:51:12

Generated On: 20 Jul 2016 20:43:03

Were Vitals Signs assessed?

Yes ☒

If No, please specify the reason: _____

Has the subject smoked within 15 minutes prior to
assessment

No ☒

Time of assessment

11:27
hour:min 24-hour clock

Pulse rate

53
beats per minute

Respiratory rate

12
breaths per minute

Blood Pressure (systolic)

114
mmHg

Blood Pressure (diastolic)

71
mmHg

Vital Signs Position of Subject

Supine ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 2

Form: Plasma Nicotine Sample

Data signed: (hfarmer1) 27 Mar 2015 14:51:11

Generated On: 20 Jul 2016 20:43:03

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

If Not Done, please specify the reason: _____

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

Time hour:min 24-hour clock	21:02
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 2

Form: Plasma Cotinine Sample

Data signed: (hfarmer1) 27 Mar 2015 14:51:11

Generated On: 20 Jul 2016 20:43:03

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

If Not Done, please specify the reason: _____

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

Time hour:min 24-hour clock	21:02
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 2

Form: CoHb Blood Sample

Data signed: (hfarmer1) 27 Mar 2015 14:51:11

Generated On: 20 Jul 2016 20:43:03

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

If Not Done, please specify the reason: _____

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

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

Time hour:min 24-hour clock	21:02
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 2


Form: CO Breath Test <SA arm/> (1)

Data signed: (hfarmer1) 27 Mar 2015 14:51:12

Generated On: 20 Jul 2016 20:43:03

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

If Not Done, please specify the reason: _____

Scheduled Time	08:00 - 09:30 
----------------	---

Actual Time of Assessment hour:min 24-hour clock	08:55
---	-------

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 2

Form: CO Breath Test <SA arm/> (2)

Data signed: (hfarmer1) 27 Mar 2015 14:51:12

Generated On: 20 Jul 2016 20:43:03

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	12:25
---	-------

Result(ppm)	2
-------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 2

Form: CO Breath Test <SA arm/> (3)

Data signed: (hfarmer1) 27 Mar 2015 14:51:12

Generated On: 20 Jul 2016 20:43:03

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	16:33
---	-------

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 2

Form: CO Breath Test <SA arm/> (4)

Data signed: (hfarmer1) 27 Mar 2015 14:51:12

Generated On: 20 Jul 2016 20:43:03

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	20:17
---	-------

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 2

Form: 24 hour urine collections

Data signed: (hfarmer1) 27 Mar 2015 14:51:12

Generated On: 20 Jul 2016 20:43:03

Start Time	06:09
	hour:min 24-hour clock

End Date	16 MAR 2014
	DD/MMM/YYYY

End Time	06:06
	hour:min 24-hour clock

Volume	2524
	mL

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 2

Form: Sample Urine Collection

Data signed: (hfarmer1) 27 Mar 2015 14:51:12

Generated On: 20 Jul 2016 20:43:03

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: 1202**

Folder: Day 2

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Data signed: (hfarmer1) 27 Mar 2015 14:51:12

Generated On: 20 Jul 2016 20:43:03

Date of Birth

(b) (6)

Date of assessment
DD/MMM/YYYY

2014 MAR 15
DD/MMM/YYYY

Time of assessment

06:45
hour:min 24-hour clock

Assessment Status

Completed ☒

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

How have you been feeling over the past 24 hours?

None ☐

1. Angry, irritable, frustrated

How have you been feeling over the past 24 hours?

Slight ☐

2. Anxious, nervous

How have you been feeling over the past 24 hours?

Mild ☐

3. Depressed Mood, sad

How have you been feeling over the past 24 hours?

Mild ☐

4. Desire or craving to smoke

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 2

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Data signed: (hfarmer1) 27 Mar 2015 14:51:12

Generated On: 20 Jul 2016 20:43:03

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

5. Difficulty concentrating

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

6. Increased appetite, hungry, weight gain

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

7. Insomnia, sleep problems, awakening at night

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

8. Restless

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

9. Impatient

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

10. Constipation

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

11. Dizziness

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

12. Coughing

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 2

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Data signed: (hfarmer1) 27 Mar 2015 14:51:12

Generated On: 20 Jul 2016 20:43:03

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: 1202**

Folder: Day 2

Form: Cough Assessment

Data signed: (hfarmer1) 27 Mar 2015 14:51:12

Generated On: 20 Jul 2016 20:43:03

Date of Birth

(b) (6)

Date of assessment
DD/MMM/YYYY

2014 MAR 15
DD/MMM/YYYY

Time of assessment

06:43
hour:min 24-hour clock

Assessment Status

Completed ☒

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

No ☒

If YES, please answer the following questions:

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

-9

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

Not Applicable ☒

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

Not Applicable ☒

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

Not Applicable ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 2

Form: Lab_BU_COHB (1)

Data signed: (hfarmer1) 27 Mar 2015 14:51:13

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05115150001413
----------------	----------------

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

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

Result	2.60
--------	------

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

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

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

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

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

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

Day of Visit	2
--------------	---

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

Date of Collection	2014-MAR-15
--------------------	-------------

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 2

Form: Lab_BU_COHB (1)

Data signed: (hfarmer1) 27 Mar 2015 14:51:13

Generated On: 20 Jul 2016 20:43:03

Start Day (24 hour urine only) _____

End Day (24 hour Urine Only) _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 2

Form: Questionnaire on smoking urges (QSU)

Data signed: (hfarmer1) 27 Mar 2015 14:51:13

Generated On: 20 Jul 2016 20:43:03

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

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

Date of assessment	2014 MAR 15
--------------------	-------------

DD/MMM/YYYY

Time of assessment	20:30
--------------------	-------

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	Agree <input type="radio"/>
--	-----------------------------

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

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

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

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 2

Form: Questionnaire on smoking urges (QSU)

Data signed: (hfarmer1) 27 Mar 2015 14:51:13

Generated On: 20 Jul 2016 20:43:03

7. A cigarette would taste good now Strongly agree ☐

8. I would do almost anything for a cigarette now Somewhat agree ☐

9. Smoking would make me less depressed Somewhat agree ☐

10. I am going to smoke as soon as possible Somewhat agree ☐

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 2

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

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

Generated On: 20 Jul 2016 20:43:03

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 2

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

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

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05112450002279
Analyte	HPMA
Sample type	URINE
Result	230
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	2
Celerion Study Number	AA99128-03
Date of Collection	2014-MAR-15
Timepoint-minutes	
Urine Start Day	2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 2

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

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

Generated On: 20 Jul 2016 20:43:03

Urine End Day

3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 2

Form: Biomarker-Urine (CEMA, HPMa, HBMA) (2)

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

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05112450002279
Analyte	CEMA
Sample type	URINE
Result	9.77
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	2
Celerion Study Number	AA99128-03
Date of Collection	2014-MAR-15
Timepoint-minutes	
Urine Start Day	2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 2

Form: Biomarker-Urine (CEMA, HPMa, HBMA) (2)

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

Generated On: 20 Jul 2016 20:43:03

Urine End Day

3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 2

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (3)

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

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05112450002279
Analyte	HBMA
Sample type	URINE
Result	39.3
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	2
Celerion Study Number	AA99128-03
Date of Collection	2014-MAR-15
Timepoint-minutes	
Urine Start Day	2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 2

Form: Biomarker-Urine (CEMA, HPMa, HBMA) (3)

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

Generated On: 20 Jul 2016 20:43:03

Urine End Day

3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 2

Form: Biomarker-Urine (NNN, NNAL)

Data signed: (hfarmer1) 27 Mar 2015 14:51:13

Generated On: 20 Jul 2016 20:43:03

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 2

Form: Biomarker-Urine (NNN, NNAL) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:51:13

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05112460002722
Analyte	NNAL
Sample type	URINE
Result	.
Result Unit	PG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	2
Celerion Study Number	AA99128-04
Date of Collection	2014-MAR-15
Timepoint-minutes	
Urine Start Day	2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 2

Form: Biomarker-Urine (NNN, NNAL) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:51:13

Generated On: 20 Jul 2016 20:43:03

Urine End Day

3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 2

Form: Biomarker-Urine (NNN, NNAL) (2)

Data signed: (hfarmer1) 27 Mar 2015 14:51:13

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05112460002722
Analyte	NNN
Sample type	URINE
Result	.
Result Unit	PG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	2
Celerion Study Number	AA99128-04
Date of Collection	2014-MAR-15
Timepoint-minutes	
Urine Start Day	2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 2

Form: Biomarker-Urine (NNN, NNAL) (2)

Data signed: (hfarmer1) 27 Mar 2015 14:51:13

Generated On: 20 Jul 2016 20:43:03

Urine End Day

3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 2

Form: Biomarker-Urine (HEMA)

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

Generated On: 20 Jul 2016 20:43:03

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 2

Form: Biomarker-Urine (HEMA) (2)

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

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05112470001349
Analyte	HEMA
Sample type	URINE
Result	0.633
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	2
Celerion Study Number	AA99128-05
Date of Collection	2014-MAR-15
Timepoint-minutes	
Urine Start Day	2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 2

Form: Biomarker-Urine (HEMA) (2)

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

Generated On: 20 Jul 2016 20:43:03

Urine End Day

3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 2

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

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

Generated On: 20 Jul 2016 20:43:03

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 2

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

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

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05112550000258
Analyte	COT
Sample type	URINE
Result	148
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	2
Celerion Study Number	AA99128-13
Date of Collection	2014-MAR-15
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 2

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

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

Generated On: 20 Jul 2016 20:43:03

Urine Start Day	2
-----------------	---

Urine End Day	3
---------------	---

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1202

Folder: Day 2

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

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

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05112550000258
Analyte	COT-GLUC
Sample type	URINE
Result	444
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	2
Celerion Study Number	AA99128-13
Date of Collection	2014-MAR-15
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 2

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

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

Generated On: 20 Jul 2016 20:43:03

Urine Start Day	2
-----------------	---

Urine End Day	3
---------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 2

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(3)**

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

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05112550000258
Analyte	NIC
Sample type	URINE
Result	BLQ<(10.0)
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	2
Celerion Study Number	AA99128-13
Date of Collection	2014-MAR-15
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 2

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(3)**

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

Generated On: 20 Jul 2016 20:43:03

Urine Start Day	2
-----------------	---

Urine End Day	3
---------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 2

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

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

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05112550000258
Analyte	NIC-GLUC
Sample type	URINE
Result	BLQ<(10.0)
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	2
Celerion Study Number	AA99128-13
Date of Collection	2014-MAR-15
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 2

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

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

Generated On: 20 Jul 2016 20:43:03

Urine Start Day	2
-----------------	---

Urine End Day	3
---------------	---

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1202

Folder: Day 2

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

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

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05112550000258
Analyte	THCOT
Sample type	URINE
Result	382
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	2
Celerion Study Number	AA99128-13
Date of Collection	2014-MAR-15
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 2

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

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

Generated On: 20 Jul 2016 20:43:03

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: 1202**

Folder: Day 2

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(6)**

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

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05112550000258
Analyte	THCOT-GLUC
Sample type	URINE
Result	188
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	2
Celerion Study Number	AA99128-13
Date of Collection	2014-MAR-15
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 2

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(6)**

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

Generated On: 20 Jul 2016 20:43:03

Urine Start Day	2
-----------------	---

Urine End Day	3
---------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 2

Form: Biomarker-Urine (3-OH BaP)

Data signed: (hfarmer1) 27 Mar 2015 14:51:15

Generated On: 20 Jul 2016 20:43:03

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 2

Form: Biomarker-Urine (3-OH BaP) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:51:15

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05112490001358
Analyte	3-OH BAP
Sample type	URINE
Result	.
Result Unit	FG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	2
Celerion Study Number	AA99128-07
Date of Collection	2014-MAR-15
Timepoint-minutes	
Urine Start Day	2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 2

Form: Biomarker-Urine (3-OH BaP) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:51:15

Generated On: 20 Jul 2016 20:43:03

Urine End Day

3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 2

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP)

Data signed: (hfarmer1) 27 Mar 2015 14:51:15

Generated On: 20 Jul 2016 20:43:03

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 2

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:51:15

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05112510001380
Analyte	1-NA
Sample type	URINE
Result	3.09
Result Unit	PG/ML
Lab Status	OTHER
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	2
Celerion Study Number	AA99128-09
Date of Collection	2014-MAR-15
Timepoint-minutes	
Urine Start Day	2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 2

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:51:15

Generated On: 20 Jul 2016 20:43:03

Urine End Day

3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 2

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (2)

Data signed: (hfarmer1) 27 Mar 2015 14:51:15

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05112510001380
Analyte	2-NA
Sample type	URINE
Result	BLQ<(2.50)
Result Unit	PG/ML
Lab Status	OTHER
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	2
Celerion Study Number	AA99128-09
Date of Collection	2014-MAR-15
Timepoint-minutes	
Urine Start Day	2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 2

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (2)

Data signed: (hfarmer1) 27 Mar 2015 14:51:15

Generated On: 20 Jul 2016 20:43:03

Urine End Day

3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 2

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (3)

Data signed: (hfarmer1) 27 Mar 2015 14:51:15

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05112510001380
Analyte	4-ABP
Sample type	URINE
Result	2.05
Result Unit	PG/ML
Lab Status	OTHER
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	2
Celerion Study Number	AA99128-09
Date of Collection	2014-MAR-15
Timepoint-minutes	
Urine Start Day	2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 2

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (3)

Data signed: (hfarmer1) 27 Mar 2015 14:51:15

Generated On: 20 Jul 2016 20:43:03

Urine End Day

3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 2

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (4)

Data signed: (hfarmer1) 27 Mar 2015 14:51:15

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05112510001380
Analyte	O-TOL
Sample type	URINE
Result	BLQ<(50.0)
Result Unit	PG/ML
Lab Status	OTHER
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	2
Celerion Study Number	AA99128-09
Date of Collection	2014-MAR-15
Timepoint-minutes	
Urine Start Day	2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 2

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (4)

Data signed: (hfarmer1) 27 Mar 2015 14:51:15

Generated On: 20 Jul 2016 20:43:03

Urine End Day

3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 2

Form: Biomarker-Urine (1-OHP)

Data signed: (hfarmer1) 27 Mar 2015 14:51:15

Generated On: 20 Jul 2016 20:43:03

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 2

Form: Biomarker-Urine (1-OHP) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:51:15

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05115190001611
Analyte	1-OHP
Sample type	URINE
Result	.
Result Unit	PG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	2
Celerion Study Number	AA99598-03
Date of Collection	2014-MAR-15
Timepoint-minutes	
Urine Start Day	2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 2

Form: Biomarker-Urine (1-OHP) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:51:15

Generated On: 20 Jul 2016 20:43:03

Urine End Day

3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 2

Form: Biomarker-Urine (SPMA, SBMA)

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

Generated On: 20 Jul 2016 20:43:03

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 2

Form: Biomarker-Urine (SPMA, SBMA) (1)

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

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05115170001589
Analyte	SBMA
Sample type	URINE
Result	.
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	2
Celerion Study Number	AA99598-01
Date of Collection	2014-MAR-15
Timepoint-minutes	
Urine Start Day	2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 2

Form: Biomarker-Urine (SPMA, SBMA) (1)

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

Generated On: 20 Jul 2016 20:43:03

Urine End Day

3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 2

Form: Biomarker-Urine (SPMA, SBMA) (2)

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

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05115170001589
Analyte	SPMA
Sample type	URINE
Result	.
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	2
Celerion Study Number	AA99598-01
Date of Collection	2014-MAR-15
Timepoint-minutes	
Urine Start Day	2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 2

Form: Biomarker-Urine (SPMA, SBMA) (2)

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

Generated On: 20 Jul 2016 20:43:03

Urine End Day

3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 2

Form: Biomarker-Urine (MHBMA)

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

Generated On: 20 Jul 2016 20:43:03

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 2

Form: Biomarker-Urine (MHBMA) (1)

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

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05115180001611
Analyte	MHBMA
Sample type	URINE
Result	.
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	2
Celerion Study Number	AA99598-02
Date of Collection	2014-MAR-15
Timepoint-minutes	
Urine Start Day	2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 2

Form: Biomarker-Urine (MHBMA) (1)

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

Generated On: 20 Jul 2016 20:43:03

Urine End Day

3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 2

Form: Biomarker-Urine (Creatinine)

Data signed: (hfarmer1) 27 Mar 2015 14:51:15

Generated On: 20 Jul 2016 20:43:03

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 2

Form: Biomarker-Urine (Creatinine) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:51:15

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05115160001358
Analyte	CREATININE
Sample type	URINE
Result	.
Result Unit	MG/DL
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	SPECTROPHOTOMETRIC
Planned time point (Hour)	0
Day of Visit	2
Celerion Study Number	AA99128-14
Date of Collection	2014-MAR-15
Timepoint-minutes	
Urine Start Day	2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 2

Form: Biomarker-Urine (Creatinine) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:51:15

Generated On: 20 Jul 2016 20:43:03

Urine End Day

3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 2

Form: Biomarker-Plasma (Nic, Cot, tHCot)

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

Generated On: 20 Jul 2016 20:43:03

Sample type

PLASMA

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 2

Form: Biomarker-Plasma (Nic, Cot, tHCot) (1)

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

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05112440000233
Analyte	COT
Sample type	PLASMA
Result	19.0
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	2
Celerion Study Number	AA99128-02
Date of Collection	2014-MAR-15
Timepoint-minutes	0
Urine Start Day	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 2

Form: Biomarker-Plasma (Nic, Cot, tHCot) (1)

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

Generated On: 20 Jul 2016 20:43:03

Urine End Day

2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 2

Form: Biomarker-Plasma (Nic, Cot, tHCot) (2)

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

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05112440000233
----------------	----------------

Analyte	NIC
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Sample type	PLASMA
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Result	BLQ<(0.200)
--------	-------------

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

Lab Status	OTHER
------------	-------

Sample comment	ANALYZED IN ERROR
----------------	-------------------

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	2
--------------	---

Celerion Study Number	AA99128-02
-----------------------	------------

Date of Collection	2014-MAR-15
--------------------	-------------

Timepoint-minutes	0
-------------------	---

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 2

Form: Biomarker-Plasma (Nic, Cot, tHCot) (2)

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

Generated On: 20 Jul 2016 20:43:03

Urine End Day

2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 3

Form: Date of Visit

Data signed: (hfarmer1) 27 Mar 2015 14:51:16

Generated On: 20 Jul 2016 20:43:03

Date of Visit

16 MAR 2014
DD/MMM/YYYY

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 3

Form: Vital Signs

Data signed: (hfarmer1) 27 Mar 2015 14:51:16

Generated On: 20 Jul 2016 20:43:03

Were Vitals Signs assessed?

Yes ☒

If No, please specify the reason: _____

Has the subject smoked within 15 minutes prior to
assessment

No ☒

Time of assessment

10:05
hour:min 24-hour clock

Pulse rate

50
beats per minute

Respiratory rate

16
breaths per minute

Blood Pressure (systolic)

98
mmHg

Blood Pressure (diastolic)

59
mmHg

Vital Signs Position of Subject

Supine ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 3

Form: Plasma Nicotine Sample

Data signed: (hfarmer1) 27 Mar 2015 14:51:15

Generated On: 20 Jul 2016 20:43:03

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	16 MAR 2014
---------------------	-------------

Time hour:min 24-hour clock	20:26
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 3

Form: Plasma Cotinine Sample

Data signed: (hfarmer1) 27 Mar 2015 14:51:15

Generated On: 20 Jul 2016 20:43:03

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	16 MAR 2014
---------------------	-------------

Time hour:min 24-hour clock	20:26
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 3

Form: CoHb Blood Sample

Data signed: (hfarmer1) 27 Mar 2015 14:51:15

Generated On: 20 Jul 2016 20:43:03

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	16 MAR 2014
---------------------	-------------

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

Time hour:min 24-hour clock	20:26
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 3

Form: CO Breath Test <SA arm/> (1)

Data signed: (hfarmer1) 27 Mar 2015 14:51:16

Generated On: 20 Jul 2016 20:43:03

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

If Not Done, please specify the reason: _____

Scheduled Time	08:00 - 09:30 <input checked="" type="radio"/>
----------------	--

Actual Time of Assessment hour:min 24-hour clock	08:04
---	-------

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 3

Form: CO Breath Test <SA arm/> (2)

Data signed: (hfarmer1) 27 Mar 2015 14:51:16

Generated On: 20 Jul 2016 20:43:03

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	12:39
---	-------

Result(ppm)	1
-------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 3

Form: CO Breath Test <SA arm/> (3)

Data signed: (hfarmer1) 27 Mar 2015 14:51:16

Generated On: 20 Jul 2016 20:43:03

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

If Not Done, please specify the reason: _____

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

Actual Time of Assessment hour:min 24-hour clock	17:30
---	-------

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 3

Form: CO Breath Test <SA arm/> (4)

Data signed: (hfarmer1) 27 Mar 2015 14:51:16

Generated On: 20 Jul 2016 20:43:03

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	20:10
---	-------

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 3

Form: 24 hour urine collections

Data signed: (hfarmer1) 27 Mar 2015 14:51:15

Generated On: 20 Jul 2016 20:43:03

Start Time	06:06
	hour:min 24-hour clock

End Date	17 MAR 2014
	DD/MMM/YYYY

End Time	06:04
	hour:min 24-hour clock

Volume	2486
	mL

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 3

Form: Sample Urine Collection

Data signed: (hfarmer1) 27 Mar 2015 14:51:15

Generated On: 20 Jul 2016 20:43:03

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: 1202**

Folder: Day 3

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Data signed: (hfarmer1) 27 Mar 2015 14:51:17

Generated On: 20 Jul 2016 20:43:03

Date of Birth

(b) (6)

Date of assessment
DD/MMM/YYYY

2014 MAR 16
DD/MMM/YYYY

Time of assessment

06:13
hour:min 24-hour clock

Assessment Status

Completed ☒

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

How have you been feeling over the past 24 hours?

Mild ☒

1. Angry, irritable, frustrated

How have you been feeling over the past 24 hours?

Mild ☒

2. Anxious, nervous

How have you been feeling over the past 24 hours?

Mild ☒

3. Depressed Mood, sad

How have you been feeling over the past 24 hours?

Moderate ☒

4. Desire or craving to smoke

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 3

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Data signed: (hfarmer1) 27 Mar 2015 14:51:17

Generated On: 20 Jul 2016 20:43:03

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

5. Difficulty concentrating

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

6. Increased appetite, hungry, weight gain

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

7. Insomnia, sleep problems, awakening at night

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

8. Restless

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

9. Impatient

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

10. Constipation

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

11. Dizziness

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

12. Coughing

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 3

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Data signed: (hfarmer1) 27 Mar 2015 14:51:17

Generated On: 20 Jul 2016 20:43:03

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: 1202**

Folder: Day 3

Form: Cough Assessment

Data signed: (hfarmer1) 27 Mar 2015 14:51:17

Generated On: 20 Jul 2016 20:43:03

Date of Birth

(b) (6)

Date of assessment
DD/MMM/YYYY

2014 MAR 16
DD/MMM/YYYY

Time of assessment

06:12
hour:min 24-hour clock

Assessment Status

Completed ☒

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

No ☒

If YES, please answer the following questions:

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

-9

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

Not Applicable ☒

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

Not Applicable ☒

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

Not Applicable ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 3

Form: Lab_BU_COHB (1)

Data signed: (hfarmer1) 27 Mar 2015 14:51:17

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05115150001414
----------------	----------------

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

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

Result	1.80
--------	------

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

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

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

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

Lower limit of quantification	0.500
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Planned time point (Hour)	20
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Day of Visit	3
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Celerion Study Number	AA99128-16
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Date of Collection	2014-MAR-16
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Timepoint-minutes	
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 3

Form: Lab_BU_COHB (1)

Data signed: (hfarmer1) 27 Mar 2015 14:51:17

Generated On: 20 Jul 2016 20:43:03

Start Day (24 hour urine only) _____

End Day (24 hour Urine Only) _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 3

Form: Questionnaire on smoking urges (QSU)

Data signed: (hfarmer1) 27 Mar 2015 14:51:17

Generated On: 20 Jul 2016 20:43:03

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

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

Date of assessment	2014 MAR 16
--------------------	-------------

DD/MMM/YYYY

Time of assessment	20:12
--------------------	-------

hour:min 24-hour clock

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	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	Somewhat agree <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: 1202**

Folder: Day 3

Form: Questionnaire on smoking urges (QSU)

Data signed: (hfarmer1) 27 Mar 2015 14:51:17

Generated On: 20 Jul 2016 20:43:03

7. A cigarette would taste good now Disagree ☐

8. I would do almost anything for a cigarette now Strongly disagree ☐

9. Smoking would make me less depressed Disagree ☐

10. I am going to smoke as soon as possible Strongly disagree ☐

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 3

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

Data signed: (hfarmer1) 27 Mar 2015 14:51:18

Generated On: 20 Jul 2016 20:43:03

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 3

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

Data signed: (hfarmer1) 27 Mar 2015 14:51:18

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05112450002280
Analyte	HPMA
Sample type	URINE
Result	118
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	3
Celerion Study Number	AA99128-03
Date of Collection	2014-MAR-16
Timepoint-minutes	
Urine Start Day	3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 3

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

Data signed: (hfarmer1) 27 Mar 2015 14:51:18

Generated On: 20 Jul 2016 20:43:03

Urine End Day

4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 3

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (2)

Data signed: (hfarmer1) 27 Mar 2015 14:51:18

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05112450002280
Analyte	CEMA
Sample type	URINE
Result	6.15
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	3
Celerion Study Number	AA99128-03
Date of Collection	2014-MAR-16
Timepoint-minutes	
Urine Start Day	3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 3

Form: Biomarker-Urine (CEMA, HPMa, HBMA) (2)

Data signed: (hfarmer1) 27 Mar 2015 14:51:18

Generated On: 20 Jul 2016 20:43:03

Urine End Day

4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 3

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (3)

Data signed: (hfarmer1) 27 Mar 2015 14:51:18

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05112450002280
Analyte	HBMA
Sample type	URINE
Result	30.3
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	3
Celerion Study Number	AA99128-03
Date of Collection	2014-MAR-16
Timepoint-minutes	
Urine Start Day	3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 3

Form: Biomarker-Urine (CEMA, HPMa, HBMA) (3)

Data signed: (hfarmer1) 27 Mar 2015 14:51:18

Generated On: 20 Jul 2016 20:43:03

Urine End Day

4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 3

Form: Biomarker-Urine (NNN, NNAL)

Data signed: (hfarmer1) 27 Mar 2015 14:51:17

Generated On: 20 Jul 2016 20:43:03

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 3

Form: Biomarker-Urine (NNN, NNAL) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:51:17

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05112460002723
Analyte	NNAL
Sample type	URINE
Result	.
Result Unit	PG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	3
Celerion Study Number	AA99128-04
Date of Collection	2014-MAR-16
Timepoint-minutes	
Urine Start Day	3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 3

Form: Biomarker-Urine (NNN, NNAL) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:51:17

Generated On: 20 Jul 2016 20:43:03

Urine End Day

4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 3

Form: Biomarker-Urine (NNN, NNAL) (2)

Data signed: (hfarmer1) 27 Mar 2015 14:51:17

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05112460002723
Analyte	NNN
Sample type	URINE
Result	.
Result Unit	PG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	3
Celerion Study Number	AA99128-04
Date of Collection	2014-MAR-16
Timepoint-minutes	
Urine Start Day	3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 3

Form: Biomarker-Urine (NNN, NNAL) (2)

Data signed: (hfarmer1) 27 Mar 2015 14:51:17

Generated On: 20 Jul 2016 20:43:03

Urine End Day

4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 3

Form: Biomarker-Urine (HEMA)

Data signed: (hfarmer1) 27 Mar 2015 14:51:17

Generated On: 20 Jul 2016 20:43:03

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 3

Form: Biomarker-Urine (HEMA) (2)

Data signed: (hfarmer1) 27 Mar 2015 14:51:17

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05112470001350
Analyte	HEMA
Sample type	URINE
Result	0.424
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	3
Celerion Study Number	AA99128-05
Date of Collection	2014-MAR-16
Timepoint-minutes	
Urine Start Day	3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 3

Form: Biomarker-Urine (HEMA) (2)

Data signed: (hfarmer1) 27 Mar 2015 14:51:17

Generated On: 20 Jul 2016 20:43:03

Urine End Day

4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 3

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

Data signed: (hfarmer1) 27 Mar 2015 14:51:18

Generated On: 20 Jul 2016 20:43:03

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 3

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

Data signed: (hfarmer1) 27 Mar 2015 14:51:18

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05112550000259
Analyte	COT
Sample type	URINE
Result	39.3
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	3
Celerion Study Number	AA99128-13
Date of Collection	2014-MAR-16
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 3

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

Data signed: (hfarmer1) 27 Mar 2015 14:51:18

Generated On: 20 Jul 2016 20:43:03

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: 1202

Folder: Day 3

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

Data signed: (hfarmer1) 27 Mar 2015 14:51:18

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05112550000259
Analyte	COT-GLUC
Sample type	URINE
Result	126
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	3
Celerion Study Number	AA99128-13
Date of Collection	2014-MAR-16
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 3

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

Data signed: (hfarmer1) 27 Mar 2015 14:51:18

Generated On: 20 Jul 2016 20:43:03

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: 1202**

Folder: Day 3

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(3)**

Data signed: (hfarmer1) 27 Mar 2015 14:51:18

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05112550000259
Analyte	NIC
Sample type	URINE
Result	BLQ<(10.0)
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	3
Celerion Study Number	AA99128-13
Date of Collection	2014-MAR-16
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 3

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(3)**

Data signed: (hfarmer1) 27 Mar 2015 14:51:18

Generated On: 20 Jul 2016 20:43:03

Urine Start Day	3
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Urine End Day	4
---------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 3

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

Data signed: (hfarmer1) 27 Mar 2015 14:51:18

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05112550000259
Analyte	NIC-GLUC
Sample type	URINE
Result	BLQ<(10.0)
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	3
Celerion Study Number	AA99128-13
Date of Collection	2014-MAR-16
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 3

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

Data signed: (hfarmer1) 27 Mar 2015 14:51:18

Generated On: 20 Jul 2016 20:43:03

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: 1202**

Folder: Day 3

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

Data signed: (hfarmer1) 27 Mar 2015 14:51:18

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05112550000259
Analyte	THCOT
Sample type	URINE
Result	100
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	3
Celerion Study Number	AA99128-13
Date of Collection	2014-MAR-16
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 3

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

Data signed: (hfarmer1) 27 Mar 2015 14:51:18

Generated On: 20 Jul 2016 20:43:03

Urine Start Day	3
-----------------	---

Urine End Day	4
---------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 3

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(6)**

Data signed: (hfarmer1) 27 Mar 2015 14:51:18

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05112550000259
Analyte	THCOT-GLUC
Sample type	URINE
Result	62.9
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	3
Celerion Study Number	AA99128-13
Date of Collection	2014-MAR-16
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 3

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(6)**

Data signed: (hfarmer1) 27 Mar 2015 14:51:18

Generated On: 20 Jul 2016 20:43:03

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: 1202**

Folder: Day 3

Form: Biomarker-Urine (3-OH BaP)

Data signed: (hfarmer1) 27 Mar 2015 14:51:19

Generated On: 20 Jul 2016 20:43:03

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 3

Form: Biomarker-Urine (3-OH BaP) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:51:19

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05112490001359
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Analyte	3-OH BAP
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Sample type	URINE
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Result	.
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Result Unit	FG/ML
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Lab Status	OTHER
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Sample comment	ANALYSIS NOT REQUIRED
----------------	-----------------------

Detection method	LC-MS/MS
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Planned time point (Hour)	0
---------------------------	---

Day of Visit	3
--------------	---

Celerion Study Number	AA99128-07
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Date of Collection	2014-MAR-16
--------------------	-------------

Timepoint-minutes	
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Urine Start Day	3
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 3

Form: Biomarker-Urine (3-OH BaP) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:51:19

Generated On: 20 Jul 2016 20:43:03

Urine End Day

4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 3

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP)

Data signed: (hfarmer1) 27 Mar 2015 14:51:19

Generated On: 20 Jul 2016 20:43:03

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 3

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:51:19

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05112510001381
Analyte	1-NA
Sample type	URINE
Result	BLQ<(2.50)
Result Unit	PG/ML
Lab Status	OTHER
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	3
Celerion Study Number	AA99128-09
Date of Collection	2014-MAR-16
Timepoint-minutes	
Urine Start Day	3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 3

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:51:19

Generated On: 20 Jul 2016 20:43:03

Urine End Day

4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 3

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (2)

Data signed: (hfarmer1) 27 Mar 2015 14:51:19

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05112510001381
Analyte	2-NA
Sample type	URINE
Result	BLQ<(2.50)
Result Unit	PG/ML
Lab Status	OTHER
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	3
Celerion Study Number	AA99128-09
Date of Collection	2014-MAR-16
Timepoint-minutes	
Urine Start Day	3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 3

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (2)

Data signed: (hfarmer1) 27 Mar 2015 14:51:19

Generated On: 20 Jul 2016 20:43:03

Urine End Day

4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 3

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (3)

Data signed: (hfarmer1) 27 Mar 2015 14:51:19

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05112510001381
Analyte	4-ABP
Sample type	URINE
Result	BLQ<(1.50)
Result Unit	PG/ML
Lab Status	OTHER
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	3
Celerion Study Number	AA99128-09
Date of Collection	2014-MAR-16
Timepoint-minutes	
Urine Start Day	3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 3

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (3)

Data signed: (hfarmer1) 27 Mar 2015 14:51:19

Generated On: 20 Jul 2016 20:43:03

Urine End Day

4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 3

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (4)

Data signed: (hfarmer1) 27 Mar 2015 14:51:19

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05112510001381
Analyte	O-TOL
Sample type	URINE
Result	BLQ<(50.0)
Result Unit	PG/ML
Lab Status	OTHER
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	3
Celerion Study Number	AA99128-09
Date of Collection	2014-MAR-16
Timepoint-minutes	
Urine Start Day	3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 3

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (4)

Data signed: (hfarmer1) 27 Mar 2015 14:51:19

Generated On: 20 Jul 2016 20:43:03

Urine End Day

4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 3

Form: Biomarker-Urine (1-OHP)

Data signed: (hfarmer1) 27 Mar 2015 14:51:19

Generated On: 20 Jul 2016 20:43:03

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 3

Form: Biomarker-Urine (1-OHP) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:51:19

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05115190001612
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Analyte	1-OHP
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Sample type	URINE
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Result	.
--------	---

Result Unit	PG/ML
-------------	-------

Lab Status	OTHER
------------	-------

Sample comment	ANALYSIS NOT REQUIRED
----------------	-----------------------

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	3
--------------	---

Celerion Study Number	AA99598-03
-----------------------	------------

Date of Collection	2014-MAR-16
--------------------	-------------

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

Urine Start Day	3
-----------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 3

Form: Biomarker-Urine (1-OHP) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:51:19

Generated On: 20 Jul 2016 20:43:03

Urine End Day

4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 3

Form: Biomarker-Urine (SPMA, SBMA)

Data signed: (hfarmer1) 27 Mar 2015 14:51:18

Generated On: 20 Jul 2016 20:43:03

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 3

Form: Biomarker-Urine (SPMA, SBMA) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:51:18

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05115170001590
Analyte	SBMA
Sample type	URINE
Result	.
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	3
Celerion Study Number	AA99598-01
Date of Collection	2014-MAR-16
Timepoint-minutes	
Urine Start Day	3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 3

Form: Biomarker-Urine (SPMA, SBMA) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:51:18

Generated On: 20 Jul 2016 20:43:03

Urine End Day

4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 3

Form: Biomarker-Urine (SPMA, SBMA) (2)

Data signed: (hfarmer1) 27 Mar 2015 14:51:18

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05115170001590
Analyte	SPMA
Sample type	URINE
Result	.
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	3
Celerion Study Number	AA99598-01
Date of Collection	2014-MAR-16
Timepoint-minutes	
Urine Start Day	3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 3

Form: Biomarker-Urine (SPMA, SBMA) (2)

Data signed: (hfarmer1) 27 Mar 2015 14:51:18

Generated On: 20 Jul 2016 20:43:03

Urine End Day

4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 3

Form: Biomarker-Urine (MHBMA)

Data signed: (hfarmer1) 27 Mar 2015 14:51:18

Generated On: 20 Jul 2016 20:43:03

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 3

Form: Biomarker-Urine (MHBMA) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:51:18

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05115180001612
Analyte	MHBMA
Sample type	URINE
Result	.
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	3
Celerion Study Number	AA99598-02
Date of Collection	2014-MAR-16
Timepoint-minutes	
Urine Start Day	3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 3

Form: Biomarker-Urine (MHBMA) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:51:18

Generated On: 20 Jul 2016 20:43:03

Urine End Day

4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 3

Form: Biomarker-Urine (Creatinine)

Data signed: (hfarmer1) 27 Mar 2015 14:51:19

Generated On: 20 Jul 2016 20:43:03

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 3

Form: Biomarker-Urine (Creatinine) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:51:19

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05115160001359
Analyte	CREATININE
Sample type	URINE
Result	.
Result Unit	MG/DL
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	SPECTROPHOTOMETRIC
Planned time point (Hour)	0
Day of Visit	3
Celerion Study Number	AA99128-14
Date of Collection	2014-MAR-16
Timepoint-minutes	
Urine Start Day	3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 3

Form: Biomarker-Urine (Creatinine) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:51:19

Generated On: 20 Jul 2016 20:43:03

Urine End Day

4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 3

Form: Biomarker-Plasma (Nic, Cot, tHCot)

Data signed: (hfarmer1) 27 Mar 2015 14:51:18

Generated On: 20 Jul 2016 20:43:03

Sample type

PLASMA

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 3

Form: Biomarker-Plasma (Nic, Cot, tHCot) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:51:18

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05112440000234
Analyte	COT
Sample type	PLASMA
Result	7.02
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	3
Celerion Study Number	AA99128-02
Date of Collection	2014-MAR-16
Timepoint-minutes	0
Urine Start Day	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 3

Form: Biomarker-Plasma (Nic, Cot, tHCot) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:51:18

Generated On: 20 Jul 2016 20:43:03

Urine End Day

3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 3

Form: Biomarker-Plasma (Nic, Cot, tHCot) (2)

Data signed: (hfarmer1) 27 Mar 2015 14:51:18

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05112440000234
----------------	----------------

Analyte	NIC
---------	-----

Sample type	PLASMA
-------------	--------

Result	BLQ<(0.200)
--------	-------------

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

Lab Status	OTHER
------------	-------

Sample comment	ANALYZED IN ERROR
----------------	-------------------

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	3
--------------	---

Celerion Study Number	AA99128-02
-----------------------	------------

Date of Collection	2014-MAR-16
--------------------	-------------

Timepoint-minutes	0
-------------------	---

Urine Start Day	
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 3

Form: Biomarker-Plasma (Nic, Cot, tHCot) (2)

Data signed: (hfarmer1) 27 Mar 2015 14:51:18

Generated On: 20 Jul 2016 20:43:03

Urine End Day

3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 4

Form: Date of Visit

Data signed: (hfarmer1) 27 Mar 2015 14:51:23

Generated On: 20 Jul 2016 20:43:03

Date of Visit

17 MAR 2014
DD/MMM/YYYY

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 4

Form: Vital Signs

Data signed: (hfarmer1) 27 Mar 2015 14:51:23

Generated On: 20 Jul 2016 20:43:03

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

09:44
hour:min 24-hour clock

Pulse rate

61
beats per minute

Respiratory rate

18
breaths per minute

Blood Pressure (systolic)

109
mmHg

Blood Pressure (diastolic)

64
mmHg

Vital Signs Position of Subject

Supine ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 4

Form: Socio-Economic Status

Data signed: (hfarmer1) 27 Mar 2015 14:51:22

Generated On: 20 Jul 2016 20:43:03

Was paper questionnaire used? Yes ☒

Reason not done _____

Date 17 MAR 2014
DD/MMM/YYYY

Time 06:35
hour:min 24-hour clock

Q1. What is the highest level of education you have completed? Some College ☒

Q2. What is your current occupational status? Looking for work, unemployed ☒

SPECIFY _____

Q3. How many people are currently living in your household, including yourself? 01

Q4. Of these people, how many are children? 00

Q5. Of these people, how many are adults? 01

Q6. Of the adults, how many bring income into the household? 01

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 4

Form: Socio-Economic Status

Data signed: (hfarmer1) 27 Mar 2015 14:51:22

Generated On: 20 Jul 2016 20:43:03

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.

\$75,000 through \$99,999 ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 4

Form: Plasma Nicotine Sample

Data signed: (hfarmer1) 27 Mar 2015 14:51:21

Generated On: 20 Jul 2016 20:43:03

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	17 MAR 2014
---------------------	-------------

Time hour:min 24-hour clock	20:37
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 4

Form: Plasma Cotinine Sample

Data signed: (hfarmer1) 27 Mar 2015 14:51:20

Generated On: 20 Jul 2016 20:43:03

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	17 MAR 2014
---------------------	-------------

Time hour:min 24-hour clock	20:37
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 4

Form: CoHb Blood Sample

Data signed: (hfarmer1) 27 Mar 2015 14:51:20

Generated On: 20 Jul 2016 20:43:03

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	17 MAR 2014
---------------------	-------------

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

Time hour:min 24-hour clock	20:37
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 4

Form: CO Breath Test <SA arm/> (1)

Data signed: (hfarmer1) 27 Mar 2015 14:51:23

Generated On: 20 Jul 2016 20:43:03

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

If Not Done, please specify the reason: _____

Scheduled Time	08:00 - 09:30 <input checked="" type="radio"/>
----------------	--

Actual Time of Assessment hour:min 24-hour clock	08:01
---	-------

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 4

Form: CO Breath Test <SA arm/> (2)

Data signed: (hfarmer1) 27 Mar 2015 14:51:23

Generated On: 20 Jul 2016 20:43:03

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	12:47
---	-------

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 4

Form: CO Breath Test <SA arm/> (3)

Data signed: (hfarmer1) 27 Mar 2015 14:51:23

Generated On: 20 Jul 2016 20:43:03

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

If Not Done, please specify the reason: _____

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

Actual Time of Assessment hour:min 24-hour clock	16:21
---	-------

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 4

Form: CO Breath Test <SA arm/> (4)

Data signed: (hfarmer1) 27 Mar 2015 14:51:23

Generated On: 20 Jul 2016 20:43:03

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	20:09
---	-------

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 4

Form: 24 hour urine collections

Data signed: (hfarmer1) 27 Mar 2015 14:51:23

Generated On: 20 Jul 2016 20:43:03

Start Time	06:04
	hour:min 24-hour clock

End Date	18 MAR 2014
	DD/MMM/YYYY

End Time	06:17
	hour:min 24-hour clock

Volume	1798
	mL

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 4

Form: Sample Urine Collection

Data signed: (hfarmer1) 27 Mar 2015 14:51:22

Generated On: 20 Jul 2016 20:43:03

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: 1202**

Folder: Day 4

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Data signed: (hfarmer1) 27 Mar 2015 14:51:23

Generated On: 20 Jul 2016 20:43:03

Date of Birth

(b) (6)

Date of assessment
DD/MMM/YYYY

2014 MAR 17
DD/MMM/YYYY

Time of assessment

06:01
hour:min 24-hour clock

Assessment Status

Completed ☒

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

How have you been feeling over the past 24 hours?

Mild ☒

1. Angry, irritable, frustrated

How have you been feeling over the past 24 hours?

Mild ☒

2. Anxious, nervous

How have you been feeling over the past 24 hours?

Mild ☒

3. Depressed Mood, sad

How have you been feeling over the past 24 hours?

Moderate ☒

4. Desire or craving to smoke

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 4

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Data signed: (hfarmer1) 27 Mar 2015 14:51:23

Generated On: 20 Jul 2016 20:43:03

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

5. Difficulty concentrating

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

6. Increased appetite, hungry, weight gain

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

7. Insomnia, sleep problems, awakening at night

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

8. Restless

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

9. Impatient

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

10. Constipation

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

11. Dizziness

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

12. Coughing

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 4

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Data signed: (hfarmer1) 27 Mar 2015 14:51:23

Generated On: 20 Jul 2016 20:43:03

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?

Slight ☐

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: 1202**

Folder: Day 4

Form: Cough Assessment

Data signed: (hfarmer1) 27 Mar 2015 14:51:23

Generated On: 20 Jul 2016 20:43:03

Date of Birth

(b) (6)

Date of assessment
DD/MMM/YYYY

2014 MAR 17
DD/MMM/YYYY

Time of assessment

05:59
hour:min 24-hour clock

Assessment Status

Completed ☒

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

No ☒

If YES, please answer the following questions:

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

-9

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

Not Applicable ☒

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

Not Applicable ☒

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

Not Applicable ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 4

Form: Lab_BU_COHB (1)

Data signed: (hfarmer1) 27 Mar 2015 14:51:25

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05115150001415
Analyte	CARBOXYHEMOGLOBIN
Sample type	BLOOD
Result	1.80
Result Unit	%
Lab Status	OK
Sample comment	
Detection method	SPECTROPHOTOMETRIC
Lower limit of quantification	0.500
Planned time point (Hour)	20
Day of Visit	4
Celerion Study Number	AA99128-16
Date of Collection	2014-MAR-17
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 4

Form: Lab_BU_COHB (1)

Data signed: (hfarmer1) 27 Mar 2015 14:51:25

Generated On: 20 Jul 2016 20:43:03

Start Day (24 hour urine only) _____

End Day (24 hour Urine Only) _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 4

Form: Questionnaire on smoking urges (QSU)

Data signed: (hfarmer1) 27 Mar 2015 14:51:25

Generated On: 20 Jul 2016 20:43:03

Type	QSU
Date of Birth	(b) (6)
Date of assessment DD/MMM/YYYY	2014 MAR 17
Time of assessment hour:min 24-hour clock	20:02
Assessment Status	Completed <input type="radio"/>
1. I have a desire for a cigarette right now	Disagree <input type="radio"/>
2. Nothing would be better than smoking a cigarette right now	Disagree <input type="radio"/>
3. If it were possible I would probably smoke now	Disagree <input type="radio"/>
4. I could control things better right now if I could smoke	Somewhat 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: 1202**

Folder: Day 4

Form: Questionnaire on smoking urges (QSU)

Data signed: (hfarmer1) 27 Mar 2015 14:51:25

Generated On: 20 Jul 2016 20:43:03

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 Strongly disagree ☐

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 4

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

Data signed: (hfarmer1) 27 Mar 2015 14:51:26

Generated On: 20 Jul 2016 20:43:03

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 4

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

Data signed: (hfarmer1) 27 Mar 2015 14:51:26

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05112450002281
Analyte	HPMA
Sample type	URINE
Result	282
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	4
Celerion Study Number	AA99128-03
Date of Collection	2014-MAR-17
Timepoint-minutes	
Urine Start Day	4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 4

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

Data signed: (hfarmer1) 27 Mar 2015 14:51:26

Generated On: 20 Jul 2016 20:43:03

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 4

Form: Biomarker-Urine (CEMA, HPMa, HBMA) (2)

Data signed: (hfarmer1) 27 Mar 2015 14:51:26

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05112450002281
Analyte	CEMA
Sample type	URINE
Result	11.7
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	4
Celerion Study Number	AA99128-03
Date of Collection	2014-MAR-17
Timepoint-minutes	
Urine Start Day	4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 4

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (2)

Data signed: (hfarmer1) 27 Mar 2015 14:51:26

Generated On: 20 Jul 2016 20:43:03

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 4

Form: Biomarker-Urine (CEMA, HPMa, HBMA) (3)

Data signed: (hfarmer1) 27 Mar 2015 14:51:26

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05112450002281
Analyte	HBMA
Sample type	URINE
Result	65.4
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	4
Celerion Study Number	AA99128-03
Date of Collection	2014-MAR-17
Timepoint-minutes	
Urine Start Day	4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 4

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (3)

Data signed: (hfarmer1) 27 Mar 2015 14:51:26

Generated On: 20 Jul 2016 20:43:03

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 4

Form: Biomarker-Urine (NNN, NNAL)

Data signed: (hfarmer1) 27 Mar 2015 14:51:25

Generated On: 20 Jul 2016 20:43:03

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 4

Form: Biomarker-Urine (NNN, NNAL) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:51:25

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05112460002724
Analyte	NNAL
Sample type	URINE
Result	.
Result Unit	PG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	4
Celerion Study Number	AA99128-04
Date of Collection	2014-MAR-17
Timepoint-minutes	
Urine Start Day	4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 4

Form: Biomarker-Urine (NNN, NNAL) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:51:25

Generated On: 20 Jul 2016 20:43:03

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 4

Form: Biomarker-Urine (NNN, NNAL) (2)

Data signed: (hfarmer1) 27 Mar 2015 14:51:25

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05112460002724
Analyte	NNN
Sample type	URINE
Result	.
Result Unit	PG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	4
Celerion Study Number	AA99128-04
Date of Collection	2014-MAR-17
Timepoint-minutes	
Urine Start Day	4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 4

Form: Biomarker-Urine (NNN, NNAL) (2)

Data signed: (hfarmer1) 27 Mar 2015 14:51:25

Generated On: 20 Jul 2016 20:43:03

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 4

Form: Biomarker-Urine (HEMA)

Data signed: (hfarmer1) 27 Mar 2015 14:51:25

Generated On: 20 Jul 2016 20:43:03

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 4

Form: Biomarker-Urine (HEMA) (2)

Data signed: (hfarmer1) 27 Mar 2015 14:51:25

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05112470001351
Analyte	HEMA
Sample type	URINE
Result	0.707
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	4
Celerion Study Number	AA99128-05
Date of Collection	2014-MAR-17
Timepoint-minutes	
Urine Start Day	4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 4

Form: Biomarker-Urine (HEMA) (2)

Data signed: (hfarmer1) 27 Mar 2015 14:51:25

Generated On: 20 Jul 2016 20:43:03

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 4

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

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

Generated On: 20 Jul 2016 20:43:03

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 4

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

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

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05112550000260
Analyte	COT
Sample type	URINE
Result	19.8
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	4
Celerion Study Number	AA99128-13
Date of Collection	2014-MAR-17
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 4

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

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

Generated On: 20 Jul 2016 20:43:03

Urine Start Day	4
<hr/>	
Urine End Day	5
<hr/>	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 4

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

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

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05112550000260
Analyte	COT-GLUC
Sample type	URINE
Result	69.0
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	4
Celerion Study Number	AA99128-13
Date of Collection	2014-MAR-17
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 4

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

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

Generated On: 20 Jul 2016 20:43:03

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: 1202**

Folder: Day 4

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(3)**

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

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05112550000260
Analyte	NIC
Sample type	URINE
Result	BLQ<(10.0)
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	4
Celerion Study Number	AA99128-13
Date of Collection	2014-MAR-17
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 4

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(3)**

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

Generated On: 20 Jul 2016 20:43:03

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: 1202**

Folder: Day 4

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

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

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05112550000260
Analyte	NIC-GLUC
Sample type	URINE
Result	BLQ<(10.0)
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	4
Celerion Study Number	AA99128-13
Date of Collection	2014-MAR-17
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 4

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

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

Generated On: 20 Jul 2016 20:43:03

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: 1202**

Folder: Day 4

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

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

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05112550000260
Analyte	THCOT
Sample type	URINE
Result	77.2
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	4
Celerion Study Number	AA99128-13
Date of Collection	2014-MAR-17
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 4

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

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

Generated On: 20 Jul 2016 20:43:03

Urine Start Day	4
-----------------	---

Urine End Day	5
---------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 4

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(6)**

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

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05112550000260
Analyte	THCOT-GLUC
Sample type	URINE
Result	50.2
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	4
Celerion Study Number	AA99128-13
Date of Collection	2014-MAR-17
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 4

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(6)**

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

Generated On: 20 Jul 2016 20:43:03

Urine Start Day	4
-----------------	---

Urine End Day	5
---------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 4

Form: Biomarker-Urine (3-OH BaP)

Data signed: (hfarmer1) 27 Mar 2015 14:51:28

Generated On: 20 Jul 2016 20:43:03

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 4

Form: Biomarker-Urine (3-OH BaP) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:51:28

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05112490001360
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Analyte	3-OH BAP
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Sample type	URINE
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Result	.
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Result Unit	FG/ML
-------------	-------

Lab Status	OTHER
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Sample comment	ANALYSIS NOT REQUIRED
----------------	-----------------------

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	4
--------------	---

Celerion Study Number	AA99128-07
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Date of Collection	2014-MAR-17
--------------------	-------------

Timepoint-minutes	
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Urine Start Day	4
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 4

Form: Biomarker-Urine (3-OH BaP) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:51:28

Generated On: 20 Jul 2016 20:43:03

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 4

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP)

Data signed: (hfarmer1) 27 Mar 2015 14:51:28

Generated On: 20 Jul 2016 20:43:03

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 4

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:51:28

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05112510001382
Analyte	1-NA
Sample type	URINE
Result	BLQ<(2.50)
Result Unit	PG/ML
Lab Status	OTHER
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	4
Celerion Study Number	AA99128-09
Date of Collection	2014-MAR-17
Timepoint-minutes	
Urine Start Day	4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 4

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:51:28

Generated On: 20 Jul 2016 20:43:03

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 4

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (2)

Data signed: (hfarmer1) 27 Mar 2015 14:51:28

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05112510001382
Analyte	2-NA
Sample type	URINE
Result	BLQ<(2.50)
Result Unit	PG/ML
Lab Status	OTHER
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	4
Celerion Study Number	AA99128-09
Date of Collection	2014-MAR-17
Timepoint-minutes	
Urine Start Day	4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 4

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (2)

Data signed: (hfarmer1) 27 Mar 2015 14:51:28

Generated On: 20 Jul 2016 20:43:03

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 4

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (3)

Data signed: (hfarmer1) 27 Mar 2015 14:51:28

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05112510001382
Analyte	4-ABP
Sample type	URINE
Result	BLQ<(1.50)
Result Unit	PG/ML
Lab Status	OTHER
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	4
Celerion Study Number	AA99128-09
Date of Collection	2014-MAR-17
Timepoint-minutes	
Urine Start Day	4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 4

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (3)

Data signed: (hfarmer1) 27 Mar 2015 14:51:28

Generated On: 20 Jul 2016 20:43:03

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 4

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (4)

Data signed: (hfarmer1) 27 Mar 2015 14:51:28

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05112510001382
Analyte	O-TOL
Sample type	URINE
Result	BLQ<(50.0)
Result Unit	PG/ML
Lab Status	OTHER
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	4
Celerion Study Number	AA99128-09
Date of Collection	2014-MAR-17
Timepoint-minutes	
Urine Start Day	4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 4

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (4)

Data signed: (hfarmer1) 27 Mar 2015 14:51:28

Generated On: 20 Jul 2016 20:43:03

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 4

Form: Biomarker-Urine (1-OHP)

Data signed: (hfarmer1) 27 Mar 2015 14:51:31

Generated On: 20 Jul 2016 20:43:03

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 4

Form: Biomarker-Urine (1-OHP) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:51:31

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05115190001613
Analyte	1-OHP
Sample type	URINE
Result	.
Result Unit	PG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	4
Celerion Study Number	AA99598-03
Date of Collection	2014-MAR-17
Timepoint-minutes	
Urine Start Day	4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 4

Form: Biomarker-Urine (1-OHP) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:51:31

Generated On: 20 Jul 2016 20:43:03

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 4

Form: Biomarker-Urine (SPMA, SBMA)

Data signed: (hfarmer1) 27 Mar 2015 14:51:25

Generated On: 20 Jul 2016 20:43:03

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 4

Form: Biomarker-Urine (SPMA, SBMA) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:51:25

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05115170001591
Analyte	SBMA
Sample type	URINE
Result	.
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	4
Celerion Study Number	AA99598-01
Date of Collection	2014-MAR-17
Timepoint-minutes	
Urine Start Day	4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 4

Form: Biomarker-Urine (SPMA, SBMA) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:51:25

Generated On: 20 Jul 2016 20:43:03

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 4

Form: Biomarker-Urine (SPMA, SBMA) (2)

Data signed: (hfarmer1) 27 Mar 2015 14:51:25

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05115170001591
Analyte	SPMA
Sample type	URINE
Result	.
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	4
Celerion Study Number	AA99598-01
Date of Collection	2014-MAR-17
Timepoint-minutes	
Urine Start Day	4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 4

Form: Biomarker-Urine (SPMA, SBMA) (2)

Data signed: (hfarmer1) 27 Mar 2015 14:51:25

Generated On: 20 Jul 2016 20:43:03

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 4

Form: Biomarker-Urine (MHBMA)

Data signed: (hfarmer1) 27 Mar 2015 14:51:25

Generated On: 20 Jul 2016 20:43:03

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 4

Form: Biomarker-Urine (MHBMA) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:51:25

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05115180001613
Analyte	MHBMA
Sample type	URINE
Result	.
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	4
Celerion Study Number	AA99598-02
Date of Collection	2014-MAR-17
Timepoint-minutes	
Urine Start Day	4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 4

Form: Biomarker-Urine (MHBMA) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:51:25

Generated On: 20 Jul 2016 20:43:03

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 4

Form: Biomarker-Urine (Creatinine)

Data signed: (hfarmer1) 27 Mar 2015 14:51:30

Generated On: 20 Jul 2016 20:43:03

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 4

Form: Biomarker-Urine (Creatinine) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:51:30

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05115160001360
Analyte	CREATININE
Sample type	URINE
Result	.
Result Unit	MG/DL
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	SPECTROPHOTOMETRIC
Planned time point (Hour)	0
Day of Visit	4
Celerion Study Number	AA99128-14
Date of Collection	2014-MAR-17
Timepoint-minutes	
Urine Start Day	4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 4

Form: Biomarker-Urine (Creatinine) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:51:30

Generated On: 20 Jul 2016 20:43:03

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 4

Form: Biomarker-Plasma (Nic, Cot, tHCot)

Data signed: (hfarmer1) 27 Mar 2015 14:51:25

Generated On: 20 Jul 2016 20:43:03

Sample type

PLASMA

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 4

Form: Biomarker-Plasma (Nic, Cot, tHCot) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:51:25

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05112440000235
Analyte	COT
Sample type	PLASMA
Result	2.62
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	4
Celerion Study Number	AA99128-02
Date of Collection	2014-MAR-17
Timepoint-minutes	0
Urine Start Day	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 4

Form: Biomarker-Plasma (Nic, Cot, tHCot) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:51:25

Generated On: 20 Jul 2016 20:43:03

Urine End Day

4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 4

Form: Biomarker-Plasma (Nic, Cot, tHCot) (2)

Data signed: (hfarmer1) 27 Mar 2015 14:51:25

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05112440000235
Analyte	NIC
Sample type	PLASMA
Result	BLQ<(0.200)
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	4
Celerion Study Number	AA99128-02
Date of Collection	2014-MAR-17
Timepoint-minutes	0
Urine Start Day	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 4

Form: Biomarker-Plasma (Nic, Cot, tHCot) (2)

Data signed: (hfarmer1) 27 Mar 2015 14:51:25

Generated On: 20 Jul 2016 20:43:03

Urine End Day

4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 5

Form: Date of Visit

Data signed: (hfarmer1) 27 Mar 2015 14:51:36

Generated On: 20 Jul 2016 20:43:03

Date of Visit

18 MAR 2014
DD/MMM/YYYY

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 5

Form: Vital Signs

Data signed: (hfarmer1) 27 Mar 2015 14:51:36

Generated On: 20 Jul 2016 20:43:03

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

09:23
hour:min 24-hour clock

Pulse rate

63
beats per minute

Respiratory rate

16
breaths per minute

Blood Pressure (systolic)

120
mmHg

Blood Pressure (diastolic)

70
mmHg

Vital Signs Position of Subject

Supine ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 5

Form: Plasma Nicotine Sample

Data signed: (hfarmer1) 27 Mar 2015 14:51:38

Generated On: 20 Jul 2016 20:43:03

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	18 MAR 2014
---------------------	-------------

Time hour:min 24-hour clock	21:09
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 5

Form: Plasma Cotinine Sample

Data signed: (hfarmer1) 27 Mar 2015 14:51:38

Generated On: 20 Jul 2016 20:43:03

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	18 MAR 2014
---------------------	-------------

Time hour:min 24-hour clock	21:09
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 5

Form: CoHb Blood Sample(SA) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:51:36

Generated On: 20 Jul 2016 20:43:03

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	18 MAR 2014
---------------------	-------------

Scheduled Time	08:00 - 09:30 <input checked="" type="checkbox"/>
----------------	---

Time hour:min 24-hour clock	09:00
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 5

Form: CoHb Blood Sample(SA) (2)

Data signed: (hfarmer1) 27 Mar 2015 14:51:36

Generated On: 20 Jul 2016 20:43:03

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	18 MAR 2014
---------------------	-------------

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

Time hour:min 24-hour clock	12:55
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 5

Form: CoHb Blood Sample(SA) (3)

Data signed: (hfarmer1) 27 Mar 2015 14:51:36

Generated On: 20 Jul 2016 20:43:03

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	18 MAR 2014
---------------------	-------------

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

Time hour:min 24-hour clock	16:24
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 5

Form: CoHb Blood Sample(SA) (4)

Data signed: (hfarmer1) 27 Mar 2015 14:51:36

Generated On: 20 Jul 2016 20:43:03

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	18 MAR 2014
---------------------	-------------

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

Time hour:min 24-hour clock	21:09
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 5

Form: CO Breath Test <SA arm/> (1)

Data signed: (hfarmer1) 27 Mar 2015 14:51:36

Generated On: 20 Jul 2016 20:43:03

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

If Not Done, please specify the reason: _____

Scheduled Time	08:00 - 09:30 <input checked="" type="radio"/>
----------------	--

Actual Time of Assessment hour:min 24-hour clock	08:17
---	-------

Result(ppm)	2
-------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 5

Form: CO Breath Test <SA arm/> (2)

Data signed: (hfarmer1) 27 Mar 2015 14:51:36

Generated On: 20 Jul 2016 20:43:03

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	12:35
---	-------

Result(ppm)	1
-------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 5

Form: CO Breath Test <SA arm/> (3)

Data signed: (hfarmer1) 27 Mar 2015 14:51:36

Generated On: 20 Jul 2016 20:43:03

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	16:28
---	-------

Result(ppm)	1
-------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 5

Form: CO Breath Test <SA arm/> (4)

Data signed: (hfarmer1) 27 Mar 2015 14:51:36

Generated On: 20 Jul 2016 20:43:03

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	20:59
---	-------

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

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1202

Folder: Day 5

Form: CYP1A2 activity Sample

Data signed: (hfarmer1) 27 Mar 2015 14:51:31

Generated On: 20 Jul 2016 20:43:03

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

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

If Not Done, please specify the reason: _____

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 5

Form: 24 hour urine collections

Data signed: (hfarmer1) 27 Mar 2015 14:51:36

Generated On: 20 Jul 2016 20:43:03

Start Time	06:17
	hour:min 24-hour clock

End Date	19 MAR 2014
	DD/MMM/YYYY

End Time	06:52
	hour:min 24-hour clock

Volume	2487
	mL

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 5

Form: Sample Urine Collection

Data signed: (hfarmer1) 27 Mar 2015 14:51:36

Generated On: 20 Jul 2016 20:43:03

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: 1202**

Folder: Day 5

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Data signed: (hfarmer1) 27 Mar 2015 14:51:38

Generated On: 20 Jul 2016 20:43:03

Date of Birth

(b) (6)

Date of assessment
DD/MMM/YYYY

2014 MAR 18
DD/MMM/YYYY

Time of assessment

06:21
hour:min 24-hour clock

Assessment Status

Completed ☒

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

How have you been feeling over the past 24 hours?

Mild ☒

1. Angry, irritable, frustrated

How have you been feeling over the past 24 hours?

Slight ☒

2. Anxious, nervous

How have you been feeling over the past 24 hours?

Mild ☒

3. Depressed Mood, sad

How have you been feeling over the past 24 hours?

Mild ☒

4. Desire or craving to smoke

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 5

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Data signed: (hfarmer1) 27 Mar 2015 14:51:38

Generated On: 20 Jul 2016 20:43:03

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

5. Difficulty concentrating

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

6. Increased appetite, hungry, weight gain

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

7. Insomnia, sleep problems, awakening at night

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

8. Restless

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

9. Impatient

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

10. Constipation

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

11. Dizziness

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

12. Coughing

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 5

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Data signed: (hfarmer1) 27 Mar 2015 14:51:38

Generated On: 20 Jul 2016 20:43:03

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: 1202**

Folder: Day 5

Form: Cough Assessment

Data signed: (hfarmer1) 27 Mar 2015 14:51:38

Generated On: 20 Jul 2016 20:43:03

Date of Birth

(b) (6)

Date of assessment
DD/MMM/YYYY

2014 MAR 18
DD/MMM/YYYY

Time of assessment

06:20
hour:min 24-hour clock

Assessment Status

Completed ☒

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

No ☒

If YES, please answer the following questions:

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

-9

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

Not Applicable ☒

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

Not Applicable ☒

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

Not Applicable ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 5

Form: Lab_BU_COHB (1)

Data signed: (hfarmer1) 27 Mar 2015 14:51:39

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05115150001416
----------------	----------------

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

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

Result	2.00
--------	------

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

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

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

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

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

Planned time point (Hour)	8
---------------------------	---

Day of Visit	5
--------------	---

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

Date of Collection	2014-MAR-18
--------------------	-------------

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 5

Form: Lab_BU_COHB (1)

Data signed: (hfarmer1) 27 Mar 2015 14:51:39

Generated On: 20 Jul 2016 20:43:03

Start Day (24 hour urine only) _____

End Day (24 hour Urine Only) _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 5

Form: Lab_BU_COHB (2)

Data signed: (hfarmer1) 27 Mar 2015 14:51:39

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05115150001417
----------------	----------------

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

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

Result	2.40
--------	------

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

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

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

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

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

Planned time point (Hour)	12
---------------------------	----

Day of Visit	5
--------------	---

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

Date of Collection	2014-MAR-18
--------------------	-------------

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 5

Form: Lab_BU_COHB (2)

Data signed: (hfarmer1) 27 Mar 2015 14:51:39

Generated On: 20 Jul 2016 20:43:03

Start Day (24 hour urine only) _____

End Day (24 hour Urine Only) _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 5

Form: Lab_BU_COHB (3)

Data signed: (hfarmer1) 27 Mar 2015 14:51:39

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05115150001418
----------------	----------------

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

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

Result	2.10
--------	------

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

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

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

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

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

Planned time point (Hour)	16
---------------------------	----

Day of Visit	5
--------------	---

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

Date of Collection	2014-MAR-18
--------------------	-------------

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 5

Form: Lab_BU_COHB (3)

Data signed: (hfarmer1) 27 Mar 2015 14:51:39

Generated On: 20 Jul 2016 20:43:03

Start Day (24 hour urine only)

End Day (24 hour Urine Only)

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 5

Form: Lab_BU_COHB (4)

Data signed: (hfarmer1) 27 Mar 2015 14:51:39

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05115150001419
----------------	----------------

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

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

Result	2.10
--------	------

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

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

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

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

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

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

Day of Visit	5
--------------	---

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

Date of Collection	2014-MAR-18
--------------------	-------------

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 5

Form: Lab_BU_COHB (4)

Data signed: (hfarmer1) 27 Mar 2015 14:51:39

Generated On: 20 Jul 2016 20:43:03

Start Day (24 hour urine only)

End Day (24 hour Urine Only)

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 5

Form: Behavioral Risk Factor Surveillance System Questionnaire

Data signed: (hfarmer1) 27 Mar 2015 14:51:31

Generated On: 20 Jul 2016 20:43:03

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

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

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

Date of assessment	18 MAR 2014 DD/MMM/YYYY
--------------------	----------------------------

Time of assessment	20:53 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: 1202**

Folder: Day 5

Form: Behavioral Risk Factor Surveillance System Questionnaire

Data signed: (hfarmer1) 27 Mar 2015 14:51:31

Generated On: 20 Jul 2016 20:43:03

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: 1202

Folder: Day 5

Form: Smoking Questionnaire (SQ)

Data signed: (hfarmer1) 27 Mar 2015 14:51:32

Generated On: 20 Jul 2016 20:43:03

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

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

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

Date of assessment	18 MAR 2014 DD/MMM/YYYY
--------------------	----------------------------

Time of assessment	20:56 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?	17 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: 1202**

Folder: Day 5

Form: Smoking Questionnaire (SQ)

Data signed: (hfarmer1) 27 Mar 2015 14:51:32

Generated On: 20 Jul 2016 20:43:03

Months _____

Days _____

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

Years _____

Months _____

Days _____

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

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1202

Folder: Day 5

Form: Smoking Questionnaire (SQ) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:51:32

Generated On: 20 Jul 2016 20:43:03

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

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

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

Date of assessment	18 MAR 2014 DD/MMM/YYYY
--------------------	----------------------------

Time of assessment	20:56 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?	17 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: 1202**

Folder: Day 5

Form: Smoking Questionnaire (SQ) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:51:32

Generated On: 20 Jul 2016 20:43:03

Months _____

Days _____

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

Years _____

Months _____

Days _____

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

Time

Currently (last 3 months) ☒

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: 1202**

Folder: Day 5

Form: Smoking Questionnaire (SQ) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:51:32

Generated On: 20 Jul 2016 20:43:03

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: 1202

Folder: Day 5

Form: Smoking Questionnaire (SQ) (2)

Data signed: (hfarmer1) 27 Mar 2015 14:51:32

Generated On: 20 Jul 2016 20:43:03

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

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

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

Date of assessment	18 MAR 2014 DD/MMM/YYYY
--------------------	----------------------------

Time of assessment	20:56 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?	17 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: 1202

Folder: Day 5

Form: Smoking Questionnaire (SQ) (2)

Data signed: (hfarmer1) 27 Mar 2015 14:51:32

Generated On: 20 Jul 2016 20:43:03

Months

Days

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

Years

Months

Days

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

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: 1202**

Folder: Day 5

Form: Smoking Questionnaire (SQ) (2)

Data signed: (hfarmer1) 27 Mar 2015 14:51:32

Generated On: 20 Jul 2016 20:43:03

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: 1202

Folder: Day 5

Form: Smoking Questionnaire (SQ) (3)

Data signed: (hfarmer1) 27 Mar 2015 14:51:32

Generated On: 20 Jul 2016 20:43:03

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

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

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

Date of assessment	18 MAR 2014 DD/MMM/YYYY
--------------------	----------------------------

Time of assessment	20:56 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?	17 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: 1202

Folder: Day 5

Form: Smoking Questionnaire (SQ) (3)

Data signed: (hfarmer1) 27 Mar 2015 14:51:32

Generated On: 20 Jul 2016 20:43:03

Months

Days

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

Years

Months

Days

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

Time

5 years ago ☒

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

Manufactured Cigarettes
per day

10

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

None ☒

Hand-rolled Cigarettes
per day

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 5

Form: Smoking Questionnaire (SQ) (3)

Data signed: (hfarmer1) 27 Mar 2015 14:51:32

Generated On: 20 Jul 2016 20:43:03

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: 1202

Folder: Day 5

Form: Smoking Questionnaire (SQ) (4)

Data signed: (hfarmer1) 27 Mar 2015 14:51:32

Generated On: 20 Jul 2016 20:43:03

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

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

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

Date of assessment	18 MAR 2014 DD/MMM/YYYY
--------------------	----------------------------

Time of assessment	20:56 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?	17 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: 1202

Folder: Day 5

Form: Smoking Questionnaire (SQ) (4)

Data signed: (hfarmer1) 27 Mar 2015 14:51:32

Generated On: 20 Jul 2016 20:43:03

Months

Days

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

Years

Months

Days

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

Time

10 years ago ☒

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

Manufactured Cigarettes
per day

05

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: 1202**

Folder: Day 5

Form: Smoking Questionnaire (SQ) (4)

Data signed: (hfarmer1) 27 Mar 2015 14:51:32

Generated On: 20 Jul 2016 20:43:03

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: 1202

Folder: Day 5

Form: Smoking Questionnaire (SQ) (5)

Data signed: (hfarmer1) 27 Mar 2015 14:51:32

Generated On: 20 Jul 2016 20:43:03

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

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

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

Date of assessment	18 MAR 2014 DD/MMM/YYYY
--------------------	----------------------------

Time of assessment	20:56 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?	17 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: 1202

Folder: Day 5

Form: Smoking Questionnaire (SQ) (5)

Data signed: (hfarmer1) 27 Mar 2015 14:51:32

Generated On: 20 Jul 2016 20:43:03

Months

Days

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

Years

Months

Days

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

Time

15 years ago ☒

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

Manufactured Cigarettes
per day

5

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: 1202**

Folder: Day 5

Form: Smoking Questionnaire (SQ) (5)

Data signed: (hfarmer1) 27 Mar 2015 14:51:32

Generated On: 20 Jul 2016 20:43:03

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: 1202

Folder: Day 5

Form: Smoking Questionnaire (SQ) (6)

Data signed: (hfarmer1) 27 Mar 2015 14:51:32

Generated On: 20 Jul 2016 20:43:03

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

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

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

Date of assessment	18 MAR 2014 DD/MMM/YYYY
--------------------	----------------------------

Time of assessment	20:56 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?	17 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: 1202

Folder: Day 5

Form: Smoking Questionnaire (SQ) (6)

Data signed: (hfarmer1) 27 Mar 2015 14:51:32

Generated On: 20 Jul 2016 20:43:03

Months

Days

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

Years

Months

Days

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

Time

20 years ago ☒

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

Manufactured Cigarettes
per day

2

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: 1202**

Folder: Day 5

Form: Smoking Questionnaire (SQ) (6)

Data signed: (hfarmer1) 27 Mar 2015 14:51:32

Generated On: 20 Jul 2016 20:43:03

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: 1202

Folder: Day 5

Form: Smoking Questionnaire (SQ) (7)

Data signed: (hfarmer1) 27 Mar 2015 14:51:32

Generated On: 20 Jul 2016 20:43:03

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

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

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

Date of assessment	18 MAR 2014 DD/MMM/YYYY
--------------------	----------------------------

Time of assessment	20:56 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?	17 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: 1202

Folder: Day 5

Form: Smoking Questionnaire (SQ) (7)

Data signed: (hfarmer1) 27 Mar 2015 14:51:32

Generated On: 20 Jul 2016 20:43:03

Months

Days

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

Years

Months

Days

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

Time

More than 20 years ago ☒

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

Manufactured Cigarettes
per day

0

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: 1202**

Folder: Day 5

Form: Smoking Questionnaire (SQ) (7)

Data signed: (hfarmer1) 27 Mar 2015 14:51:32

Generated On: 20 Jul 2016 20:43:03

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: 1202**

Folder: Day 5

Form: Supplemental Questions

Data signed: (hfarmer1) 27 Mar 2015 14:51:35

Generated On: 20 Jul 2016 20:43:03

Was paper questionnaire used? Yes ☒

Reason not done

Date of Assessment 18 MAR 2014
DD/MMM/YYYY

Time of assessment 20:57

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

Comments (open-end) NONE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 5

Form: Supplemental Questions (1)

Data signed: (hfarmer1) 27 Mar 2015 14:51:35

Generated On: 20 Jul 2016 20:43:03

Was paper questionnaire used? Yes ☐

Reason not done _____

Date of Assessment 18 MAR 2014
DD/MMM/YYYY

Time of assessment 20:57

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

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

Answer Yes ☐

Comments (open-end) NONE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 5

Form: Supplemental Questions (2)

Data signed: (hfarmer1) 27 Mar 2015 14:51:35

Generated On: 20 Jul 2016 20:43:03

Was paper questionnaire used? Yes ☐

Reason not done

Date of Assessment 18 MAR 2014
DD/MMM/YYYY

Time of assessment 20:57

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

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

Answer Yes ☐

Comments (open-end) NONE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 5

Form: Supplemental Questions (3)

Data signed: (hfarmer1) 27 Mar 2015 14:51:35

Generated On: 20 Jul 2016 20:43:03

Was paper questionnaire used? Yes ☐

Reason not done _____

Date of Assessment 18 MAR 2014
DD/MMM/YYYY

Time of assessment 20:57

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

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

Answer Yes ☐

Comments (open-end) NONE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 5

Form: Supplemental Questions (4)

Data signed: (hfarmer1) 27 Mar 2015 14:51:35

Generated On: 20 Jul 2016 20:43:03

Was paper questionnaire used? Yes ☐

Reason not done _____

Date of Assessment 18 MAR 2014
DD/MMM/YYYY

Time of assessment 20:57

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

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

Answer Yes ☐

Comments (open-end) NONE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 5

Form: Supplemental Questions (5)

Data signed: (hfarmer1) 27 Mar 2015 14:51:35

Generated On: 20 Jul 2016 20:43:03

Was paper questionnaire used? Yes ☐

Reason not done

Date of Assessment 18 MAR 2014
DD/MMM/YYYY

Time of assessment 20:57

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

Question 6. Was the SQ ☐
self-explaining?

Answer Yes ☐

Comments (open-end) NONE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 5

Form: Supplemental Questions (6)

Data signed: (hfarmer1) 27 Mar 2015 14:51:35

Generated On: 20 Jul 2016 20:43:03

Was paper questionnaire used? Yes ☐

Reason not done

Date of Assessment 18 MAR 2014
DD/MMM/YYYY

Time of assessment 20:57

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

Question 7. Was the SQ easy to use? ☐

Answer Yes ☐

Comments (open-end) NONE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 5

Form: Questionnaire on smoking urges (QSU)

Data signed: (hfarmer1) 27 Mar 2015 14:51:38

Generated On: 20 Jul 2016 20:43:03

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

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

Date of assessment	2014 MAR 18
--------------------	-------------

DD/MMM/YYYY

Time of assessment	20:19
--------------------	-------

hour:min 24-hour clock

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

1. I have a desire for a cigarette right now	Agree <input checked="" type="radio"/>
--	--

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

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

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

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

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 5

Form: Questionnaire on smoking urges (QSU)

Data signed: (hfarmer1) 27 Mar 2015 14:51:38

Generated On: 20 Jul 2016 20:43:03

7. A cigarette would taste good now Agree ☐

8. I would do almost anything for a cigarette now Somewhat agree ☐

9. Smoking would make me less depressed Somewhat agree ☐

10. I am going to smoke as soon as possible Somewhat agree ☐

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 5

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

Data signed: (hfarmer1) 27 Mar 2015 14:51:39

Generated On: 20 Jul 2016 20:43:03

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 5

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

Data signed: (hfarmer1) 27 Mar 2015 14:51:39

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05112450002282
Analyte	HPMA
Sample type	URINE
Result	170
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	5
Celerion Study Number	AA99128-03
Date of Collection	2014-MAR-18
Timepoint-minutes	
Urine Start Day	5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 5

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

Data signed: (hfarmer1) 27 Mar 2015 14:51:39

Generated On: 20 Jul 2016 20:43:03

Urine End Day

6

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 5

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (2)

Data signed: (hfarmer1) 27 Mar 2015 14:51:39

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05112450002282
Analyte	CEMA
Sample type	URINE
Result	7.55
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	5
Celerion Study Number	AA99128-03
Date of Collection	2014-MAR-18
Timepoint-minutes	
Urine Start Day	5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 5

Form: Biomarker-Urine (CEMA, HPMa, HBMA) (2)

Data signed: (hfarmer1) 27 Mar 2015 14:51:39

Generated On: 20 Jul 2016 20:43:03

Urine End Day

6

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 5

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (3)

Data signed: (hfarmer1) 27 Mar 2015 14:51:39

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05112450002282
Analyte	HBMA
Sample type	URINE
Result	99.4
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	5
Celerion Study Number	AA99128-03
Date of Collection	2014-MAR-18
Timepoint-minutes	
Urine Start Day	5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 5

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (3)

Data signed: (hfarmer1) 27 Mar 2015 14:51:39

Generated On: 20 Jul 2016 20:43:03

Urine End Day

6

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 5

Form: Biomarker-Urine (NNN, NNAL)

Data signed: (hfarmer1) 27 Mar 2015 14:51:39

Generated On: 20 Jul 2016 20:43:03

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 5

Form: Biomarker-Urine (NNN, NNAL) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:51:39

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05112460002725
Analyte	NNAL
Sample type	URINE
Result	.
Result Unit	PG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	5
Celerion Study Number	AA99128-04
Date of Collection	2014-MAR-18
Timepoint-minutes	
Urine Start Day	5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 5

Form: Biomarker-Urine (NNN, NNAL) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:51:39

Generated On: 20 Jul 2016 20:43:03

Urine End Day

6

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 5

Form: Biomarker-Urine (NNN, NNAL) (2)

Data signed: (hfarmer1) 27 Mar 2015 14:51:39

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05112460002725
Analyte	NNN
Sample type	URINE
Result	.
Result Unit	PG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	5
Celerion Study Number	AA99128-04
Date of Collection	2014-MAR-18
Timepoint-minutes	
Urine Start Day	5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 5

Form: Biomarker-Urine (NNN, NNAL) (2)

Data signed: (hfarmer1) 27 Mar 2015 14:51:39

Generated On: 20 Jul 2016 20:43:03

Urine End Day

6

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 5

Form: Biomarker-Urine (HEMA)

Data signed: (hfarmer1) 27 Mar 2015 14:51:39

Generated On: 20 Jul 2016 20:43:03

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 5

Form: Biomarker-Urine (HEMA) (2)

Data signed: (hfarmer1) 27 Mar 2015 14:51:39

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05112470001352
Analyte	HEMA
Sample type	URINE
Result	0.644
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	5
Celerion Study Number	AA99128-05
Date of Collection	2014-MAR-18
Timepoint-minutes	
Urine Start Day	5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 5

Form: Biomarker-Urine (HEMA) (2)

Data signed: (hfarmer1) 27 Mar 2015 14:51:39

Generated On: 20 Jul 2016 20:43:03

Urine End Day

6

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 5

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

Data signed: (hfarmer1) 27 Mar 2015 14:51:40

Generated On: 20 Jul 2016 20:43:03

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 5

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

Data signed: (hfarmer1) 27 Mar 2015 14:51:40

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05112550000261
Analyte	COT
Sample type	URINE
Result	BLQ<(10.0)
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	5
Celerion Study Number	AA99128-13
Date of Collection	2014-MAR-18
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 5

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(1)**

Data signed: (hfarmer1) 27 Mar 2015 14:51:40

Generated On: 20 Jul 2016 20:43:03

Urine Start Day	5
<hr/>	
Urine End Day	6
<hr/>	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 5

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(2)**

Data signed: (hfarmer1) 27 Mar 2015 14:51:40

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05112550000261
Analyte	COT-GLUC
Sample type	URINE
Result	BLQ<(20.0)
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	5
Celerion Study Number	AA99128-13
Date of Collection	2014-MAR-18
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 5

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(2)**

Data signed: (hfarmer1) 27 Mar 2015 14:51:40

Generated On: 20 Jul 2016 20:43:03

Urine Start Day	5
-----------------	---

Urine End Day	6
---------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 5

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(3)**

Data signed: (hfarmer1) 27 Mar 2015 14:51:40

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05112550000261
Analyte	NIC
Sample type	URINE
Result	BLQ<(10.0)
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	5
Celerion Study Number	AA99128-13
Date of Collection	2014-MAR-18
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 5

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(3)**

Data signed: (hfarmer1) 27 Mar 2015 14:51:40

Generated On: 20 Jul 2016 20:43:03

Urine Start Day	5
-----------------	---

Urine End Day	6
---------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 5

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(4)**

Data signed: (hfarmer1) 27 Mar 2015 14:51:40

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05112550000261
Analyte	NIC-GLUC
Sample type	URINE
Result	BLQ<(10.0)
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	5
Celerion Study Number	AA99128-13
Date of Collection	2014-MAR-18
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 5

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(4)**

Data signed: (hfarmer1) 27 Mar 2015 14:51:40

Generated On: 20 Jul 2016 20:43:03

Urine Start Day	5
<hr/>	
Urine End Day	6
<hr/>	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 5

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(5)**

Data signed: (hfarmer1) 27 Mar 2015 14:51:40

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05112550000261
Analyte	THCOT
Sample type	URINE
Result	20.7
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	5
Celerion Study Number	AA99128-13
Date of Collection	2014-MAR-18
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 5

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(5)**

Data signed: (hfarmer1) 27 Mar 2015 14:51:40

Generated On: 20 Jul 2016 20:43:03

Urine Start Day	5
-----------------	---

Urine End Day	6
---------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 5

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(6)**

Data signed: (hfarmer1) 27 Mar 2015 14:51:40

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05112550000261
Analyte	THCOT-GLUC
Sample type	URINE
Result	BLQ<(50.0)
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	5
Celerion Study Number	AA99128-13
Date of Collection	2014-MAR-18
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 5

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(6)**

Data signed: (hfarmer1) 27 Mar 2015 14:51:40

Generated On: 20 Jul 2016 20:43:03

Urine Start Day	5
<hr/>	
Urine End Day	6
<hr/>	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 5

Form: Biomarker-Urine (3-OH BaP)

Data signed: (hfarmer1) 27 Mar 2015 14:51:40

Generated On: 20 Jul 2016 20:43:03

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 5

Form: Biomarker-Urine (3-OH BaP) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:51:40

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05112490001361
Analyte	3-OH BAP
Sample type	URINE
Result	.
Result Unit	FG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	5
Celerion Study Number	AA99128-07
Date of Collection	2014-MAR-18
Timepoint-minutes	
Urine Start Day	5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 5

Form: Biomarker-Urine (3-OH BaP) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:51:40

Generated On: 20 Jul 2016 20:43:03

Urine End Day

6

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 5

Form: Biomarker-Plasma (Caffeine, Paraxanthine)

Generated On: 20 Jul 2016 20:43:03

Sample type

PLASMA

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 5

Form: Biomarker-Plasma (Caffeine, Paraxanthine) (1)

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05112500000371
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Analyte	CAFFEINE
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Sample type	PLASMA
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Result	1580
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Result Unit	NG/ML
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Lab Status	OTHER
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Sample comment	ANALYZED IN ERROR
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Detection method	LC-MS/MS
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Planned time point (Hour)	6
---------------------------	---

Day of Visit	5
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Celerion Study Number	AA99128-08
-----------------------	------------

Date of Collection	2014-MAR-18
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Timepoint-minutes	0
-------------------	---

Urine Start Day	
-----------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 5

Form: Biomarker-Plasma (Caffeine, Paraxanthine) (1)

Generated On: 20 Jul 2016 20:43:03

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 5

Form: Biomarker-Plasma (Caffeine, Paraxanthine) (2)

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05112500000371
----------------	----------------

Analyte	PARAXANTHINE
---------	--------------

Sample type	PLASMA
-------------	--------

Result	1440
--------	------

Result Unit	NG/ML
-------------	-------

Lab Status	OTHER
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Sample comment	ANALYZED IN ERROR
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Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	6
---------------------------	---

Day of Visit	5
--------------	---

Celerion Study Number	AA99128-08
-----------------------	------------

Date of Collection	2014-MAR-18
--------------------	-------------

Timepoint-minutes	0
-------------------	---

Urine Start Day	
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 5

Form: Biomarker-Plasma (Caffeine, Paraxanthine) (2)

Generated On: 20 Jul 2016 20:43:03

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 5

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP)

Data signed: (hfarmer1) 27 Mar 2015 14:51:40

Generated On: 20 Jul 2016 20:43:03

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 5

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:51:40

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05112510001383
Analyte	1-NA
Sample type	URINE
Result	BLQ<(2.50)
Result Unit	PG/ML
Lab Status	OTHER
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	5
Celerion Study Number	AA99128-09
Date of Collection	2014-MAR-18
Timepoint-minutes	
Urine Start Day	5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 5

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:51:40

Generated On: 20 Jul 2016 20:43:03

Urine End Day

6

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 5

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (2)

Data signed: (hfarmer1) 27 Mar 2015 14:51:40

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05112510001383
Analyte	2-NA
Sample type	URINE
Result	BLQ<(2.50)
Result Unit	PG/ML
Lab Status	OTHER
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	5
Celerion Study Number	AA99128-09
Date of Collection	2014-MAR-18
Timepoint-minutes	
Urine Start Day	5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 5

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (2)

Data signed: (hfarmer1) 27 Mar 2015 14:51:40

Generated On: 20 Jul 2016 20:43:03

Urine End Day

6

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 5

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (3)

Data signed: (hfarmer1) 27 Mar 2015 14:51:40

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05112510001383
Analyte	4-ABP
Sample type	URINE
Result	BLQ<(1.50)
Result Unit	PG/ML
Lab Status	OTHER
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	5
Celerion Study Number	AA99128-09
Date of Collection	2014-MAR-18
Timepoint-minutes	
Urine Start Day	5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 5

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (3)

Data signed: (hfarmer1) 27 Mar 2015 14:51:40

Generated On: 20 Jul 2016 20:43:03

Urine End Day

6

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 5

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (4)

Data signed: (hfarmer1) 27 Mar 2015 14:51:40

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05112510001383
Analyte	O-TOL
Sample type	URINE
Result	BLQ<(50.0)
Result Unit	PG/ML
Lab Status	OTHER
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	5
Celerion Study Number	AA99128-09
Date of Collection	2014-MAR-18
Timepoint-minutes	
Urine Start Day	5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 5

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (4)

Data signed: (hfarmer1) 27 Mar 2015 14:51:40

Generated On: 20 Jul 2016 20:43:03

Urine End Day

6

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 5

Form: Biomarker-Urine (11-dTXb2)

Data signed: (hfarmer1) 27 Mar 2015 14:51:39

Generated On: 20 Jul 2016 20:43:03

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 5

Form: Biomarker-Urine (11-dTXb2) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:51:39

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05112530000431
Analyte	11-DTXB2
Sample type	URINE
Result	.
Result Unit	PG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	5
Celerion Study Number	AA99128-11
Date of Collection	2014-MAR-18
Timepoint-minutes	
Urine Start Day	5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 5

Form: Biomarker-Urine (11-dTXb2) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:51:39

Generated On: 20 Jul 2016 20:43:03

Urine End Day

6

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 5

Form: Biomarker-Urine (iPF2a-III)

Data signed: (hfarmer1) 27 Mar 2015 14:51:39

Generated On: 20 Jul 2016 20:43:03

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 5

Form: Biomarker-Urine (iPF2a-III) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:51:39

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05112540000424
Analyte	IPF2A-III
Sample type	URINE
Result	162
Result Unit	PG/ML
Lab Status	OTHER
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	5
Celerion Study Number	AA99128-12
Date of Collection	2014-MAR-18
Timepoint-minutes	
Urine Start Day	5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 5

Form: Biomarker-Urine (iPF2a-III) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:51:39

Generated On: 20 Jul 2016 20:43:03

Urine End Day

6

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 5

Form: Biomarker-Urine (Ames)

Data signed: (hfarmer1) 27 Mar 2015 14:51:40

Generated On: 20 Jul 2016 20:43:03

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 5

Form: Biomarker-Urine (Ames) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:51:40

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05113320000140
Analyte	AMES
Sample type	URINE
Result	.
Result Unit	REV/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	COUNT
Planned time point (Hour)	0
Day of Visit	5
Celerion Study Number	AA99128-15
Date of Collection	2014-MAR-18
Timepoint-minutes	
Urine Start Day	5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 5

Form: Biomarker-Urine (Ames) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:51:40

Generated On: 20 Jul 2016 20:43:03

Urine End Day

6

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 5

Form: Biomarker-Urine (1-OHP)

Data signed: (hfarmer1) 27 Mar 2015 14:51:40

Generated On: 20 Jul 2016 20:43:03

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 5

Form: Biomarker-Urine (1-OHP) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:51:40

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05115190001614
Analyte	1-OHP
Sample type	URINE
Result	.
Result Unit	PG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	5
Celerion Study Number	AA99598-03
Date of Collection	2014-MAR-18
Timepoint-minutes	
Urine Start Day	5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 5

Form: Biomarker-Urine (1-OHP) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:51:40

Generated On: 20 Jul 2016 20:43:03

Urine End Day

6

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 5

Form: Biomarker-Urine (SPMA, SBMA)

Data signed: (hfarmer1) 27 Mar 2015 14:51:39

Generated On: 20 Jul 2016 20:43:03

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 5

Form: Biomarker-Urine (SPMA, SBMA) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:51:39

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05115170001592
Analyte	SBMA
Sample type	URINE
Result	.
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	5
Celerion Study Number	AA99598-01
Date of Collection	2014-MAR-18
Timepoint-minutes	
Urine Start Day	5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 5

Form: Biomarker-Urine (SPMA, SBMA) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:51:39

Generated On: 20 Jul 2016 20:43:03

Urine End Day

6

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 5

Form: Biomarker-Urine (SPMA, SBMA) (2)

Data signed: (hfarmer1) 27 Mar 2015 14:51:39

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05115170001592
Analyte	SPMA
Sample type	URINE
Result	.
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	5
Celerion Study Number	AA99598-01
Date of Collection	2014-MAR-18
Timepoint-minutes	
Urine Start Day	5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 5

Form: Biomarker-Urine (SPMA, SBMA) (2)

Data signed: (hfarmer1) 27 Mar 2015 14:51:39

Generated On: 20 Jul 2016 20:43:03

Urine End Day

6

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 5

Form: Biomarker-Urine (MHBMA)

Data signed: (hfarmer1) 27 Mar 2015 14:51:39

Generated On: 20 Jul 2016 20:43:03

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 5

Form: Biomarker-Urine (MHBMA) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:51:39

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05115180001614
Analyte	MHBMA
Sample type	URINE
Result	.
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	5
Celerion Study Number	AA99598-02
Date of Collection	2014-MAR-18
Timepoint-minutes	
Urine Start Day	5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 5

Form: Biomarker-Urine (MHBMA) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:51:39

Generated On: 20 Jul 2016 20:43:03

Urine End Day

6

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 5

Form: Biomarker-Urine (Creatinine)

Data signed: (hfarmer1) 27 Mar 2015 14:51:40

Generated On: 20 Jul 2016 20:43:03

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 5

Form: Biomarker-Urine (Creatinine) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:51:40

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05115160001361
Analyte	CREATININE
Sample type	URINE
Result	.
Result Unit	MG/DL
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	SPECTROPHOTOMETRIC
Planned time point (Hour)	0
Day of Visit	5
Celerion Study Number	AA99128-14
Date of Collection	2014-MAR-18
Timepoint-minutes	
Urine Start Day	5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 5

Form: Biomarker-Urine (Creatinine) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:51:40

Generated On: 20 Jul 2016 20:43:03

Urine End Day

6

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot)

Data signed: (hfarmer1) 27 Mar 2015 14:51:39

Generated On: 20 Jul 2016 20:43:03

Sample type

PLASMA

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:51:39

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05112440000236
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Analyte	COT
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Sample type	PLASMA
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Result	BLQ<(1.00)
--------	------------

Result Unit	NG/ML
-------------	-------

Lab Status	OTHER
------------	-------

Sample comment	ANALYZED IN ERROR
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Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	5
--------------	---

Celerion Study Number	AA99128-02
-----------------------	------------

Date of Collection	2014-MAR-18
--------------------	-------------

Timepoint-minutes	0
-------------------	---

Urine Start Day	
-----------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:51:39

Generated On: 20 Jul 2016 20:43:03

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (2)

Data signed: (hfarmer1) 27 Mar 2015 14:51:39

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05112440000236
----------------	----------------

Analyte	NIC
---------	-----

Sample type	PLASMA
-------------	--------

Result	BLQ<(0.200)
--------	-------------

Result Unit	NG/ML
-------------	-------

Lab Status	OTHER
------------	-------

Sample comment	ANALYZED IN ERROR
----------------	-------------------

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	5
--------------	---

Celerion Study Number	AA99128-02
-----------------------	------------

Date of Collection	2014-MAR-18
--------------------	-------------

Timepoint-minutes	0
-------------------	---

Urine Start Day	
-----------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (2)

Data signed: (hfarmer1) 27 Mar 2015 14:51:39

Generated On: 20 Jul 2016 20:43:03

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 6

Form: Date of Visit

Data signed: (hfarmer1) 27 Mar 2015 14:51:41

Generated On: 20 Jul 2016 20:43:03

Date of Visit

19 MAR 2014
DD/MMM/YYYY

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 6

Form: Plasma Nicotine Sample

Data signed: (hfarmer1) 27 Mar 2015 14:51:41

Generated On: 20 Jul 2016 20:43:03

Not Done	False
----------	-------

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	19 MAR 2014
---------------------	-------------

Time hour:min 24-hour clock	08:16
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 6

Form: Plasma Cotinine Sample

Data signed: (hfarmer1) 27 Mar 2015 14:51:41

Generated On: 20 Jul 2016 20:43:03

Not Done	False
----------	-------

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	19 MAR 2014
---------------------	-------------

Time hour:min 24-hour clock	08:16
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 6

Form: CoHb Blood Sample <prior to gas transfer>

Data signed: (hfarmer1) 27 Mar 2015 14:51:41

Generated On: 20 Jul 2016 20:43:03

Not Done	False
----------	-------

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	19 MAR 2014
---------------------	-------------

Timepoint	Prior to gas transfer assessment <input checked="" type="radio"/>
-----------	--

Time hour:min 24-hour clock	07:01
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 6

Form: Oxysterols

Data signed: (hfarmer1) 27 Mar 2015 14:51:41

Generated On: 20 Jul 2016 20:43:03

Not Done	False
----------	-------

If Not Done, please specify the reason: _____

Was the subject fasting for at least 10 hours at time of sample collection?	Yes <input checked="" type="radio"/>
--	--------------------------------------

Date DD/MMM/YYYY	19 MAR 2014
---------------------	-------------

Time hour:min 24-hour clock	07:01
--------------------------------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1202

Folder: Day 6

Form: CYP2A6 activity Sample

Data signed: (hfarmer1) 27 Mar 2015 14:51:40

Generated On: 20 Jul 2016 20:43:03

Not Done	False
----------	-------

If Not Done, please specify the reason: _____

Date of sample collection
DD/MMM/YYYY

Time of sample collection
hour:min 24-hour clock

Parameter

19 MAR 2014

07:01

trans-3'-hydroxyc
otinine

19 MAR 2014

07:01

cotinine

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 6

Form: Risk Marker: sICAM-1

Data signed: (hfarmer1) 27 Mar 2015 14:51:40

Generated On: 20 Jul 2016 20:43:03

Not Done	False
----------	-------

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	19 MAR 2014
---------------------	-------------

Time hour:min 24-hour clock	07:01
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 6

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Data signed: (hfarmer1) 27 Mar 2015 14:51:41

Generated On: 20 Jul 2016 20:43:03

Date of Birth

(b) (6)

Date of assessment
DD/MMM/YYYY

2014 MAR 19
DD/MMM/YYYY

Time of assessment

06:12
hour:min 24-hour clock

Assessment Status

Completed ☒

Please indicate for each of the items below, how you have been feeling over the past 24 hours

How have you been feeling over the past 24 hours?

Mild ☒

1. Angry, irritable, frustrated

How have you been feeling over the past 24 hours?

Moderate ☒

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: 1202**

Folder: Day 6

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Data signed: (hfarmer1) 27 Mar 2015 14:51:41

Generated On: 20 Jul 2016 20:43:03

How have you been feeling over the past 24 hours? Mild ☐

5. Difficulty concentrating

How have you been feeling over the past 24 hours? Severe ☐

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? Mild ☐

8. Restless

How have you been feeling over the past 24 hours? None ☐

9. Impatient

How have you been feeling over the past 24 hours? None ☐

10. Constipation

How have you been feeling over the past 24 hours? None ☐

11. Dizziness

How have you been feeling over the past 24 hours? None ☐

12. Coughing

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 6

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Data signed: (hfarmer1) 27 Mar 2015 14:51:41

Generated On: 20 Jul 2016 20:43:03

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: 1202**

Folder: Day 6

Form: Cough Assessment

Data signed: (hfarmer1) 27 Mar 2015 14:51:41

Generated On: 20 Jul 2016 20:43:03

Date of Birth

(b) (6)

Date of assessment
DD/MMM/YYYY

2014 MAR 19
DD/MMM/YYYY

Time of assessment

06:11
hour:min 24-hour clock

Assessment Status

Completed ☒

Have you experienced a regular need to cough e.g.
coughing several times in the last 24 hrs?

No ☒

If YES, please answer the following questions:

First Question: Cough Impact Scale
How much is your cough bothering you?

-9

Second Question: Cough Intensity Scale:
How intense is your cough?

Not Applicable ☒

Third Question: Cough Frequency Scale:
How frequently do you normally have to cough each
day?

Not Applicable ☒

Fourth Question: Sputum Production
To what extent do you produce sputum when coughing?

Not Applicable ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 6

Form: Bio-banking (Transcriptomics)

Data signed: (hfarmer1) 27 Mar 2015 14:51:41

Generated On: 20 Jul 2016 20:43:03

Was a Bio-banking sample for transcriptomics taken?

Yes ☒

Time of Sample Collection

07:01
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: 1202**

Folder: Day 6

Form: Bio-banking (Biomarkers of exposure and risk markers)

Data signed: (hfarmer1) 27 Mar 2015 14:51:41

Generated On: 20 Jul 2016 20:43:03

Was a Bio-banking sample for biomarkers of exposure
and risk markers taken?

Yes ☒

Time of Sample Collection

07:01
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: 1202**

Folder: Day 6

Form: Bio-banking (nasal epithelial collection/buccal collection)

Data signed: (hfarmer1) 27 Mar 2015 14:51:41

Generated On: 20 Jul 2016 20:43:03

Was a Bio-banking sample for nasal epithelial collection/buccal collection taken?	Yes <input checked="" type="radio"/>
---	--------------------------------------

Time of Buccal Collection	10:03
	hour:min 24-hour clock

Time of Nasal Epithelial Collection	09:59
	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: 1202**

Folder: Day 6

Form: Oxysterol results (1)

Generated On: 20 Jul 2016 20:43:03

Sample Accession number	3281676015
-------------------------	------------

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: 1202**

Folder: Day 6

Form: Oxysterol results (2)

Generated On: 20 Jul 2016 20:43:03

Sample Accession number	3281676015
-------------------------	------------

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: 1202**

Folder: Day 6

Form: Oxysterol results (3)

Generated On: 20 Jul 2016 20:43:03

Sample Accession number	3281676015
-------------------------	------------

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: 1202**

Folder: Day 6

Form: Oxysterol results (4)

Generated On: 20 Jul 2016 20:43:03

Sample Accession number	3281676015
-------------------------	------------

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: 1202**

Folder: Day 6

Form: Oxysterol results (5)

Generated On: 20 Jul 2016 20:43:03

Sample Accession number	3281676015
-------------------------	------------

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: 1202**

Folder: Day 6

Form: Oxysterol results (6)

Generated On: 20 Jul 2016 20:43:03

Sample Accession number	3281676015
-------------------------	------------

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: 1202**

Folder: Day 6

Form: Oxysterol results (7)

Generated On: 20 Jul 2016 20:43:03

Sample Accession number	3281676015
-------------------------	------------

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: 1202**

Folder: Day 6

Form: Oxysterol results (8)

Generated On: 20 Jul 2016 20:43:03

Sample Accession number	3281676015
-------------------------	------------

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: 1202**

Folder: Day 6

Form: Oxysterol results (9)

Generated On: 20 Jul 2016 20:43:03

Sample Accession number	3281676015
-------------------------	------------

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: 1202**

Folder: Day 6

Form: Oxysterol results (10)

Generated On: 20 Jul 2016 20:43:03

Sample Accession number	3281676015
-------------------------	------------

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: 1202**

Folder: Day 6

Form: Oxysterol results (11)

Generated On: 20 Jul 2016 20:43:03

Sample Accession number	3281676015
-------------------------	------------

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: 1202**

Folder: Day 6

Form: Oxysterol results (12)

Generated On: 20 Jul 2016 20:43:03

Sample Accession number	3281676015
-------------------------	------------

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: 1202**

Folder: Day 6

Form: Lab_BU_COHB (1)

Data signed: (hfarmer1) 27 Mar 2015 14:51:42

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05115150001420
----------------	----------------

Analyte	CARBOXYHEMOGLOBIN
---------	-------------------

Sample type	BLOOD
-------------	-------

Result	2.10
--------	------

Result Unit	%
-------------	---

Lab Status	OK
------------	----

Sample comment	
----------------	--

Detection method	SPECTROPHOTOMETRIC
------------------	--------------------

Lower limit of quantification	0.500
-------------------------------	-------

Planned time point (Hour)	6
---------------------------	---

Day of Visit	6
--------------	---

Celerion Study Number	AA99128-16
-----------------------	------------

Date of Collection	2014-MAR-19
--------------------	-------------

Timepoint-minutes	
-------------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 6

Form: Lab_BU_COHB (1)

Data signed: (hfarmer1) 27 Mar 2015 14:51:42

Generated On: 20 Jul 2016 20:43:03

Start Day (24 hour urine only) _____

End Day (24 hour Urine Only) _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 6

Form: Questionnaire on smoking urges (QSU)

Data signed: (hfarmer1) 27 Mar 2015 14:51:41

Generated On: 20 Jul 2016 20:43:03

Type	QSU
------	-----

Date of Birth	(b) (6)
---------------	---------

Date of assessment	2014 MAR 19
--------------------	-------------

DD/MMM/YYYY

Time of assessment	06:12
--------------------	-------

hour:min 24-hour clock

Assessment Status	Completed <input checked="" type="radio"/>
-------------------	--

1. I have a desire for a cigarette right now	Agree <input checked="" type="radio"/>
--	--

2. Nothing would be better than smoking a cigarette right now	Do not agree or disagree <input checked="" type="radio"/>
---	---

3. If it were possible I would probably smoke now	Do not agree or disagree <input checked="" type="radio"/>
---	---

4. I could control things better right now if I could smoke	Do not agree or disagree <input checked="" type="radio"/>
---	---

5. All I want right now is a cigarette	Somewhat agree <input checked="" type="radio"/>
--	---

6. I have an urge for a cigarette	Somewhat agree <input checked="" type="radio"/>
-----------------------------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 6

Form: Questionnaire on smoking urges (QSU)

Data signed: (hfarmer1) 27 Mar 2015 14:51:41

Generated On: 20 Jul 2016 20:43:03

7. A cigarette would taste good now Somewhat agree ☐

8. I would do almost anything for a cigarette now Somewhat agree ☐

9. Smoking would make me less depressed Somewhat agree ☐

10. I am going to smoke as soon as possible Somewhat agree ☐

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1202

Folder: Day 6

Form: Risk Markers(CCLS) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:51:41

Generated On: 20 Jul 2016 20:43:03

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	1202
----------------------	------

Subject Sex	M
-------------	---

Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	DAY6
------------	------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	W816760
--------------	---------

Actual Collection Date	2014 03 19
------------------------	------------

Actual Collection Time	07:01
------------------------	-------

Specimen Condition	
--------------------	--

Battery ID	IM2293
------------	--------

Battery Name	SICAM-1
--------------	---------

Lab Test ID	IMT1768
-------------	---------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1202

Folder: Day 6

Form: Risk Markers(CCLS) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:51:41

Generated On: 20 Jul 2016 20:43:03

Lab Test Name	SICAM-1-RUO
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	134.7
Reported Numeric Result	134.7
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: 1202**

Folder: Day 6

Form: Risk Markers(CCLS) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:51:41

Generated On: 20 Jul 2016 20:43:03

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: 1202**

Folder: Day 6

Form: Biomarker-Plasma (Nic, Cot, tHCot)

Generated On: 20 Jul 2016 20:43:03

Sample type

PLASMA

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 6

Form: Biomarker-Plasma (Nic, Cot, tHCot) (1)

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05112440000237
----------------	----------------

Analyte	COT
---------	-----

Sample type	PLASMA
-------------	--------

Result	BLQ<(1.00)
--------	------------

Result Unit	NG/ML
-------------	-------

Lab Status	OTHER
------------	-------

Sample comment	ANALYZED IN ERROR
----------------	-------------------

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	6
--------------	---

Celerion Study Number	AA99128-02
-----------------------	------------

Date of Collection	2014-MAR-19
--------------------	-------------

Timepoint-minutes	0
-------------------	---

Urine Start Day	
-----------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 6

Form: Biomarker-Plasma (Nic, Cot, tHCot) (1)

Generated On: 20 Jul 2016 20:43:03

Urine End Day

6

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 6

Form: Biomarker-Plasma (Nic, Cot, tHCot) (2)

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05112440000237
----------------	----------------

Analyte	NIC
---------	-----

Sample type	PLASMA
-------------	--------

Result	BLQ<(0.200)
--------	-------------

Result Unit	NG/ML
-------------	-------

Lab Status	OTHER
------------	-------

Sample comment	ANALYZED IN ERROR
----------------	-------------------

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	6
--------------	---

Celerion Study Number	AA99128-02
-----------------------	------------

Date of Collection	2014-MAR-19
--------------------	-------------

Timepoint-minutes	0
-------------------	---

Urine Start Day	
-----------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 6

Form: Biomarker-Plasma (Nic, Cot, tHCot) (2)

Generated On: 20 Jul 2016 20:43:03

Urine End Day

6

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 6

Form: Biomarker-Plasma (Nic, Cot, tHCot) (3)

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05112520000371
----------------	----------------

Analyte	COT
---------	-----

Sample type	PLASMA
-------------	--------

Result	BLQ<(1.00)
--------	------------

Result Unit	NG/ML
-------------	-------

Lab Status	OTHER
------------	-------

Sample comment	ANALYZED IN ERROR
----------------	-------------------

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	6
--------------	---

Celerion Study Number	AA99128-10
-----------------------	------------

Date of Collection	2014-MAR-19
--------------------	-------------

Timepoint-minutes	0
-------------------	---

Urine Start Day	
-----------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 6

Form: Biomarker-Plasma (Nic, Cot, tHCot) (3)

Generated On: 20 Jul 2016 20:43:03

Urine End Day

6

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 6

Form: Biomarker-Plasma (Nic, Cot, tHCot) (4)

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05112520000371
----------------	----------------

Analyte	THCOT
---------	-------

Sample type	PLASMA
-------------	--------

Result	BLQ<(1.00)
--------	------------

Result Unit	NG/ML
-------------	-------

Lab Status	OTHER
------------	-------

Sample comment	ANALYZED IN ERROR
----------------	-------------------

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	6
--------------	---

Celerion Study Number	AA99128-10
-----------------------	------------

Date of Collection	2014-MAR-19
--------------------	-------------

Timepoint-minutes	0
-------------------	---

Urine Start Day	
-----------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 6

Form: Biomarker-Plasma (Nic, Cot, tHCot) (4)

Generated On: 20 Jul 2016 20:43:03

Urine End Day

6

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Discharge (Confinement)

Form: Date of Discharge

Data signed: (hfarmer1) 27 Mar 2015 14:51:43

Generated On: 20 Jul 2016 20:43:03

Date of Visit	19 MAR 2014 DD/MMM/YYYY
---------------	----------------------------

Discharge Time	10:49 hour:min 24-hour clock
----------------	---------------------------------

Is the subject continuing in the ambulatory period?	Yes <input type="radio"/>
---	---------------------------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Discharge (Confinement)

Form: Vital Signs

Data signed: (hfarmer1) 27 Mar 2015 14:51:43

Generated On: 20 Jul 2016 20:43:03

Were Vitals Signs assessed? Yes ☒

If No, please specify the reason: _____

Has the subject smoked within 15 minutes prior to assessment No ☒

Time of assessment 07:31
hour:min 24-hour clock

Pulse rate 50
beats per minute

Respiratory rate 16
breaths per minute

Blood Pressure (systolic) 118
mmHg

Blood Pressure (diastolic) 70
mmHg

Vital Signs Position of Subject Supine ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Discharge (Confinement)

Form: Advice on the risk of smoking and debriefing

Data signed: (hfarmer1) 27 Mar 2015 14:51:43

Generated On: 20 Jul 2016 20:43:03

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: 1202**

Folder: Discharge (Confinement)

Form: Physical Examination

Data signed: (hfarmer1) 27 Mar 2015 14:51:42

Generated On: 20 Jul 2016 20:43:03

Was the physical examination performed?

Yes ☒

If No, please specify the reason:

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Discharge (Confinement)

Form: Physical Examination (1)

Data signed: (hfarmer1) 27 Mar 2015 14:51:42

Generated On: 20 Jul 2016 20:43:03

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: 1202**

Folder: Discharge (Confinement)

Form: Physical Examination (2)

Data signed: (hfarmer1) 27 Mar 2015 14:51:42

Generated On: 20 Jul 2016 20:43:03

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: 1202**

Folder: Discharge (Confinement)

Form: Physical Examination (3)

Data signed: (hfarmer1) 27 Mar 2015 14:51:42

Generated On: 20 Jul 2016 20:43:03

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: 1202**

Folder: Discharge (Confinement)

Form: Physical Examination (4)

Data signed: (hfarmer1) 27 Mar 2015 14:51:42

Generated On: 20 Jul 2016 20:43:03

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: 1202**

Folder: Discharge (Confinement)

Form: Physical Examination (5)

Data signed: (hfarmer1) 27 Mar 2015 14:51:42

Generated On: 20 Jul 2016 20:43:03

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: 1202**

Folder: Discharge (Confinement)

Form: Physical Examination (6)

Data signed: (hfarmer1) 27 Mar 2015 14:51:42

Generated On: 20 Jul 2016 20:43:03

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: 1202**

Folder: Discharge (Confinement)

Form: Physical Examination (7)

Data signed: (hfarmer1) 27 Mar 2015 14:51:42

Generated On: 20 Jul 2016 20:43:03

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: 1202**

Folder: Discharge (Confinement)

Form: Physical Examination (8)

Data signed: (hfarmer1) 27 Mar 2015 14:51:42

Generated On: 20 Jul 2016 20:43:03

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: 1202**

Folder: Discharge (Confinement)

Form: Physical Examination (9)

Data signed: (hfarmer1) 27 Mar 2015 14:51:42

Generated On: 20 Jul 2016 20:43:03

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: 1202**

Folder: Discharge (Confinement)

Form: Physical Examination (10)

Data signed: (hfarmer1) 27 Mar 2015 14:51:42

Generated On: 20 Jul 2016 20:43:03

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: 1202**

Folder: Discharge (Confinement)

Form: Physical Examination (11)

Data signed: (hfarmer1) 27 Mar 2015 14:51:42

Generated On: 20 Jul 2016 20:43:03

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: 1202**

Folder: Discharge (Confinement)

Form: Physical Examination (12)

Data signed: (hfarmer1) 27 Mar 2015 14:51:42

Generated On: 20 Jul 2016 20:43:03

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

System Musculoskeletal ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Discharge (Confinement)

Form: Physical Examination (13)

Data signed: (hfarmer1) 27 Mar 2015 14:51:42

Generated On: 20 Jul 2016 20:43:03

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: 1202**

Folder: Discharge (Confinement)

Form: Physical Examination (14)

Data signed: (hfarmer1) 27 Mar 2015 14:51:42

Generated On: 20 Jul 2016 20:43:03

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: 1202**

Folder: Discharge (Confinement)

Form: Physical Examination (15)

Data signed: (hfarmer1) 27 Mar 2015 14:51:42

Generated On: 20 Jul 2016 20:43:03

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: 1202**

Folder: Discharge (Confinement)

Form: Physical Examination (16)

Data signed: (hfarmer1) 27 Mar 2015 14:51:42

Generated On: 20 Jul 2016 20:43:03

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: 1202**

Folder: Discharge (Confinement)

Form: Physical Examination (17)

Data signed: (hfarmer1) 27 Mar 2015 14:51:42

Generated On: 20 Jul 2016 20:43:03

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: 1202**

Folder: Discharge (Confinement)

Form: Physical Examination (18)

Data signed: (hfarmer1) 27 Mar 2015 14:51:42

Generated On: 20 Jul 2016 20:43:03

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: 1202**

Folder: Discharge (Confinement)

Form: Physical Examination (19)

Data signed: (hfarmer1) 27 Mar 2015 14:51:42

Generated On: 20 Jul 2016 20:43:03

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: 1202**

Folder: Discharge (Confinement)

Form: Weight

Data signed: (hfarmer1) 27 Mar 2015 14:51:43

Generated On: 20 Jul 2016 20:43:03

Measurement(s) assessed?

Yes ☒

If No, please specify the reason: _____

Date of Assessment

19 MAR 2014
DD/MMM/YYYY

Time of assessment

09:45
hour:min 24-hour clock

Weight

73.1
kg

BMI

24.1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Discharge (Confinement)

Form: ECG (12-Lead Standard)

Data signed: (hfarmer1) 27 Mar 2015 14:51:42

Generated On: 20 Jul 2016 20:43:03

Was the ECG performed? Yes ☒

If No, please specify the reason: _____

Position Supine ☒

Heart Rate 50
beats per minute

QRS Interval 118
msec

QT Interval 433
msec

QTcB Interval 397
msec

PR Interval 158
msec

QTcF Interval 409
msec

Interpretation Abnormal ☒

If Abnormal, Clinical Significance Not clinically significant ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Discharge (Confinement)

Form: ECG (12-Lead Standard)

Data signed: (hfarmer1) 27 Mar 2015 14:51:42

Generated On: 20 Jul 2016 20:43:03

If Not Clinically significant or clinically Significant, Please specify the finding(s)	SINUS BRADYCARDIA WITH INTRAVENTRICULAR CONDUCTION DELAY
---	--

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1202

Folder: Discharge (Confinement)

Form: Gas Transfer

Data signed: (hfarmer1) 27 Mar 2015 14:51:43

Generated On: 20 Jul 2016 20:43:03

Was the Gas Transfer performed?

Yes ☒

If No, please specify the reason: _____

Category _____

Position

SITTING

Date of assessment
DD/MMM/YYYY

19 MAR 2014

Time of assessment

09:12

DLCO value

27.58
ml/min/mmHg

KCO value

1.37
mmol/min/kPa/L

DLCO/VA value

4.03
mL/min/mmHg/L

Interpretation

Normal ☒

If Abnormal, Clinical Significance _____

If Not Clinically Significant or Clinically Significant, Please
specify the finding(s) _____

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1202

Folder: Discharge (Confinement)

Form: Lung Volume Measurements

Data signed: (hfarmer1) 27 Mar 2015 14:51:43

Generated On: 20 Jul 2016 20:43:03

Were the Lung Volume Measurements performed? Yes ☒

If No, please specify the reason: _____

Category _____

Position SITTING

Date of assessment 19 MAR 2014
DD/MMM/YYYY

Time of assessment 09:23

VC value 5.07
L

TLC value 6.92
L

IC value 3.69
L

FRC value 3.23
L

Interpretation Normal ☒

If Abnormal, Clinical Significance _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Discharge (Confinement)

Form: Lung Volume Measurements

Data signed: (hfarmer1) 27 Mar 2015 14:51:43

Generated On: 20 Jul 2016 20:43:03

If Not Clinically Significant or Clinically Significant, Please
specify the finding(s) _____

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1202

Folder: Discharge (Confinement)

Form: Spirometry with a short-acting bronchodilator

Data signed: (hfarmer1) 27 Mar 2015 14:51:43

Generated On: 20 Jul 2016 20:43:03

Was the Spirometry with a short-acting bronchodilator performed?

Yes ☒

If No, please specify the reason: _____

Category

With short-acting
bronchodilator ☒

Position

SITTING

Date of assessment
DD/MMM/YYYY

19 MAR 2014

Time of assessment

09:55

Name of bronchodilator

ALBUTEROL SULFATE

Dose

180 MCG

Predicted FVC value

5.13
L

Best measured FVC value

5.07
L

Percent of predicted FVC value

98
%

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1202

Folder: Discharge (Confinement)

Form: Spirometry with a short-acting bronchodilator

Data signed: (hfarmer1) 27 Mar 2015 14:51:43

Generated On: 20 Jul 2016 20:43:03

Best measured FEV1 value	3.95 L
--------------------------	-----------

Predicted FEV1 value	4.14 L
----------------------	-----------

Percent of predicted FEV1 value	95 %
---------------------------------	---------

Calculated ratio between FEV1/FVC	_____
-----------------------------------	-------

MEF 25/75 value	3.35 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: 1202**

Folder: Discharge (Confinement)

Form: Haematology

Data signed: (hfarmer1) 27 Mar 2015 14:51:42

Generated On: 20 Jul 2016 20:43:03

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: 1202**

Folder: Discharge (Confinement)

Form: Clinical Chemistry

Data signed: (hfarmer1) 27 Mar 2015 14:51:42

Generated On: 20 Jul 2016 20:43:03

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: 1202**

Folder: Discharge (Confinement)

Form: Urine analysis

Data signed: (hfarmer1) 27 Mar 2015 14:51:42

Generated On: 20 Jul 2016 20:43:03

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: 1202**

Folder: Discharge (Confinement)

Form: CO Breath Test

Data signed: (hfarmer1) 27 Mar 2015 14:51:42

Generated On: 20 Jul 2016 20:43:03

Assessment not done	False
---------------------	-------

If Not Done, please specify the reason: _____

Actual Time of Assessment	07:34
	hour:min 24-hour clock

Result	2
	ppm

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (1)

Data signed: (hfarmer1) 27 Mar 2015 14:51:44

Generated On: 20 Jul 2016 20:43:03

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	<hr/>
----------------------	-------

Subject Sex	M
-------------	---

Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	W816760
--------------	---------

Actual Collection Date	2014 03 19
------------------------	------------

Actual Collection Time	07:01
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	RC1029
------------	--------

Battery Name	TRIGLYCERIDES
--------------	---------------

Lab Test ID	RCT19
-------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (1)

Data signed: (hfarmer1) 27 Mar 2015 14:51:44

Generated On: 20 Jul 2016 20:43:03

Lab Test Name	TRIGLYCERIDES (GPO)
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	120
Reported Numeric Result	120
Reference Range low	50
Reference Range high	321
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: 1202**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (1)

Data signed: (hfarmer1) 27 Mar 2015 14:51:44

Generated On: 20 Jul 2016 20:43:03

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (2)

Data signed: (hfarmer1) 27 Mar 2015 14:51:44

Generated On: 20 Jul 2016 20:43:03

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	<hr/>
----------------------	-------

Subject Sex	M
-------------	---

Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	W816760
--------------	---------

Actual Collection Date	2014 03 19
------------------------	------------

Actual Collection Time	07:01
------------------------	-------

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: 1202

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (2)

Data signed: (hfarmer1) 27 Mar 2015 14:51:44

Generated On: 20 Jul 2016 20:43:03

Lab Test Name	FASTING GLUCOSE
Test ID	
Test Status	Done <input checked="" 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: 1202**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (2)

Data signed: (hfarmer1) 27 Mar 2015 14:51:44

Generated On: 20 Jul 2016 20:43:03

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (3)

Data signed: (hfarmer1) 27 Mar 2015 14:51:44

Generated On: 20 Jul 2016 20:43:03

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	<hr/>
----------------------	-------

Subject Sex	M
-------------	---

Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	W816760
--------------	---------

Actual Collection Date	2014 03 19
------------------------	------------

Actual Collection Time	07:01
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	RC272
------------	-------

Battery Name	TOTAL CHOLESTEROL
--------------	-------------------

Lab Test ID	RCT20
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (3)

Data signed: (hfarmer1) 27 Mar 2015 14:51:44

Generated On: 20 Jul 2016 20:43:03

Lab Test Name	CHOLESTEROL (HIGH PERFORMANCE)
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	201
Reported Numeric Result	201
Reference Range low	150
Reference Range high	264
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: 1202**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (3)

Data signed: (hfarmer1) 27 Mar 2015 14:51:44

Generated On: 20 Jul 2016 20:43:03

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: 1202**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (4)

Data signed: (hfarmer1) 27 Mar 2015 14:51:44

Generated On: 20 Jul 2016 20:43:03

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6)

Visit Name _____

Visit Type Scheduled ☒

Accession ID W816760

Actual Collection Date 2014 03 19

Actual Collection Time 07:01

Specimen Condition _____

Battery ID RC9255

Battery Name CHEMISTRY PANEL

Lab Test ID RCT1

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1202

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (4)

Data signed: (hfarmer1) 27 Mar 2015 14:51:44

Generated On: 20 Jul 2016 20:43:03

Lab Test Name	TOTAL BILIRUBIN
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	1.1
Reported Numeric Result	1.1
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: 1202**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (4)

Data signed: (hfarmer1) 27 Mar 2015 14:51:44

Generated On: 20 Jul 2016 20:43:03

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (5)

Data signed: (hfarmer1) 27 Mar 2015 14:51:44

Generated On: 20 Jul 2016 20:43:03

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6)

Visit Name _____

Visit Type Scheduled ☒

Accession ID W816760

Actual Collection Date 2014 03 19

Actual Collection Time 07:01

Specimen Condition _____

Battery ID RC9255

Battery Name CHEMISTRY PANEL

Lab Test ID RCT12

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (5)

Data signed: (hfarmer1) 27 Mar 2015 14:51:44

Generated On: 20 Jul 2016 20:43:03

Lab Test Name	TOTAL PROTEIN
Test ID	
Test Status	Done <input type="checkbox"/>
Reported Text Result	7.3
Reported Numeric Result	7.3
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: 1202**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (5)

Data signed: (hfarmer1) 27 Mar 2015 14:51:44

Generated On: 20 Jul 2016 20:43:03

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (6)

Data signed: (hfarmer1) 27 Mar 2015 14:51:44

Generated On: 20 Jul 2016 20:43:03

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6)

Visit Name _____

Visit Type Scheduled ☒

Accession ID W816760

Actual Collection Date 2014 03 19

Actual Collection Time 07:01

Specimen Condition _____

Battery ID RC9255

Battery Name CHEMISTRY PANEL

Lab Test ID RCT13

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (6)

Data signed: (hfarmer1) 27 Mar 2015 14:51:44

Generated On: 20 Jul 2016 20:43:03

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: 1202**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (6)

Data signed: (hfarmer1) 27 Mar 2015 14:51:44

Generated On: 20 Jul 2016 20:43:03

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (7)

Data signed: (hfarmer1) 27 Mar 2015 14:51:44

Generated On: 20 Jul 2016 20:43:03

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
----------------------	-------

Subject Sex	M
-------------	---

Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	W816760
--------------	---------

Actual Collection Date	2014 03 19
------------------------	------------

Actual Collection Time	07:01
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	RC9255
------------	--------

Battery Name	CHEMISTRY PANEL
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Lab Test ID	RCT1407
-------------	---------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1202

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (7)

Data signed: (hfarmer1) 27 Mar 2015 14:51:44

Generated On: 20 Jul 2016 20:43:03

Lab Test Name	ALKALINE PHOSPHATASE
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	70
Reported Numeric Result	70
Reference Range low	31
Reference Range high	129
Range Units	U/L
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (7)

Data signed: (hfarmer1) 27 Mar 2015 14:51:44

Generated On: 20 Jul 2016 20:43:03

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (8)

Data signed: (hfarmer1) 27 Mar 2015 14:51:44

Generated On: 20 Jul 2016 20:43:03

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	<hr/>
----------------------	-------

Subject Sex	M
-------------	---

Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	W816760
--------------	---------

Actual Collection Date	2014 03 19
------------------------	------------

Actual Collection Time	07:01
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	RC9255
------------	--------

Battery Name	CHEMISTRY PANEL
--------------	-----------------

Lab Test ID	RCT1408
-------------	---------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1202

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (8)

Data signed: (hfarmer1) 27 Mar 2015 14:51:44

Generated On: 20 Jul 2016 20:43:03

Lab Test Name	LDH
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	109
Reported Numeric Result	109
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: 1202**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (8)

Data signed: (hfarmer1) 27 Mar 2015 14:51:44

Generated On: 20 Jul 2016 20:43:03

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (9)

Data signed: (hfarmer1) 27 Mar 2015 14:51:44

Generated On: 20 Jul 2016 20:43:03

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	M
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Subject Date of Birth	(b) (6)
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	W816760
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Actual Collection Date	2014 03 19
------------------------	------------

Actual Collection Time	07:01
------------------------	-------

Specimen Condition	<hr/>
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Battery ID	RC9255
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Battery Name	CHEMISTRY PANEL
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Lab Test ID	RCT15
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1202

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (9)

Data signed: (hfarmer1) 27 Mar 2015 14:51:44

Generated On: 20 Jul 2016 20:43:03

Lab Test Name	SERUM SODIUM
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	139
Reported Numeric Result	139
Reference Range low	132
Reference Range high	147
Range Units	MEQ/L
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (9)

Data signed: (hfarmer1) 27 Mar 2015 14:51:44

Generated On: 20 Jul 2016 20:43:03

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (10)

Data signed: (hfarmer1) 27 Mar 2015 14:51:44

Generated On: 20 Jul 2016 20:43:03

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	M
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Subject Date of Birth	(b) (6)
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	W816760
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Actual Collection Date	2014 03 19
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Actual Collection Time	07:01
------------------------	-------

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: 1202

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (10)

Data signed: (hfarmer1) 27 Mar 2015 14:51:44

Generated On: 20 Jul 2016 20:43:03

Lab Test Name	SERUM POTASSIUM
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	3.9
Reported Numeric Result	3.9
Reference Range low	3.4
Reference Range high	5.4
Range Units	MEQ/L
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (10)

Data signed: (hfarmer1) 27 Mar 2015 14:51:44

Generated On: 20 Jul 2016 20:43:03

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (11)

Data signed: (hfarmer1) 27 Mar 2015 14:51:44

Generated On: 20 Jul 2016 20:43:03

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	M
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Subject Date of Birth	(b) (6)
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	W816760
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Actual Collection Date	2014 03 19
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Actual Collection Time	07:01
------------------------	-------

Specimen Condition	<hr/>
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Battery ID	RC9255
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Battery Name	CHEMISTRY PANEL
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Lab Test ID	RCT29
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1202

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (11)

Data signed: (hfarmer1) 27 Mar 2015 14:51:44

Generated On: 20 Jul 2016 20:43:03

Lab Test Name	DIRECT BILIRUBIN
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	0.2
Reported Numeric Result	0.2
Reference Range low	0.0
Reference Range high	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: 1202**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (11)

Data signed: (hfarmer1) 27 Mar 2015 14:51:44

Generated On: 20 Jul 2016 20:43:03

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (12)

Data signed: (hfarmer1) 27 Mar 2015 14:51:44

Generated On: 20 Jul 2016 20:43:03

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	M
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Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	W816760
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Actual Collection Date	2014 03 19
------------------------	------------

Actual Collection Time	07:01
------------------------	-------

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: 1202

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (12)

Data signed: (hfarmer1) 27 Mar 2015 14:51:44

Generated On: 20 Jul 2016 20:43:03

Lab Test Name	GGT
Test ID	
Test Status	Done <input type="checkbox"/>
Reported Text Result	27
Reported Numeric Result	27
Reference Range low	10
Reference Range high	61
Range Units	U/L
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (12)

Data signed: (hfarmer1) 27 Mar 2015 14:51:44

Generated On: 20 Jul 2016 20:43:03

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (13)

Data signed: (hfarmer1) 27 Mar 2015 14:51:44

Generated On: 20 Jul 2016 20:43:03

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	M
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Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	W816760
--------------	---------

Actual Collection Date	2014 03 19
------------------------	------------

Actual Collection Time	07:01
------------------------	-------

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: 1202**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (13)

Data signed: (hfarmer1) 27 Mar 2015 14:51:44

Generated On: 20 Jul 2016 20:43:03

Lab Test Name	CREATININE (RATE BLANKED)
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Test ID	<hr/>
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Test Status	Done <input checked="" type="radio"/>
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Reported Text Result	1.0
----------------------	-----

Reported Numeric Result	1.0
-------------------------	-----

Reference Range low	0.5
---------------------	-----

Reference Range high	1.2
----------------------	-----

Range Units	MG/DL
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Conventional Text Result	<hr/>
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Conventional Numeric Result	<hr/>
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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: 1202**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (13)

Data signed: (hfarmer1) 27 Mar 2015 14:51:44

Generated On: 20 Jul 2016 20:43:03

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (14)

Data signed: (hfarmer1) 27 Mar 2015 14:51:44

Generated On: 20 Jul 2016 20:43:03

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	M
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Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	W816760
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Actual Collection Date	2014 03 19
------------------------	------------

Actual Collection Time	07:01
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Specimen Condition	<hr/>
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Battery ID	RC9255
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Battery Name	CHEMISTRY PANEL
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Lab Test ID	RCT4
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1202

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (14)

Data signed: (hfarmer1) 27 Mar 2015 14:51:44

Generated On: 20 Jul 2016 20:43:03

Lab Test Name	ALT (SGPT)
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	16
Reported Numeric Result	16
Reference Range low	6
Reference Range high	43
Range Units	U/L
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (14)

Data signed: (hfarmer1) 27 Mar 2015 14:51:44

Generated On: 20 Jul 2016 20:43:03

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (15)

Data signed: (hfarmer1) 27 Mar 2015 14:51:44

Generated On: 20 Jul 2016 20:43:03

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	M
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Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	W816760
--------------	---------

Actual Collection Date	2014 03 19
------------------------	------------

Actual Collection Time	07:01
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	RC9255
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Battery Name	CHEMISTRY PANEL
--------------	-----------------

Lab Test ID	RCT5
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (15)

Data signed: (hfarmer1) 27 Mar 2015 14:51:44

Generated On: 20 Jul 2016 20:43:03

Lab Test Name	AST (SGOT)
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	21
Reported Numeric Result	21
Reference Range low	11
Reference Range high	36
Range Units	U/L
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (15)

Data signed: (hfarmer1) 27 Mar 2015 14:51:44

Generated On: 20 Jul 2016 20:43:03

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (16)

Data signed: (hfarmer1) 27 Mar 2015 14:51:44

Generated On: 20 Jul 2016 20:43:03

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	M
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Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	W816760
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Actual Collection Date	2014 03 19
------------------------	------------

Actual Collection Time	07:01
------------------------	-------

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: 1202

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (16)

Data signed: (hfarmer1) 27 Mar 2015 14:51:44

Generated On: 20 Jul 2016 20:43:03

Lab Test Name	UREA NITROGEN
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	15
Reported Numeric Result	15
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: 1202**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (16)

Data signed: (hfarmer1) 27 Mar 2015 14:51:44

Generated On: 20 Jul 2016 20:43:03

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (17)

Data signed: (hfarmer1) 27 Mar 2015 14:51:44

Generated On: 20 Jul 2016 20:43:03

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
----------------------	-------

Subject Sex	M
-------------	---

Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	W816760
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Actual Collection Date	2014 03 19
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Actual Collection Time	07:01
------------------------	-------

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: 1202**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (17)

Data signed: (hfarmer1) 27 Mar 2015 14:51:44

Generated On: 20 Jul 2016 20:43:03

Lab Test Name	MONOCYTES
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	0.75
Reported Numeric Result	0.75
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: 1202**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (17)

Data signed: (hfarmer1) 27 Mar 2015 14:51:44

Generated On: 20 Jul 2016 20:43:03

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1202

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (18)

Data signed: (hfarmer1) 27 Mar 2015 14:51:44

Generated On: 20 Jul 2016 20:43:03

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
----------------------	-------

Subject Sex	M
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Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	W816760
--------------	---------

Actual Collection Date	2014 03 19
------------------------	------------

Actual Collection Time	07:01
------------------------	-------

Specimen Condition	<hr/>
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Battery ID	HM1604
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Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
--------------	-----------------------------------

Lab Test ID	HMT100
-------------	--------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1202

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (18)

Data signed: (hfarmer1) 27 Mar 2015 14:51:44

Generated On: 20 Jul 2016 20:43:03

Lab Test Name	MCH
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	26
Reported Numeric Result	26
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: 1202**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (18)

Data signed: (hfarmer1) 27 Mar 2015 14:51:44

Generated On: 20 Jul 2016 20:43:03

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (19)

Data signed: (hfarmer1) 27 Mar 2015 14:51:44

Generated On: 20 Jul 2016 20:43:03

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	M
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Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	W816760
--------------	---------

Actual Collection Date	2014 03 19
------------------------	------------

Actual Collection Time	07:01
------------------------	-------

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: 1202**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (19)

Data signed: (hfarmer1) 27 Mar 2015 14:51:44

Generated On: 20 Jul 2016 20:43:03

Lab Test Name	MCHC
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	32
Reported Numeric Result	32
Reference Range low	31
Reference Range high	38
Range Units	G/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (19)

Data signed: (hfarmer1) 27 Mar 2015 14:51:44

Generated On: 20 Jul 2016 20:43:03

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (20)

Data signed: (hfarmer1) 27 Mar 2015 14:51:44

Generated On: 20 Jul 2016 20:43:03

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	M
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Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	W816760
--------------	---------

Actual Collection Date	2014 03 19
------------------------	------------

Actual Collection Time	07:01
------------------------	-------

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: 1202

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (20)

Data signed: (hfarmer1) 27 Mar 2015 14:51:44

Generated On: 20 Jul 2016 20:43:03

Lab Test Name	EOSINOPHILS
Test ID	
Test Status	Done <input checked="" type="checkbox"/>
Reported Text Result	0.10
Reported Numeric Result	0.10
Reference Range low	0.00
Reference Range high	0.57
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: 1202**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (20)

Data signed: (hfarmer1) 27 Mar 2015 14:51:44

Generated On: 20 Jul 2016 20:43:03

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (21)

Data signed: (hfarmer1) 27 Mar 2015 14:51:44

Generated On: 20 Jul 2016 20:43:03

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	M
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Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	W816760
--------------	---------

Actual Collection Date	2014 03 19
------------------------	------------

Actual Collection Time	07:01
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	HM1604
------------	--------

Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
--------------	-----------------------------------

Lab Test ID	HMT12
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1202

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (21)

Data signed: (hfarmer1) 27 Mar 2015 14:51:44

Generated On: 20 Jul 2016 20:43:03

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: 1202**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (21)

Data signed: (hfarmer1) 27 Mar 2015 14:51:44

Generated On: 20 Jul 2016 20:43:03

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (22)

Data signed: (hfarmer1) 27 Mar 2015 14:51:44

Generated On: 20 Jul 2016 20:43:03

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	M
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Subject Date of Birth	(b) (6)
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	W816760
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Actual Collection Date	2014 03 19
------------------------	------------

Actual Collection Time	07:01
------------------------	-------

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: 1202**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (22)

Data signed: (hfarmer1) 27 Mar 2015 14:51:44

Generated On: 20 Jul 2016 20:43:03

Lab Test Name	PLATELETS
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	313
Reported Numeric Result	313
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: 1202**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (22)

Data signed: (hfarmer1) 27 Mar 2015 14:51:44

Generated On: 20 Jul 2016 20:43:03

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1202

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (23)

Data signed: (hfarmer1) 27 Mar 2015 14:51:44

Generated On: 20 Jul 2016 20:43:03

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	M
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Subject Date of Birth	(b) (6)
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	W816760
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Actual Collection Date	2014 03 19
------------------------	------------

Actual Collection Time	07:01
------------------------	-------

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: 1202

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (23)

Data signed: (hfarmer1) 27 Mar 2015 14:51:44

Generated On: 20 Jul 2016 20:43:03

Lab Test Name	NEUTROPHILS (%)
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	51.9
Reported Numeric Result	51.9
Reference Range low	40.5
Reference Range high	75.0
Range Units	%
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (23)

Data signed: (hfarmer1) 27 Mar 2015 14:51:44

Generated On: 20 Jul 2016 20:43:03

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (24)

Data signed: (hfarmer1) 27 Mar 2015 14:51:44

Generated On: 20 Jul 2016 20:43:03

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	M
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Subject Date of Birth	(b) (6)
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	W816760
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Actual Collection Date	2014 03 19
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Actual Collection Time	07:01
------------------------	-------

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: 1202

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (24)

Data signed: (hfarmer1) 27 Mar 2015 14:51:44

Generated On: 20 Jul 2016 20:43:03

Lab Test Name	LYMPHOCYTES (%)
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	36.5
Reported Numeric Result	36.5
Reference Range low	15.4
Reference Range high	48.5
Range Units	%
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (24)

Data signed: (hfarmer1) 27 Mar 2015 14:51:44

Generated On: 20 Jul 2016 20:43:03

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (25)

Data signed: (hfarmer1) 27 Mar 2015 14:51:44

Generated On: 20 Jul 2016 20:43:03

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	M
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Subject Date of Birth	(b) (6)
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	W816760
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Actual Collection Date	2014 03 19
------------------------	------------

Actual Collection Time	07:01
------------------------	-------

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: 1202

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (25)

Data signed: (hfarmer1) 27 Mar 2015 14:51:44

Generated On: 20 Jul 2016 20:43:03

Lab Test Name	MONOCYTES (%)
Test ID	
Test Status	Done <input checked="" type="checkbox"/>
Reported Text Result	9.8
Reported Numeric Result	9.8
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: 1202**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (25)

Data signed: (hfarmer1) 27 Mar 2015 14:51:44

Generated On: 20 Jul 2016 20:43:03

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1202

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (26)

Data signed: (hfarmer1) 27 Mar 2015 14:51:44

Generated On: 20 Jul 2016 20:43:03

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	M
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Subject Date of Birth	(b) (6)
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	W816760
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Actual Collection Date	2014 03 19
------------------------	------------

Actual Collection Time	07:01
------------------------	-------

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: 1202

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (26)

Data signed: (hfarmer1) 27 Mar 2015 14:51:44

Generated On: 20 Jul 2016 20:43:03

Lab Test Name	EOSINOPHILS (%)
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	1.3
Reported Numeric Result	1.3
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: 1202**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (26)

Data signed: (hfarmer1) 27 Mar 2015 14:51:44

Generated On: 20 Jul 2016 20:43:03

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1202

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (27)

Data signed: (hfarmer1) 27 Mar 2015 14:51:44

Generated On: 20 Jul 2016 20:43:03

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	M
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Subject Date of Birth	(b) (6)
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	W816760
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Actual Collection Date	2014 03 19
------------------------	------------

Actual Collection Time	07:01
------------------------	-------

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: 1202

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (27)

Data signed: (hfarmer1) 27 Mar 2015 14:51:44

Generated On: 20 Jul 2016 20:43:03

Lab Test Name	BASOPHILS (%)
Test ID	
Test Status	Done <input 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: 1202**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (27)

Data signed: (hfarmer1) 27 Mar 2015 14:51:44

Generated On: 20 Jul 2016 20:43:03

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1202

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (28)

Data signed: (hfarmer1) 27 Mar 2015 14:51:44

Generated On: 20 Jul 2016 20:43:03

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	M
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Subject Date of Birth	(b) (6)
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	W816760
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Actual Collection Date	2014 03 19
------------------------	------------

Actual Collection Time	07:01
------------------------	-------

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: 1202

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (28)

Data signed: (hfarmer1) 27 Mar 2015 14:51:44

Generated On: 20 Jul 2016 20:43:03

Lab Test Name	HEMATOCRIT
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	45
Reported Numeric Result	45
Reference Range low	39
Reference Range high	54
Range Units	%
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (28)

Data signed: (hfarmer1) 27 Mar 2015 14:51:44

Generated On: 20 Jul 2016 20:43:03

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1202

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (29)

Data signed: (hfarmer1) 27 Mar 2015 14:51:44

Generated On: 20 Jul 2016 20:43:03

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	M
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Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	W816760
--------------	---------

Actual Collection Date	2014 03 19
------------------------	------------

Actual Collection Time	07:01
------------------------	-------

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: 1202

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (29)

Data signed: (hfarmer1) 27 Mar 2015 14:51:44

Generated On: 20 Jul 2016 20:43:03

Lab Test Name	RBC
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	5.5
Reported Numeric Result	5.5
Reference Range low	4.5
Reference Range high	6.4
Range Units	X10^6/UL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (29)

Data signed: (hfarmer1) 27 Mar 2015 14:51:44

Generated On: 20 Jul 2016 20:43:03

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (30)

Data signed: (hfarmer1) 27 Mar 2015 14:51:44

Generated On: 20 Jul 2016 20:43:03

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
----------------------	-------

Subject Sex	M
-------------	---

Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	W816760
--------------	---------

Actual Collection Date	2014 03 19
------------------------	------------

Actual Collection Time	07:01
------------------------	-------

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: 1202

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (30)

Data signed: (hfarmer1) 27 Mar 2015 14:51:44

Generated On: 20 Jul 2016 20:43:03

Lab Test Name	MCV
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	82
Reported Numeric Result	82
Reference Range low	79
Reference Range high	96
Range Units	FL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (30)

Data signed: (hfarmer1) 27 Mar 2015 14:51:44

Generated On: 20 Jul 2016 20:43:03

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (31)

Data signed: (hfarmer1) 27 Mar 2015 14:51:44

Generated On: 20 Jul 2016 20:43:03

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
----------------------	-------

Subject Sex	M
-------------	---

Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	W816760
--------------	---------

Actual Collection Date	2014 03 19
------------------------	------------

Actual Collection Time	07:01
------------------------	-------

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: 1202**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (31)

Data signed: (hfarmer1) 27 Mar 2015 14:51:44

Generated On: 20 Jul 2016 20:43:03

Lab Test Name	HEMOGLOBIN
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	14.6
Reported Numeric Result	14.6
Reference Range low	12.7
Reference Range high	18.1
Range Units	G/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (31)

Data signed: (hfarmer1) 27 Mar 2015 14:51:44

Generated On: 20 Jul 2016 20:43:03

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (32)

Data signed: (hfarmer1) 27 Mar 2015 14:51:44

Generated On: 20 Jul 2016 20:43:03

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	<hr/>
----------------------	-------

Subject Sex	M
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Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	W816760
--------------	---------

Actual Collection Date	2014 03 19
------------------------	------------

Actual Collection Time	07:01
------------------------	-------

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: 1202**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (32)

Data signed: (hfarmer1) 27 Mar 2015 14:51:44

Generated On: 20 Jul 2016 20:43:03

Lab Test Name	WBC
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	7.72
Reported Numeric Result	7.72
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: 1202**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (32)

Data signed: (hfarmer1) 27 Mar 2015 14:51:44

Generated On: 20 Jul 2016 20:43:03

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (33)

Data signed: (hfarmer1) 27 Mar 2015 14:51:44

Generated On: 20 Jul 2016 20:43:03

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	M
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Subject Date of Birth	(b) (6)
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	W816760
--------------	---------

Actual Collection Date	2014 03 19
------------------------	------------

Actual Collection Time	07:01
------------------------	-------

Specimen Condition	<hr/>
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Battery ID	HM1604
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Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
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Lab Test ID	HMT71
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1202

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (33)

Data signed: (hfarmer1) 27 Mar 2015 14:51:44


Generated On: 20 Jul 2016 20:43:03

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: 1202**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (33)

Data signed: (hfarmer1) 27 Mar 2015 14:51:44

Generated On: 20 Jul 2016 20:43:03

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (34)

Data signed: (hfarmer1) 27 Mar 2015 14:51:44

Generated On: 20 Jul 2016 20:43:03

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	<hr/>
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Subject Sex	M
-------------	---

Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	W816760
--------------	---------

Actual Collection Date	2014 03 19
------------------------	------------

Actual Collection Time	07:01
------------------------	-------

Specimen Condition	<hr/>
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Battery ID	HM1604
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Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
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Lab Test ID	HMT8
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (34)

Data signed: (hfarmer1) 27 Mar 2015 14:51:44

Generated On: 20 Jul 2016 20:43:03

Lab Test Name	NEUTROPHILS
Test ID	
Test Status	Done <input type="checkbox"/>
Reported Text Result	4.01
Reported Numeric Result	4.01
Reference Range low	1.96
Reference Range high	7.23
Range Units	X10^3/UL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (34)

Data signed: (hfarmer1) 27 Mar 2015 14:51:44

Generated On: 20 Jul 2016 20:43:03

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1202

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (35)

Data signed: (hfarmer1) 27 Mar 2015 14:51:44

Generated On: 20 Jul 2016 20:43:03

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	<hr/>
----------------------	-------

Subject Sex	M
-------------	---

Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	W816760
--------------	---------

Actual Collection Date	2014 03 19
------------------------	------------

Actual Collection Time	07:01
------------------------	-------

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: 1202**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (35)

Data signed: (hfarmer1) 27 Mar 2015 14:51:44

Generated On: 20 Jul 2016 20:43:03

Lab Test Name	LYMPHOCYTES
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	2.82
Reported Numeric Result	2.82
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: 1202**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (35)

Data signed: (hfarmer1) 27 Mar 2015 14:51:44

Generated On: 20 Jul 2016 20:43:03

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (36)

Data signed: (hfarmer1) 27 Mar 2015 14:51:44

Generated On: 20 Jul 2016 20:43:03

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	<hr/>
----------------------	-------

Subject Sex	M
-------------	---

Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	W816760
--------------	---------

Actual Collection Date	2014 03 19
------------------------	------------

Actual Collection Time	07:01
------------------------	-------

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: 1202

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (36)

Data signed: (hfarmer1) 27 Mar 2015 14:51:44


Generated On: 20 Jul 2016 20:43:03

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: 1202**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (36)

Data signed: (hfarmer1) 27 Mar 2015 14:51:44

Generated On: 20 Jul 2016 20:43:03

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (37)

Data signed: (hfarmer1) 27 Mar 2015 14:51:44

Generated On: 20 Jul 2016 20:43:03

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	<hr/>
----------------------	-------

Subject Sex	M
-------------	---

Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	W816760
--------------	---------

Actual Collection Date	2014 03 19
------------------------	------------

Actual Collection Time	07:01
------------------------	-------

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: 1202

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (37)

Data signed: (hfarmer1) 27 Mar 2015 14:51:44

Generated On: 20 Jul 2016 20:43:03

Lab Test Name	UR SPECIFIC GRAVITY
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	1.004
Reported Numeric Result	1.004
Reference Range low	1.003
Reference Range high	1.035
Range Units	
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (37)

Data signed: (hfarmer1) 27 Mar 2015 14:51:44

Generated On: 20 Jul 2016 20:43:03

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (38)

Data signed: (hfarmer1) 27 Mar 2015 14:51:44

Generated On: 20 Jul 2016 20:43:03

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	<hr/>
----------------------	-------

Subject Sex	M
-------------	---

Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	W816760
--------------	---------

Actual Collection Date	2014 03 19
------------------------	------------

Actual Collection Time	07:01
------------------------	-------

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: 1202

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (38)

Data signed: (hfarmer1) 27 Mar 2015 14:51:44

Generated On: 20 Jul 2016 20:43:03

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: 1202**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (38)

Data signed: (hfarmer1) 27 Mar 2015 14:51:44

Generated On: 20 Jul 2016 20:43:03

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (39)

Data signed: (hfarmer1) 27 Mar 2015 14:51:44

Generated On: 20 Jul 2016 20:43:03

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	<hr/>
----------------------	-------

Subject Sex	M
-------------	---

Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	W816760
--------------	---------

Actual Collection Date	2014 03 19
------------------------	------------

Actual Collection Time	07:01
------------------------	-------

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: 1202**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (39)

Data signed: (hfarmer1) 27 Mar 2015 14:51:44


Generated On: 20 Jul 2016 20:43:03

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: 1202**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (39)

Data signed: (hfarmer1) 27 Mar 2015 14:51:44

Generated On: 20 Jul 2016 20:43:03

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (40)

Data signed: (hfarmer1) 27 Mar 2015 14:51:44

Generated On: 20 Jul 2016 20:43:03

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	<hr/>
----------------------	-------

Subject Sex	M
-------------	---

Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	W816760
--------------	---------

Actual Collection Date	2014 03 19
------------------------	------------

Actual Collection Time	07:01
------------------------	-------

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: 1202

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (40)

Data signed: (hfarmer1) 27 Mar 2015 14:51:44


Generated On: 20 Jul 2016 20:43:03

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: 1202**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (40)

Data signed: (hfarmer1) 27 Mar 2015 14:51:44

Generated On: 20 Jul 2016 20:43:03

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1202

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (41)

Data signed: (hfarmer1) 27 Mar 2015 14:51:44

Generated On: 20 Jul 2016 20:43:03

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	<hr/>
----------------------	-------

Subject Sex	M
-------------	---

Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	W816760
--------------	---------

Actual Collection Date	2014 03 19
------------------------	------------

Actual Collection Time	07:01
------------------------	-------

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: 1202

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (41)

Data signed: (hfarmer1) 27 Mar 2015 14:51:44


Generated On: 20 Jul 2016 20:43:03

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: 1202**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (41)

Data signed: (hfarmer1) 27 Mar 2015 14:51:44

Generated On: 20 Jul 2016 20:43:03

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (42)

Data signed: (hfarmer1) 27 Mar 2015 14:51:44

Generated On: 20 Jul 2016 20:43:03

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	<hr/>
----------------------	-------

Subject Sex	M
-------------	---

Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	W816760
--------------	---------

Actual Collection Date	2014 03 19
------------------------	------------

Actual Collection Time	07:01
------------------------	-------

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: 1202

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (42)

Data signed: (hfarmer1) 27 Mar 2015 14:51:44


Generated On: 20 Jul 2016 20:43:03

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: 1202**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (42)

Data signed: (hfarmer1) 27 Mar 2015 14:51:44

Generated On: 20 Jul 2016 20:43:03

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 30

Form: Date of Visit

Data signed: (hfarmer1) 27 Mar 2015 14:51:58

Generated On: 20 Jul 2016 20:43:03

Visit Not Done	False
----------------	-------

If Not Done, Specify Reason	<hr/>
-----------------------------	-------

Date of Visit	14 APR 2014 DD/MMM/YYYY
---------------	----------------------------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 30

Form: Vital Signs

Data signed: (hfarmer1) 27 Mar 2015 14:51:58

Generated On: 20 Jul 2016 20:43:03

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

14 APR 2014
DD/MMM/YYYY

Time of assessment

14:42
hour:min 24-hour clock

Pulse rate

61
beats per minute

Respiratory rate

14
breaths per minute

Blood Pressure (systolic)

113
mmHg

Blood Pressure (diastolic)

63
mmHg

Vital Signs Position of Subject

Supine ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 30

Form: Advice on the risk of smoking and debriefing

Data signed: (hfarmer1) 27 Mar 2015 14:51:58

Generated On: 20 Jul 2016 20:43:03

Date	14 APR 2014 DD/MMM/YYYY
------	----------------------------

Has the subject received advices on the risks of smoking?	Yes <input type="radio"/>
---	---------------------------

Has a debriefing been performed about THS 2.2?	Yes <input type="radio"/>
--	---------------------------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 30

Form: Physical Examination

Data signed: (hfarmer1) 27 Mar 2015 14:51:56

Generated On: 20 Jul 2016 20:43:03

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of Assessment

14 APR 2014
DD/MMM/YYYY

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 30

Form: Physical Examination (1)

Data signed: (hfarmer1) 27 Mar 2015 14:51:56

Generated On: 20 Jul 2016 20:43:03

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of Assessment 14 APR 2014
DD/MMM/YYYY

System General Appearance ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 30

Form: Physical Examination (2)

Data signed: (hfarmer1) 27 Mar 2015 14:51:56

Generated On: 20 Jul 2016 20:43:03

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of Assessment

14 APR 2014
DD/MMM/YYYY

System

HEENT ☒
(head, eyes, ears, nose,
throat)

Outcome

Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done

False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 30

Form: Physical Examination (3)

Data signed: (hfarmer1) 27 Mar 2015 14:51:56

Generated On: 20 Jul 2016 20:43:03

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of Assessment 14 APR 2014
DD/MMM/YYYY

System Thyroid Gland ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 30

Form: Physical Examination (4)

Data signed: (hfarmer1) 27 Mar 2015 14:51:56

Generated On: 20 Jul 2016 20:43:03

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of Assessment

14 APR 2014
DD/MMM/YYYY

System

Heart ☒

Outcome

Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done

False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 30

Form: Physical Examination (5)

Data signed: (hfarmer1) 27 Mar 2015 14:51:56

Generated On: 20 Jul 2016 20:43:03

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of Assessment

14 APR 2014
DD/MMM/YYYY

System

Chest ☒

Outcome

Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done

False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 30

Form: Physical Examination (6)

Data signed: (hfarmer1) 27 Mar 2015 14:51:56

Generated On: 20 Jul 2016 20:43:03

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of Assessment 14 APR 2014
DD/MMM/YYYY

System Lungs ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 30

Form: Physical Examination (7)

Data signed: (hfarmer1) 27 Mar 2015 14:51:56

Generated On: 20 Jul 2016 20:43:03

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of Assessment

14 APR 2014
DD/MMM/YYYY

System

Gastrointestinal ☒

Outcome

Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done

False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 30

Form: Physical Examination (8)

Data signed: (hfarmer1) 27 Mar 2015 14:51:56

Generated On: 20 Jul 2016 20:43:03

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of Assessment 14 APR 2014
DD/MMM/YYYY

System Cardiovascular System ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 30

Form: Physical Examination (9)

Data signed: (hfarmer1) 27 Mar 2015 14:51:56

Generated On: 20 Jul 2016 20:43:03

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of Assessment

14 APR 2014
DD/MMM/YYYY

System

Neurologic ☒

Outcome

Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done

False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 30

Form: Physical Examination (10)

Data signed: (hfarmer1) 27 Mar 2015 14:51:56

Generated On: 20 Jul 2016 20:43:03

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of Assessment 14 APR 2014
DD/MMM/YYYY

System Skin ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 30

Form: Physical Examination (11)

Data signed: (hfarmer1) 27 Mar 2015 14:51:56

Generated On: 20 Jul 2016 20:43:03

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of Assessment

14 APR 2014
DD/MMM/YYYY

System

Back ☒

Outcome

Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done

False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 30

Form: Physical Examination (12)

Data signed: (hfarmer1) 27 Mar 2015 14:51:56

Generated On: 20 Jul 2016 20:43:03

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of Assessment

14 APR 2014
DD/MMM/YYYY

System

Musculoskeletal ☒

Outcome

Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done

False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 30

Form: Physical Examination (13)

Data signed: (hfarmer1) 27 Mar 2015 14:51:56

Generated On: 20 Jul 2016 20:43:03

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of Assessment

14 APR 2014
DD/MMM/YYYY

System

Abdomen ☒

Outcome

Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done

False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 30

Form: Physical Examination (14)

Data signed: (hfarmer1) 27 Mar 2015 14:51:56

Generated On: 20 Jul 2016 20:43:03

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of Assessment

14 APR 2014
DD/MMM/YYYY

System

Dentition ☒

Outcome

Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done

False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 30

Form: Physical Examination (15)

Data signed: (hfarmer1) 27 Mar 2015 14:51:56

Generated On: 20 Jul 2016 20:43:03

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of Assessment

14 APR 2014
DD/MMM/YYYY

System

Other ☒

Other, Specify _____

Outcome _____

Abnormal, please specify _____

Clinically significant _____

Not Done

True

Not Done; please specify the reason: _____

NOT EXAMINED

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 30

Form: Physical Examination (16)

Data signed: (hfarmer1) 27 Mar 2015 14:51:56

Generated On: 20 Jul 2016 20:43:03

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of Assessment

14 APR 2014
DD/MMM/YYYY

System

Other ☒

Other, Specify _____

Outcome _____

Abnormal, please specify _____

Clinically significant _____

Not Done

True

Not Done; please specify the reason: _____

NOT EXAMINED

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 30

Form: Physical Examination (17)

Data signed: (hfarmer1) 27 Mar 2015 14:51:56

Generated On: 20 Jul 2016 20:43:03

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of Assessment

14 APR 2014
DD/MMM/YYYY

System

Other ☒

Other, Specify _____

Outcome _____

Abnormal, please specify _____

Clinically significant _____

Not Done

True

Not Done; please specify the reason: _____

NOT EXAMINED

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 30

Form: Physical Examination (18)

Data signed: (hfarmer1) 27 Mar 2015 14:51:56

Generated On: 20 Jul 2016 20:43:03

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of Assessment

14 APR 2014
DD/MMM/YYYY

System

Other ☒

Other, Specify _____

Outcome _____

Abnormal, please specify _____

Clinically significant _____

Not Done

True

Not Done; please specify the reason: _____

NOT EXAMINED

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 30

Form: Physical Examination (19)

Data signed: (hfarmer1) 27 Mar 2015 14:51:56

Generated On: 20 Jul 2016 20:43:03

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of Assessment

14 APR 2014
DD/MMM/YYYY

System

Other ☒

Other, Specify _____

Outcome _____

Abnormal, please specify _____

Clinically significant _____

Not Done

True

Not Done; please specify the reason: _____

NOT EXAMINED

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 30

Form: Weight

Data signed: (hfarmer1) 27 Mar 2015 14:51:59

Generated On: 20 Jul 2016 20:43:03

Measurement(s) assessed?

Yes ☒

If No, please specify the reason: _____

Date of Assessment

14 APR 2014
DD/MMM/YYYY

Time of assessment

15:12
hour:min 24-hour clock

Weight

73.1
kg

BMI

24.1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 30

Form: ECG (12-Lead Standard)

Data signed: (hfarmer1) 27 Mar 2015 14:51:55

Generated On: 20 Jul 2016 20:43:03

Was the ECG performed?

Yes ☒

If No, please specify the reason: _____

Date of Assessment

14 APR 2014
DD/MMM/YYYY

Position

Supine ☒

Heart Rate

63
beats per minute

QRS Interval

100
msec

QT Interval

404
msec

QTcB Interval

414
msec

PR Interval

100
msec

QTcF Interval

411
msec

Interpretation

Normal ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 30

Form: ECG (12-Lead Standard)

Data signed: (hfarmer1) 27 Mar 2015 14:51:55

Generated On: 20 Jul 2016 20:43:03

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: 1202**

Folder: Day 30

Form: Haematology

Data signed: (hfarmer1) 27 Mar 2015 14:51:56

Generated On: 20 Jul 2016 20:43:03

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: 1202**

Folder: Day 30

Form: Clinical Chemistry

Data signed: (hfarmer1) 27 Mar 2015 14:51:56

Generated On: 20 Jul 2016 20:43:03

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: 1202**

Folder: Day 30

Form: Urine analysis

Data signed: (hfarmer1) 27 Mar 2015 14:51:56

Generated On: 20 Jul 2016 20:43:03

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: 1202**

Folder: Day 30

Form: Plasma Nicotine Sample

Data signed: (hfarmer1) 27 Mar 2015 14:51:56

Generated On: 20 Jul 2016 20:43:03

Not Done	False
----------	-------

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	14 APR 2014
---------------------	-------------

Time hour:min 24-hour clock	10:54
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 30

Form: Plasma Cotinine Sample

Data signed: (hfarmer1) 27 Mar 2015 14:51:56

Generated On: 20 Jul 2016 20:43:03

Not Done	False
----------	-------

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	14 APR 2014
---------------------	-------------

Time hour:min 24-hour clock	10:54
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 30

Form: CoHb Blood Sample <D30_D60>

Data signed: (hfarmer1) 27 Mar 2015 14:51:56

Generated On: 20 Jul 2016 20:43:03

Not Done	False
----------	-------

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	14 APR 2014
---------------------	-------------

Timepoint	10:00 - 11:30 <input checked="" type="radio"/>
-----------	--

Time hour:min 24-hour clock	10:54
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 30

Form: CO Breath Test

Data signed: (hfarmer1) 27 Mar 2015 14:51:55

Generated On: 20 Jul 2016 20:43:03

Assessment not done	False
---------------------	-------

If Not Done, please specify the reason: _____

Actual Date of Assessment	14 APR 2014 DD/MMM/YYYY
---------------------------	----------------------------

Actual Time of Assessment	11:02 hour:min 24-hour clock
---------------------------	---------------------------------

Result	1 ppm
--------	----------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 30

Form: Risk markers: hs-CRP, fibrinogen, homocysteine, LDL, HDL, sICAM-1

Data signed: (hfarmer1) 27 Mar 2015 14:51:56

Generated On: 20 Jul 2016 20:43:03

Not Done	False
----------	-------

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	15 APR 2014
---------------------	-------------

Time hour:min 24-hour clock	06:40
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 30

Form: 24 hour urine collections

Data signed: (hfarmer1) 27 Mar 2015 14:51:58

Generated On: 20 Jul 2016 20:43:03

Start Date	14 APR 2014 DD/MMM/YYYY
------------	----------------------------

Start Time	09:21 hour:min 24-hour clock
------------	---------------------------------

End Date	15 APR 2014 DD/MMM/YYYY
----------	----------------------------

End Time	09:03 hour:min 24-hour clock
----------	---------------------------------

Volume	2234 mL
--------	------------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 30

Form: Sample Urine Collection

Data signed: (hfarmer1) 27 Mar 2015 14:51:58

Generated On: 20 Jul 2016 20:43:03

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: 1202**

Folder: Day 30

Form: Lab_BU_CCLS (1)

Data signed: (hfarmer1) 27 Mar 2015 14:52:03

Generated On: 20 Jul 2016 20:43:03

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	<hr/>
----------------------	-------

Subject Sex	M
-------------	---

Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	V969071
--------------	---------

Actual Collection Date	2014 04 15
------------------------	------------

Actual Collection Time	06:40
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	RC1029
------------	--------

Battery Name	TRIGLYCERIDES
--------------	---------------

Lab Test ID	RCT19
-------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 30

Form: Lab_BU_CCLS (1)

Data signed: (hfarmer1) 27 Mar 2015 14:52:03

Generated On: 20 Jul 2016 20:43:03

Lab Test Name	TRIGLYCERIDES (GPO)
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	182
Reported Numeric Result	182
Reference Range low	50
Reference Range high	321
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: 1202**

Folder: Day 30

Form: Lab_BU_CCLS (1)

Data signed: (hfarmer1) 27 Mar 2015 14:52:03

Generated On: 20 Jul 2016 20:43:03

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 30

Form: Lab_BU_CCLS (2)

Data signed: (hfarmer1) 27 Mar 2015 14:52:03

Generated On: 20 Jul 2016 20:43:03

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	<hr/>
----------------------	-------

Subject Sex	M
-------------	---

Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	V969071
--------------	---------

Actual Collection Date	2014 04 15
------------------------	------------

Actual Collection Time	06:40
------------------------	-------

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: 1202**

Folder: Day 30

Form: Lab_BU_CCLS (2)

Data signed: (hfarmer1) 27 Mar 2015 14:52:03

Generated On: 20 Jul 2016 20:43:03

Lab Test Name	FASTING GLUCOSE
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	94
Reported Numeric Result	94
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: 1202**

Folder: Day 30

Form: Lab_BU_CCLS (2)

Data signed: (hfarmer1) 27 Mar 2015 14:52:03

Generated On: 20 Jul 2016 20:43:03

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 30

Form: Lab_BU_CCLS (3)

Data signed: (hfarmer1) 27 Mar 2015 14:52:03

Generated On: 20 Jul 2016 20:43:03

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	<hr/>
----------------------	-------

Subject Sex	M
-------------	---

Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	V969071
--------------	---------

Actual Collection Date	2014 04 15
------------------------	------------

Actual Collection Time	06:40
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	RC272
------------	-------

Battery Name	TOTAL CHOLESTEROL
--------------	-------------------

Lab Test ID	RCT20
-------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 30

Form: Lab_BU_CCLS (3)

Data signed: (hfarmer1) 27 Mar 2015 14:52:03

Generated On: 20 Jul 2016 20:43:03

Lab Test Name

CHOLESTEROL (HIGH
PERFORMANCE)

Test ID

Test Status

Done ☒

Reported Text Result

205

Reported Numeric Result

205

Reference Range low

150

Reference Range high

264

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: 1202**

Folder: Day 30

Form: Lab_BU_CCLS (3)

Data signed: (hfarmer1) 27 Mar 2015 14:52:03

Generated On: 20 Jul 2016 20:43:03

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: 1202**

Folder: Day 30

Form: Lab_BU_CCLS (4)

Data signed: (hfarmer1) 27 Mar 2015 14:52:03

Generated On: 20 Jul 2016 20:43:03

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	<hr/>
----------------------	-------

Subject Sex	M
-------------	---

Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	V969071
--------------	---------

Actual Collection Date	2014 04 15
------------------------	------------

Actual Collection Time	06:40
------------------------	-------

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: 1202**

Folder: Day 30

Form: Lab_BU_CCLS (4)

Data signed: (hfarmer1) 27 Mar 2015 14:52:03

Generated On: 20 Jul 2016 20:43:03

Lab Test Name	TOTAL BILIRUBIN
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	0.5
Reported Numeric Result	0.5
Reference Range low	0.2
Reference Range high	1.2
Range Units	MG/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 30

Form: Lab_BU_CCLS (4)

Data signed: (hfarmer1) 27 Mar 2015 14:52:03

Generated On: 20 Jul 2016 20:43:03

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 30

Form: Lab_BU_CCLS (5)

Data signed: (hfarmer1) 27 Mar 2015 14:52:03

Generated On: 20 Jul 2016 20:43:03

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	<hr/>
----------------------	-------

Subject Sex	M
-------------	---

Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	V969071
--------------	---------

Actual Collection Date	2014 04 15
------------------------	------------

Actual Collection Time	06:40
------------------------	-------

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: 1202**

Folder: Day 30

Form: Lab_BU_CCLS (5)

Data signed: (hfarmer1) 27 Mar 2015 14:52:03

Generated On: 20 Jul 2016 20:43:03

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: 1202**

Folder: Day 30

Form: Lab_BU_CCLS (5)

Data signed: (hfarmer1) 27 Mar 2015 14:52:03

Generated On: 20 Jul 2016 20:43:03

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 30

Form: Lab_BU_CCLS (6)

Data signed: (hfarmer1) 27 Mar 2015 14:52:03

Generated On: 20 Jul 2016 20:43:03

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	<hr/>
----------------------	-------

Subject Sex	M
-------------	---

Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	V969071
--------------	---------

Actual Collection Date	2014 04 15
------------------------	------------

Actual Collection Time	06:40
------------------------	-------

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: 1202**

Folder: Day 30

Form: Lab_BU_CCLS (6)

Data signed: (hfarmer1) 27 Mar 2015 14:52:03

Generated On: 20 Jul 2016 20:43:03

Lab Test Name	ALBUMIN
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	4.1
Reported Numeric Result	4.1
Reference Range low	3.3
Reference Range high	4.9
Range Units	G/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 30

Form: Lab_BU_CCLS (6)

Data signed: (hfarmer1) 27 Mar 2015 14:52:03

Generated On: 20 Jul 2016 20:43:03

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 30

Form: Lab_BU_CCLS (7)

Data signed: (hfarmer1) 27 Mar 2015 14:52:03

Generated On: 20 Jul 2016 20:43:03

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	<hr/>
----------------------	-------

Subject Sex	M
-------------	---

Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	V969071
--------------	---------

Actual Collection Date	2014 04 15
------------------------	------------

Actual Collection Time	06:40
------------------------	-------

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: 1202**

Folder: Day 30

Form: Lab_BU_CCLS (7)

Data signed: (hfarmer1) 27 Mar 2015 14:52:03

Generated On: 20 Jul 2016 20:43:03

Lab Test Name	ALKALINE PHOSPHATASE
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	75
Reported Numeric Result	75
Reference Range low	31
Reference Range high	129
Range Units	U/L
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 30

Form: Lab_BU_CCLS (7)

Data signed: (hfarmer1) 27 Mar 2015 14:52:03

Generated On: 20 Jul 2016 20:43:03

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 30

Form: Lab_BU_CCLS (8)

Data signed: (hfarmer1) 27 Mar 2015 14:52:03

Generated On: 20 Jul 2016 20:43:03

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	<hr/>
----------------------	-------

Subject Sex	M
-------------	---

Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	V969071
--------------	---------

Actual Collection Date	2014 04 15
------------------------	------------

Actual Collection Time	06:40
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	RC9255
------------	--------

Battery Name	CHEMISTRY PANEL
--------------	-----------------

Lab Test ID	RCT1408
-------------	---------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 30

Form: Lab_BU_CCLS (8)

Data signed: (hfarmer1) 27 Mar 2015 14:52:03

Generated On: 20 Jul 2016 20:43:03

Lab Test Name	LDH
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	107
Reported Numeric Result	107
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: 1202**

Folder: Day 30

Form: Lab_BU_CCLS (8)

Data signed: (hfarmer1) 27 Mar 2015 14:52:03

Generated On: 20 Jul 2016 20:43:03

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 30

Form: Lab_BU_CCLS (9)

Data signed: (hfarmer1) 27 Mar 2015 14:52:03

Generated On: 20 Jul 2016 20:43:03

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	<hr/>
----------------------	-------

Subject Sex	M
-------------	---

Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	V969071
--------------	---------

Actual Collection Date	2014 04 15
------------------------	------------

Actual Collection Time	06:40
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	RC9255
------------	--------

Battery Name	CHEMISTRY PANEL
--------------	-----------------

Lab Test ID	RCT15
-------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 30

Form: Lab_BU_CCLS (9)

Data signed: (hfarmer1) 27 Mar 2015 14:52:03

Generated On: 20 Jul 2016 20:43:03

Lab Test Name	SERUM SODIUM
Test ID	
Test Status	Done <input checked="" 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: 1202**

Folder: Day 30

Form: Lab_BU_CCLS (9)

Data signed: (hfarmer1) 27 Mar 2015 14:52:03

Generated On: 20 Jul 2016 20:43:03

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 30

Form: Lab_BU_CCLS (10)

Data signed: (hfarmer1) 27 Mar 2015 14:52:03

Generated On: 20 Jul 2016 20:43:03

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	M
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Subject Date of Birth	(b) (6)
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	V969071
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Actual Collection Date	2014 04 15
------------------------	------------

Actual Collection Time	06:40
------------------------	-------

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: 1202

Folder: Day 30

Form: Lab_BU_CCLS (10)

Data signed: (hfarmer1) 27 Mar 2015 14:52:03

Generated On: 20 Jul 2016 20:43:03

Lab Test Name	SERUM POTASSIUM
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	4.2
Reported Numeric Result	4.2
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: 1202**

Folder: Day 30

Form: Lab_BU_CCLS (10)

Data signed: (hfarmer1) 27 Mar 2015 14:52:03

Generated On: 20 Jul 2016 20:43:03

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 30

Form: Lab_BU_CCLS (11)

Data signed: (hfarmer1) 27 Mar 2015 14:52:03

Generated On: 20 Jul 2016 20:43:03

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	M
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Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	V969071
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Actual Collection Date	2014 04 15
------------------------	------------

Actual Collection Time	06:40
------------------------	-------

Specimen Condition	<hr/>
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Battery ID	RC9255
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Battery Name	CHEMISTRY PANEL
--------------	-----------------

Lab Test ID	RCT29
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 30

Form: Lab_BU_CCLS (11)

Data signed: (hfarmer1) 27 Mar 2015 14:52:03

Generated On: 20 Jul 2016 20:43:03

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: 1202**

Folder: Day 30

Form: Lab_BU_CCLS (11)

Data signed: (hfarmer1) 27 Mar 2015 14:52:03

Generated On: 20 Jul 2016 20:43:03

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 30

Form: Lab_BU_CCLS (12)

Data signed: (hfarmer1) 27 Mar 2015 14:52:03

Generated On: 20 Jul 2016 20:43:03

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
----------------------	-------

Subject Sex	M
-------------	---

Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	V969071
--------------	---------

Actual Collection Date	2014 04 15
------------------------	------------

Actual Collection Time	06:40
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	RC9255
------------	--------

Battery Name	CHEMISTRY PANEL
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Lab Test ID	RCT3
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1202

Folder: Day 30

Form: Lab_BU_CCLS (12)

Data signed: (hfarmer1) 27 Mar 2015 14:52:03

Generated On: 20 Jul 2016 20:43:03

Lab Test Name	GGT
Test ID	
Test Status	Done <input type="checkbox"/>
Reported Text Result	26
Reported Numeric Result	26
Reference Range low	10
Reference Range high	61
Range Units	U/L
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 30

Form: Lab_BU_CCLS (12)

Data signed: (hfarmer1) 27 Mar 2015 14:52:03

Generated On: 20 Jul 2016 20:43:03

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 30

Form: Lab_BU_CCLS (13)

Data signed: (hfarmer1) 27 Mar 2015 14:52:03

Generated On: 20 Jul 2016 20:43:03

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	M
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Subject Date of Birth	(b) (6)
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	V969071
--------------	---------

Actual Collection Date	2014 04 15
------------------------	------------

Actual Collection Time	06:40
------------------------	-------

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: 1202**

Folder: Day 30

Form: Lab_BU_CCLS (13)

Data signed: (hfarmer1) 27 Mar 2015 14:52:03

Generated On: 20 Jul 2016 20:43:03

Lab Test Name	CREATININE (RATE BLANKED)
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Test ID	<hr/>
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Test Status	Done <input checked="" type="radio"/>
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Reported Text Result	1.0
----------------------	-----

Reported Numeric Result	1.0
-------------------------	-----

Reference Range low	0.5
---------------------	-----

Reference Range high	1.2
----------------------	-----

Range Units	MG/DL
-------------	-------

Conventional Text Result	<hr/>
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Conventional Numeric Result	<hr/>
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Conventional Reference Range Low	<hr/>
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Conventional Reference Range High	<hr/>
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Conventional Units	<hr/>
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SI Text Result	<hr/>
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 30

Form: Lab_BU_CCLS (13)

Data signed: (hfarmer1) 27 Mar 2015 14:52:03

Generated On: 20 Jul 2016 20:43:03

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 30

Form: Lab_BU_CCLS (14)

Data signed: (hfarmer1) 27 Mar 2015 14:52:03

Generated On: 20 Jul 2016 20:43:03

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
----------------------	-------

Subject Sex	M
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Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	V969071
--------------	---------

Actual Collection Date	2014 04 15
------------------------	------------

Actual Collection Time	06:40
------------------------	-------

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: 1202**

Folder: Day 30

Form: Lab_BU_CCLS (14)

Data signed: (hfarmer1) 27 Mar 2015 14:52:03

Generated On: 20 Jul 2016 20:43:03

Lab Test Name	ALT (SGPT)
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	12
Reported Numeric Result	12
Reference Range low	6
Reference Range high	43
Range Units	U/L
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 30

Form: Lab_BU_CCLS (14)

Data signed: (hfarmer1) 27 Mar 2015 14:52:03

Generated On: 20 Jul 2016 20:43:03

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 30

Form: Lab_BU_CCLS (15)

Data signed: (hfarmer1) 27 Mar 2015 14:52:03

Generated On: 20 Jul 2016 20:43:03

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
----------------------	-------

Subject Sex	M
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Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	V969071
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Actual Collection Date	2014 04 15
------------------------	------------

Actual Collection Time	06:40
------------------------	-------

Specimen Condition	<hr/>
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Battery ID	RC9255
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Battery Name	CHEMISTRY PANEL
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Lab Test ID	RCT5
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 30

Form: Lab_BU_CCLS (15)

Data signed: (hfarmer1) 27 Mar 2015 14:52:03

Generated On: 20 Jul 2016 20:43:03

Lab Test Name	AST (SGOT)
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	12
Reported Numeric Result	12
Reference Range low	11
Reference Range high	36
Range Units	U/L
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 30

Form: Lab_BU_CCLS (15)

Data signed: (hfarmer1) 27 Mar 2015 14:52:03

Generated On: 20 Jul 2016 20:43:03

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 30

Form: Lab_BU_CCLS (16)

Data signed: (hfarmer1) 27 Mar 2015 14:52:03

Generated On: 20 Jul 2016 20:43:03

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	M
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Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	V969071
--------------	---------

Actual Collection Date	2014 04 15
------------------------	------------

Actual Collection Time	06:40
------------------------	-------

Specimen Condition	<hr/>
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Battery ID	RC9255
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Battery Name	CHEMISTRY PANEL
--------------	-----------------

Lab Test ID	RCT6
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 30

Form: Lab_BU_CCLS (16)

Data signed: (hfarmer1) 27 Mar 2015 14:52:03

Generated On: 20 Jul 2016 20:43:03

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: 1202**

Folder: Day 30

Form: Lab_BU_CCLS (16)

Data signed: (hfarmer1) 27 Mar 2015 14:52:03

Generated On: 20 Jul 2016 20:43:03

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 30

Form: Lab_BU_CCLS (17)

Data signed: (hfarmer1) 27 Mar 2015 14:52:03

Generated On: 20 Jul 2016 20:43:03

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
----------------------	-------

Subject Sex	M
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Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	V969071
--------------	---------

Actual Collection Date	2014 04 15
------------------------	------------

Actual Collection Time	06:40
------------------------	-------

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: 1202**

Folder: Day 30

Form: Lab_BU_CCLS (17)

Data signed: (hfarmer1) 27 Mar 2015 14:52:03

Generated On: 20 Jul 2016 20:43:03

Lab Test Name	MONOCYTES
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	0.63
Reported Numeric Result	0.63
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: 1202**

Folder: Day 30

Form: Lab_BU_CCLS (17)

Data signed: (hfarmer1) 27 Mar 2015 14:52:03

Generated On: 20 Jul 2016 20:43:03

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 30

Form: Lab_BU_CCLS (18)

Data signed: (hfarmer1) 27 Mar 2015 14:52:03

Generated On: 20 Jul 2016 20:43:03

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	M
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Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	V969071
--------------	---------

Actual Collection Date	2014 04 15
------------------------	------------

Actual Collection Time	06:40
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

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: 1202

Folder: Day 30

Form: Lab_BU_CCLS (18)

Data signed: (hfarmer1) 27 Mar 2015 14:52:03

Generated On: 20 Jul 2016 20:43:03

Lab Test Name	MCH
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	26
Reported Numeric Result	26
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: 1202**

Folder: Day 30

Form: Lab_BU_CCLS (18)

Data signed: (hfarmer1) 27 Mar 2015 14:52:03

Generated On: 20 Jul 2016 20:43:03

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 30

Form: Lab_BU_CCLS (19)

Data signed: (hfarmer1) 27 Mar 2015 14:52:03

Generated On: 20 Jul 2016 20:43:03

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
----------------------	-------

Subject Sex	M
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Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	V969071
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Actual Collection Date	2014 04 15
------------------------	------------

Actual Collection Time	06:40
------------------------	-------

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: 1202**

Folder: Day 30

Form: Lab_BU_CCLS (19)

Data signed: (hfarmer1) 27 Mar 2015 14:52:03

Generated On: 20 Jul 2016 20:43:03

Lab Test Name	MCHC
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	31
Reported Numeric Result	31
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: 1202**

Folder: Day 30

Form: Lab_BU_CCLS (19)

Data signed: (hfarmer1) 27 Mar 2015 14:52:03

Generated On: 20 Jul 2016 20:43:03

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1202

Folder: Day 30

Form: Lab_BU_CCLS (20)

Data signed: (hfarmer1) 27 Mar 2015 14:52:03

Generated On: 20 Jul 2016 20:43:03

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	
----------------------	--

Subject Sex	M
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Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	
------------	--

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	V969071
--------------	---------

Actual Collection Date	2014 04 15
------------------------	------------

Actual Collection Time	06:40
------------------------	-------

Specimen Condition	
--------------------	--

Battery ID	HM1604
------------	--------

Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
--------------	-----------------------------------

Lab Test ID	HMT11
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 30

Form: Lab_BU_CCLS (20)

Data signed: (hfarmer1) 27 Mar 2015 14:52:03

Generated On: 20 Jul 2016 20:43:03

Lab Test Name	EOSINOPHILS
Test ID	
Test Status	Done <input checked="" type="checkbox"/>
Reported Text Result	0.10
Reported Numeric Result	0.10
Reference Range low	0.00
Reference Range high	0.57
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: 1202**

Folder: Day 30

Form: Lab_BU_CCLS (20)

Data signed: (hfarmer1) 27 Mar 2015 14:52:03

Generated On: 20 Jul 2016 20:43:03

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 30

Form: Lab_BU_CCLS (21)

Data signed: (hfarmer1) 27 Mar 2015 14:52:03

Generated On: 20 Jul 2016 20:43:03

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
----------------------	-------

Subject Sex	M
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Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	V969071
--------------	---------

Actual Collection Date	2014 04 15
------------------------	------------

Actual Collection Time	06:40
------------------------	-------

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: 1202**

Folder: Day 30

Form: Lab_BU_CCLS (21)

Data signed: (hfarmer1) 27 Mar 2015 14:52:03

Generated On: 20 Jul 2016 20:43:03

Lab Test Name	BASOPHILS
Test ID	
Test Status	Done <input checked="" type="radio"/>
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: 1202**

Folder: Day 30

Form: Lab_BU_CCLS (21)

Data signed: (hfarmer1) 27 Mar 2015 14:52:03

Generated On: 20 Jul 2016 20:43:03

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 30

Form: Lab_BU_CCLS (22)

Data signed: (hfarmer1) 27 Mar 2015 14:52:03

Generated On: 20 Jul 2016 20:43:03

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
----------------------	-------

Subject Sex	M
-------------	---

Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	V969071
--------------	---------

Actual Collection Date	2014 04 15
------------------------	------------

Actual Collection Time	06:40
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	HM1604
------------	--------

Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
--------------	-----------------------------------

Lab Test ID	HMT13
-------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 30

Form: Lab_BU_CCLS (22)

Data signed: (hfarmer1) 27 Mar 2015 14:52:03

Generated On: 20 Jul 2016 20:43:03

Lab Test Name	PLATELETS
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	263
Reported Numeric Result	263
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: 1202**

Folder: Day 30

Form: Lab_BU_CCLS (22)

Data signed: (hfarmer1) 27 Mar 2015 14:52:03

Generated On: 20 Jul 2016 20:43:03

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 30

Form: Lab_BU_CCLS (23)

Data signed: (hfarmer1) 27 Mar 2015 14:52:03

Generated On: 20 Jul 2016 20:43:03

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	M
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Subject Date of Birth	(b) (6)
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	V969071
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Actual Collection Date	2014 04 15
------------------------	------------

Actual Collection Time	06:40
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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: 1202

Folder: Day 30

Form: Lab_BU_CCLS (23)

Data signed: (hfarmer1) 27 Mar 2015 14:52:03

Generated On: 20 Jul 2016 20:43:03

Lab Test Name	NEUTROPHILS (%)
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	50.0
Reported Numeric Result	50.0
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: 1202**

Folder: Day 30

Form: Lab_BU_CCLS (23)

Data signed: (hfarmer1) 27 Mar 2015 14:52:03

Generated On: 20 Jul 2016 20:43:03

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 30

Form: Lab_BU_CCLS (24)

Data signed: (hfarmer1) 27 Mar 2015 14:52:03

Generated On: 20 Jul 2016 20:43:03

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	M
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Subject Date of Birth	(b) (6)
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	V969071
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Actual Collection Date	2014 04 15
------------------------	------------

Actual Collection Time	06:40
------------------------	-------

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: 1202

Folder: Day 30

Form: Lab_BU_CCLS (24)

Data signed: (hfarmer1) 27 Mar 2015 14:52:03

Generated On: 20 Jul 2016 20:43:03

Lab Test Name	LYMPHOCYTES (%)
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	39.9
Reported Numeric Result	39.9
Reference Range low	15.4
Reference Range high	48.5
Range Units	%
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 30

Form: Lab_BU_CCLS (24)

Data signed: (hfarmer1) 27 Mar 2015 14:52:03

Generated On: 20 Jul 2016 20:43:03

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 30

Form: Lab_BU_CCLS (25)

Data signed: (hfarmer1) 27 Mar 2015 14:52:03

Generated On: 20 Jul 2016 20:43:03

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	M
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Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	V969071
--------------	---------

Actual Collection Date	2014 04 15
------------------------	------------

Actual Collection Time	06:40
------------------------	-------

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: 1202**

Folder: Day 30

Form: Lab_BU_CCLS (25)

Data signed: (hfarmer1) 27 Mar 2015 14:52:03

Generated On: 20 Jul 2016 20:43:03

Lab Test Name	MONOCYTES (%)
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	8.2
Reported Numeric Result	8.2
Reference Range low	2.6
Reference Range high	10.1
Range Units	%
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 30

Form: Lab_BU_CCLS (25)

Data signed: (hfarmer1) 27 Mar 2015 14:52:03

Generated On: 20 Jul 2016 20:43:03

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 30

Form: Lab_BU_CCLS (26)

Data signed: (hfarmer1) 27 Mar 2015 14:52:03

Generated On: 20 Jul 2016 20:43:03

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	M
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Subject Date of Birth	(b) (6)
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	V969071
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Actual Collection Date	2014 04 15
------------------------	------------

Actual Collection Time	06:40
------------------------	-------

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: 1202**

Folder: Day 30

Form: Lab_BU_CCLS (26)

Data signed: (hfarmer1) 27 Mar 2015 14:52:03

Generated On: 20 Jul 2016 20:43:03

Lab Test Name	EOSINOPHILS (%)
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	1.4
Reported Numeric Result	1.4
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: 1202**

Folder: Day 30

Form: Lab_BU_CCLS (26)

Data signed: (hfarmer1) 27 Mar 2015 14:52:03

Generated On: 20 Jul 2016 20:43:03

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 30

Form: Lab_BU_CCLS (27)

Data signed: (hfarmer1) 27 Mar 2015 14:52:03

Generated On: 20 Jul 2016 20:43:03

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	M
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Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	V969071
--------------	---------

Actual Collection Date	2014 04 15
------------------------	------------

Actual Collection Time	06:40
------------------------	-------

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: 1202**

Folder: Day 30

Form: Lab_BU_CCLS (27)

Data signed: (hfarmer1) 27 Mar 2015 14:52:03

Generated On: 20 Jul 2016 20:43:03

Lab Test Name	BASOPHILS (%)
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	0.5
Reported Numeric Result	0.5
Reference Range low	0.0
Reference Range high	2.0
Range Units	%
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 30

Form: Lab_BU_CCLS (27)

Data signed: (hfarmer1) 27 Mar 2015 14:52:03

Generated On: 20 Jul 2016 20:43:03

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 30

Form: Lab_BU_CCLS (28)

Data signed: (hfarmer1) 27 Mar 2015 14:52:03

Generated On: 20 Jul 2016 20:43:03

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	M
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Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	V969071
--------------	---------

Actual Collection Date	2014 04 15
------------------------	------------

Actual Collection Time	06:40
------------------------	-------

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: 1202

Folder: Day 30

Form: Lab_BU_CCLS (28)

Data signed: (hfarmer1) 27 Mar 2015 14:52:03

Generated On: 20 Jul 2016 20:43:03

Lab Test Name	HEMATOCRIT
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	47
Reported Numeric Result	47
Reference Range low	39
Reference Range high	54
Range Units	%
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 30

Form: Lab_BU_CCLS (28)

Data signed: (hfarmer1) 27 Mar 2015 14:52:03

Generated On: 20 Jul 2016 20:43:03

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 30

Form: Lab_BU_CCLS (29)

Data signed: (hfarmer1) 27 Mar 2015 14:52:03

Generated On: 20 Jul 2016 20:43:03

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	<hr/>
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Subject Sex	M
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Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	V969071
--------------	---------

Actual Collection Date	2014 04 15
------------------------	------------

Actual Collection Time	06:40
------------------------	-------

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: 1202**

Folder: Day 30

Form: Lab_BU_CCLS (29)

Data signed: (hfarmer1) 27 Mar 2015 14:52:03

Generated On: 20 Jul 2016 20:43:03

Lab Test Name	RBC
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	5.6
Reported Numeric Result	5.6
Reference Range low	4.5
Reference Range high	6.4
Range Units	X10^6/UL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 30

Form: Lab_BU_CCLS (29)

Data signed: (hfarmer1) 27 Mar 2015 14:52:03

Generated On: 20 Jul 2016 20:43:03

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 30

Form: Lab_BU_CCLS (30)

Data signed: (hfarmer1) 27 Mar 2015 14:52:03

Generated On: 20 Jul 2016 20:43:03

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	M
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Subject Date of Birth	(b) (6)
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	V969071
--------------	---------

Actual Collection Date	2014 04 15
------------------------	------------

Actual Collection Time	06:40
------------------------	-------

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: 1202**

Folder: Day 30

Form: Lab_BU_CCLS (30)

Data signed: (hfarmer1) 27 Mar 2015 14:52:03

Generated On: 20 Jul 2016 20:43:03

Lab Test Name	MCV
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	83
Reported Numeric Result	83
Reference Range low	79
Reference Range high	96
Range Units	FL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 30

Form: Lab_BU_CCLS (30)

Data signed: (hfarmer1) 27 Mar 2015 14:52:03

Generated On: 20 Jul 2016 20:43:03

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 30

Form: Lab_BU_CCLS (31)

Data signed: (hfarmer1) 27 Mar 2015 14:52:03

Generated On: 20 Jul 2016 20:43:03

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
----------------------	-------

Subject Sex	M
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Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	V969071
--------------	---------

Actual Collection Date	2014 04 15
------------------------	------------

Actual Collection Time	06:40
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	HM1604
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Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
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Lab Test ID	HMT40
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 30

Form: Lab_BU_CCLS (31)

Data signed: (hfarmer1) 27 Mar 2015 14:52:03

Generated On: 20 Jul 2016 20:43:03

Lab Test Name	HEMOGLOBIN
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	14.6
Reported Numeric Result	14.6
Reference Range low	12.7
Reference Range high	18.1
Range Units	G/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 30

Form: Lab_BU_CCLS (31)

Data signed: (hfarmer1) 27 Mar 2015 14:52:03

Generated On: 20 Jul 2016 20:43:03

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 30

Form: Lab_BU_CCLS (32)

Data signed: (hfarmer1) 27 Mar 2015 14:52:03

Generated On: 20 Jul 2016 20:43:03

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	<hr/>
----------------------	-------

Subject Sex	M
-------------	---

Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	V969071
--------------	---------

Actual Collection Date	2014 04 15
------------------------	------------

Actual Collection Time	06:40
------------------------	-------

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: 1202**

Folder: Day 30

Form: Lab_BU_CCLS (32)

Data signed: (hfarmer1) 27 Mar 2015 14:52:03

Generated On: 20 Jul 2016 20:43:03

Lab Test Name	WBC
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	7.68
Reported Numeric Result	7.68
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: 1202**

Folder: Day 30

Form: Lab_BU_CCLS (32)

Data signed: (hfarmer1) 27 Mar 2015 14:52:03

Generated On: 20 Jul 2016 20:43:03

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 30

Form: Lab_BU_CCLS (33)

Data signed: (hfarmer1) 27 Mar 2015 14:52:03

Generated On: 20 Jul 2016 20:43:03

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	<hr/>
----------------------	-------

Subject Sex	M
-------------	---

Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	V969071
--------------	---------

Actual Collection Date	2014 04 15
------------------------	------------

Actual Collection Time	06:40
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	HM1604
------------	--------

Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
--------------	-----------------------------------

Lab Test ID	HMT71
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 30

Form: Lab_BU_CCLS (33)

Data signed: (hfarmer1) 27 Mar 2015 14:52:03


Generated On: 20 Jul 2016 20:43:03

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: 1202**

Folder: Day 30

Form: Lab_BU_CCLS (33)

Data signed: (hfarmer1) 27 Mar 2015 14:52:03

Generated On: 20 Jul 2016 20:43:03

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 30

Form: Lab_BU_CCLS (34)

Data signed: (hfarmer1) 27 Mar 2015 14:52:03

Generated On: 20 Jul 2016 20:43:03

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	<hr/>
----------------------	-------

Subject Sex	M
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Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	V969071
--------------	---------

Actual Collection Date	2014 04 15
------------------------	------------

Actual Collection Time	06:40
------------------------	-------

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: 1202**

Folder: Day 30

Form: Lab_BU_CCLS (34)

Data signed: (hfarmer1) 27 Mar 2015 14:52:03

Generated On: 20 Jul 2016 20:43:03

Lab Test Name	NEUTROPHILS
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	3.84
Reported Numeric Result	3.84
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: 1202**

Folder: Day 30

Form: Lab_BU_CCLS (34)

Data signed: (hfarmer1) 27 Mar 2015 14:52:03

Generated On: 20 Jul 2016 20:43:03

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 30

Form: Lab_BU_CCLS (35)

Data signed: (hfarmer1) 27 Mar 2015 14:52:03

Generated On: 20 Jul 2016 20:43:03

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
----------------------	-------

Subject Sex	M
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Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	V969071
--------------	---------

Actual Collection Date	2014 04 15
------------------------	------------

Actual Collection Time	06:40
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	HM1604
------------	--------

Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
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Lab Test ID	HMT9
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 30

Form: Lab_BU_CCLS (35)

Data signed: (hfarmer1) 27 Mar 2015 14:52:03

Generated On: 20 Jul 2016 20:43:03

Lab Test Name	LYMPHOCYTES
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	3.07
Reported Numeric Result	3.07
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: 1202**

Folder: Day 30

Form: Lab_BU_CCLS (35)

Data signed: (hfarmer1) 27 Mar 2015 14:52:03

Generated On: 20 Jul 2016 20:43:03

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 30

Form: Lab_BU_CCLS (36)

Data signed: (hfarmer1) 27 Mar 2015 14:52:03

Generated On: 20 Jul 2016 20:43:03

Transmission Type Cumulative ☒

Subject ID or Number

Subject Sex M

Subject Date of Birth (b) (6)

Visit Name

Visit Type Scheduled ☒

Accession ID V969071

Actual Collection Date 2014 04 15

Actual Collection Time 06:40

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: 1202**

Folder: Day 30

Form: Lab_BU_CCLS (36)

Data signed: (hfarmer1) 27 Mar 2015 14:52:03


Generated On: 20 Jul 2016 20:43:03

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: 1202**

Folder: Day 30

Form: Lab_BU_CCLS (36)

Data signed: (hfarmer1) 27 Mar 2015 14:52:03

Generated On: 20 Jul 2016 20:43:03

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 30

Form: Lab_BU_CCLS (37)

Data signed: (hfarmer1) 27 Mar 2015 14:52:03

Generated On: 20 Jul 2016 20:43:03

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	<hr/>
----------------------	-------

Subject Sex	M
-------------	---

Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	V969071
--------------	---------

Actual Collection Date	2014 04 15
------------------------	------------

Actual Collection Time	06:40
------------------------	-------

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: 1202**

Folder: Day 30

Form: Lab_BU_CCLS (37)

Data signed: (hfarmer1) 27 Mar 2015 14:52:03

Generated On: 20 Jul 2016 20:43:03

Lab Test Name	UR SPECIFIC GRAVITY
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	1.025
Reported Numeric Result	1.025
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: 1202**

Folder: Day 30

Form: Lab_BU_CCLS (37)

Data signed: (hfarmer1) 27 Mar 2015 14:52:03

Generated On: 20 Jul 2016 20:43:03

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 30

Form: Lab_BU_CCLS (38)

Data signed: (hfarmer1) 27 Mar 2015 14:52:03

Generated On: 20 Jul 2016 20:43:03

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	<hr/>
----------------------	-------

Subject Sex	M
-------------	---

Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	V969071
--------------	---------

Actual Collection Date	2014 04 15
------------------------	------------

Actual Collection Time	06:40
------------------------	-------

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: 1202**

Folder: Day 30

Form: Lab_BU_CCLS (38)

Data signed: (hfarmer1) 27 Mar 2015 14:52:03

Generated On: 20 Jul 2016 20:43:03

Lab Test Name	UR PH
Test ID	
Test Status	Done <input type="checkbox"/>
Reported Text Result	5.5
Reported Numeric Result	5.5
Reference Range low	5.0
Reference Range high	8.0
Range Units	
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 30

Form: Lab_BU_CCLS (38)

Data signed: (hfarmer1) 27 Mar 2015 14:52:03

Generated On: 20 Jul 2016 20:43:03

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 30

Form: Lab_BU_CCLS (39)

Data signed: (hfarmer1) 27 Mar 2015 14:52:03

Generated On: 20 Jul 2016 20:43:03

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	<hr/>
----------------------	-------

Subject Sex	M
-------------	---

Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	V969071
--------------	---------

Actual Collection Date	2014 04 15
------------------------	------------

Actual Collection Time	06:40
------------------------	-------

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: 1202**

Folder: Day 30

Form: Lab_BU_CCLS (39)

Data signed: (hfarmer1) 27 Mar 2015 14:52:03


Generated On: 20 Jul 2016 20:43:03

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: 1202**

Folder: Day 30

Form: Lab_BU_CCLS (39)

Data signed: (hfarmer1) 27 Mar 2015 14:52:03

Generated On: 20 Jul 2016 20:43:03

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 30

Form: Lab_BU_CCLS (40)

Data signed: (hfarmer1) 27 Mar 2015 14:52:03

Generated On: 20 Jul 2016 20:43:03

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	<hr/>
----------------------	-------

Subject Sex	M
-------------	---

Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	V969071
--------------	---------

Actual Collection Date	2014 04 15
------------------------	------------

Actual Collection Time	06:40
------------------------	-------

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: 1202**

Folder: Day 30

Form: Lab_BU_CCLS (40)

Data signed: (hfarmer1) 27 Mar 2015 14:52:03


Generated On: 20 Jul 2016 20:43:03

Lab Test Name

UR PROTEIN

Test ID

Test Status

Done 

Reported Text Result

TRACE

Reported Numeric Result

Reference Range low

Reference Range high

Range Units

Conventional Text Result

Conventional Numeric Result

Conventional Reference Range Low

Conventional Reference Range High

Conventional Units

SI Text Result

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 30

Form: Lab_BU_CCLS (40)

Data signed: (hfarmer1) 27 Mar 2015 14:52:03

Generated On: 20 Jul 2016 20:43:03

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: 1202**

Folder: Day 30

Form: Lab_BU_CCLS (41)

Data signed: (hfarmer1) 27 Mar 2015 14:52:03

Generated On: 20 Jul 2016 20:43:03

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	<hr/>
----------------------	-------

Subject Sex	M
-------------	---

Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	V969071
--------------	---------

Actual Collection Date	2014 04 15
------------------------	------------

Actual Collection Time	06:40
------------------------	-------

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: 1202**

Folder: Day 30

Form: Lab_BU_CCLS (41)

Data signed: (hfarmer1) 27 Mar 2015 14:52:03


Generated On: 20 Jul 2016 20:43:03

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: 1202**

Folder: Day 30

Form: Lab_BU_CCLS (41)

Data signed: (hfarmer1) 27 Mar 2015 14:52:03

Generated On: 20 Jul 2016 20:43:03

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 30

Form: Lab_BU_CCLS (42)

Data signed: (hfarmer1) 27 Mar 2015 14:52:03

Generated On: 20 Jul 2016 20:43:03

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	<hr/>
----------------------	-------

Subject Sex	M
-------------	---

Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	V969071
--------------	---------

Actual Collection Date	2014 04 15
------------------------	------------

Actual Collection Time	06:40
------------------------	-------

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: 1202**

Folder: Day 30

Form: Lab_BU_CCLS (42)

Data signed: (hfarmer1) 27 Mar 2015 14:52:03


Generated On: 20 Jul 2016 20:43:03

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: 1202**

Folder: Day 30

Form: Lab_BU_CCLS (42)

Data signed: (hfarmer1) 27 Mar 2015 14:52:03

Generated On: 20 Jul 2016 20:43:03

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 30

Form: Lab_BU_COHB (1)

Data signed: (hfarmer1) 27 Mar 2015 14:52:17

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05115150001421
----------------	----------------

Analyte	CARBOXYHEMOGLOBIN
---------	-------------------

Sample type	BLOOD
-------------	-------

Result	1.70
--------	------

Result Unit	%
-------------	---

Lab Status	OK
------------	----

Sample comment	
----------------	--

Detection method	SPECTROPHOTOMETRIC
------------------	--------------------

Lower limit of quantification	0.500
-------------------------------	-------

Planned time point (Hour)	10
---------------------------	----

Day of Visit	30
--------------	----

Celerion Study Number	AA99128-16
-----------------------	------------

Date of Collection	2014-APR-14
--------------------	-------------

Timepoint-minutes	
-------------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 30

Form: Lab_BU_COHB (1)

Data signed: (hfarmer1) 27 Mar 2015 14:52:17

Generated On: 20 Jul 2016 20:43:03

Start Day (24 hour urine only) _____

End Day (24 hour Urine Only) _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 30

Form: Cough Assessment (Paper)

Data signed: (hfarmer1) 27 Mar 2015 14:51:57

Generated On: 20 Jul 2016 20:43:03

Was paper questionnaire used? Yes ☐

Reason not done _____

Date of assessment 15 APR 2014
DD/MMM/YYYY DD/MMM/YYYY

Time of assessment 06:05
hour:min 24-hour clock

Have you experienced a regular need to cough e.g. coughing several times in the last 24 hrs? No ☐

If YES, please answer the following questions:

First Question: Cough Impact Scale
How much is your cough bothering you? _____

Second Question: Cough Intensity Scale:
How intense is your cough? _____

Third Question: Cough Frequency Scale:
How frequently do you normally have to cough each day? _____

Fourth Question: Sputum Production
To what extent do you produce sputum when coughing? _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 30

Form: Cough Assessment (Paper)

Data signed: (hfarmer1) 27 Mar 2015 14:51:57

Generated On: 20 Jul 2016 20:43:03

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: 1202

Folder: Day 30

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS) (Paper)

Data signed: (hfarmer1) 27 Mar 2015 14:51:57

Generated On: 20 Jul 2016 20:43:03

Was paper questionnaire used?

Yes ☒

Reason not done

Date of assessment
DD/MMM/YYYY

15 APR 2014
DD/MMM/YYYY

Time of assessment

06:06
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: 1202

Folder: Day 30

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS) (Paper) (3)

Data signed: (hfarmer1) 27 Mar 2015 14:51:57

Generated On: 20 Jul 2016 20:43:03

	Result
3. Depressed Mood, sad	None
4. Desire or craving to smoke	Mild
5. Difficulty concentrating	Slight
6. Increased appetite, hungry, weight gain	Moderate
7. Insomnia, sleep problems, awakening at night	None
8. Restless	Slight
9. Impatient	Slight

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1202

Folder: Day 30

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS) (Paper) (10)

Data signed: (hfarmer1) 27 Mar 2015 14:51:57

Generated On: 20 Jul 2016 20:43:03

	Result
10. Constipation	None
11. Dizziness	None
12. Coughing	None
13. Dreaming or nightmares	None
14. Nausea	None
15. Sore throat	None

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 30

**Form: Prochaska "Stage of Change" Questionnaire: Intention to Quit
Smoking**

Data signed: (hfarmer1) 27 Mar 2015 14:51:58

Generated On: 20 Jul 2016 20:43:03

Was paper questionnaire used? Yes ☒

Reason not done _____

Type PROCHASKA STAGE OF
CHANGE QUESTIONNAIRE:
INTENTION TO QUIT
SMOKING

Date of assessment 14 APR 2014
DD/MMM/YYYY

Time of assessment 21:20
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: 1202**

Folder: Day 30

Form: Questionnaire on smoking urges (QSU) (Paper)

Data signed: (hfarmer1) 27 Mar 2015 14:51:58

Generated On: 20 Jul 2016 20:43:03

Type	QUESTIONNAIRE ON SMOKING URGES
------	-----------------------------------

Was paper questionnaire used?	Yes <input type="radio"/>
-------------------------------	---------------------------

Reason not done	<hr/>
-----------------	-------

Date of assessment	14 APR 2014
--------------------	-------------

DD/MMM/YYYY

Time of assessment	21:23
--------------------	-------

hour:min 24-hour clock

1. I have a desire for a cigarette right now	Agree <input type="radio"/>
--	-----------------------------

2. Nothing would be better than smoking a cigarette right now	Somewhat agree <input type="radio"/>
--	--------------------------------------

3. If it were possible I would probably smoke now	Somewhat agree <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 agree <input type="radio"/>
--	--------------------------------------

6. I have an urge for a cigarette	Somewhat agree <input type="radio"/>
-----------------------------------	--------------------------------------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 30

Form: Questionnaire on smoking urges (QSU) (Paper)

Data signed: (hfarmer1) 27 Mar 2015 14:51:58

Generated On: 20 Jul 2016 20:43:03

7. A cigarette would taste good now Somewhat agree ☐

8. I would do almost anything for a cigarette now Do not agree or disagree ☐

9. Smoking would make me less depressed Somewhat disagree ☐

10. I am going to smoke as soon as possible Somewhat agree ☐

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 30

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper)

Data signed: (hcoleman1) 18 Jun 2015 21:10:23

Generated On: 20 Jul 2016 20:43:03

Was paper questionnaire used? _____

Reason not done _____

Date of assessment

DD/MMM/YYYY _____

Time of assessment _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 30

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper) (1)

Data signed: (hcoleman1) 18 Jun 2015 21:10:23

Generated On: 20 Jul 2016 20:43:03

Was paper questionnaire used? _____

Reason not done _____

Date of assessment

DD/MMM/YYYY _____

Time of assessment _____

If you have smoked since you last completed this
questionnaire,
please mark what best represents how smoking made
you feel

Was smoking satisfying? ☒

Response _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 30

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper) (2)

Data signed: (hcoleman1) 18 Jun 2015 21:10:23

Generated On: 20 Jul 2016 20:43:03

Was paper questionnaire used? _____

Reason not done _____

Date of assessment

DD/MMM/YYYY _____

Time of assessment _____

If you have smoked since you last completed this
questionnaire,
please mark what best represents how smoking made
you feel

Did cigarettes taste good? ☐

Response _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 30

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper) (3)

Data signed: (hcoleman1) 18 Jun 2015 21:10:23

Generated On: 20 Jul 2016 20:43:03

Was paper questionnaire used? _____

Reason not done _____

Date of assessment

DD/MMM/YYYY _____

Time of assessment _____

If you have smoked since you last completed this
questionnaire,
please mark what best represents how smoking made
you feel

Did you enjoy the ☒ sensation in your throat
and chest?

Response _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 30

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper) (4)

Data signed: (hcoleman1) 18 Jun 2015 21:10:23

Generated On: 20 Jul 2016 20:43:03

Was paper questionnaire used? _____

Reason not done _____

Date of assessment

DD/MMM/YYYY _____

Time of assessment _____

If you have smoked since you last completed this
questionnaire,
please mark what best represents how smoking made
you feel

Did smoking calm you down? ☒

Response _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 30

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper) (5)

Data signed: (hcoleman1) 18 Jun 2015 21:10:23

Generated On: 20 Jul 2016 20:43:03

Was paper questionnaire used? _____

Reason not done _____

Date of assessment

DD/MMM/YYYY _____

Time of assessment _____

If you have smoked since you last completed this
questionnaire,
please mark what best represents how smoking made
you feel

Did smoking make you feel ☒ more awake?

Response _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 30

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper) (6)

Data signed: (hcoleman1) 18 Jun 2015 21:10:23

Generated On: 20 Jul 2016 20:43:03

Was paper questionnaire used? _____

Reason not done _____

Date of assessment

DD/MMM/YYYY _____

Time of assessment _____

If you have smoked since you last completed this
questionnaire,
please mark what best represents how smoking made
you feel

Did smoking make you feel ☒ less irritable?

Response _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 30

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper) (7)

Data signed: (hcoleman1) 18 Jun 2015 21:10:23

Generated On: 20 Jul 2016 20:43:03

Was paper questionnaire used? _____

Reason not done _____

Date of assessment

DD/MMM/YYYY _____

Time of assessment _____

If you have smoked since you last completed this
questionnaire,
please mark what best represents how smoking made
you feel

Did smoking help you
concentrate? ☒

Response _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 30

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper) (8)

Data signed: (hcoleman1) 18 Jun 2015 21:10:23

Generated On: 20 Jul 2016 20:43:03

Was paper questionnaire used? _____

Reason not done _____

Date of assessment

DD/MMM/YYYY _____

Time of assessment _____

If you have smoked since you last completed this
questionnaire,
please mark what best represents how smoking made
you feel

Did smoking reduce your
hunger for food? ☒

Response _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 30

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper) (9)

Data signed: (hcoleman1) 18 Jun 2015 21:10:23

Generated On: 20 Jul 2016 20:43:03

Was paper questionnaire used? _____

Reason not done _____

Date of assessment

DD/MMM/YYYY _____

Time of assessment _____

If you have smoked since you last completed this
questionnaire,
please mark what best represents how smoking made
you feel

Did smoking make you ☒ dizzy?

Response _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 30

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper) (10)

Data signed: (hcoleman1) 18 Jun 2015 21:10:23

Generated On: 20 Jul 2016 20:43:03

Was paper questionnaire used? _____

Reason not done _____

Date of assessment

DD/MMM/YYYY _____

Time of assessment _____

If you have smoked since you last completed this
questionnaire,
please mark what best represents how smoking made
you feel

Did smoking make you ☒ nauseous?

Response _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 30

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper) (11)

Data signed: (hcoleman1) 18 Jun 2015 21:10:23

Generated On: 20 Jul 2016 20:43:03

Was paper questionnaire used? _____

Reason not done _____

Date of assessment

DD/MMM/YYYY _____

Time of assessment _____

If you have smoked since you last completed this
questionnaire,
please mark what best represents how smoking made
you feel

Did smoking immediately ☒
relieve your craving for a
cigarette?

Response _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 30

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper) (12)

Data signed: (hcoleman1) 18 Jun 2015 21:10:23

Generated On: 20 Jul 2016 20:43:03

Was paper questionnaire used? _____

Reason not done _____

Date of assessment

DD/MMM/YYYY _____

Time of assessment _____

If you have smoked since you last completed this
questionnaire,
please mark what best represents how smoking made
you feel

Did you enjoy smoking? ☒

Response _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 30

Form: Risk Markers(CCLS) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:51:59

Generated On: 20 Jul 2016 20:43:03

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	1202
----------------------	------

Subject Sex	M
-------------	---

Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	DAY30
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	V969071
--------------	---------

Actual Collection Date	2014 04 15
------------------------	------------

Actual Collection Time	06:40
------------------------	-------

Specimen Condition	
--------------------	--

Battery ID	RC6871
------------	--------

Battery Name	HDL
--------------	-----

Lab Test ID	RCT1684
-------------	---------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 30

Form: Risk Markers(CCLS) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:51:59


Generated On: 20 Jul 2016 20:43:03

Lab Test Name

DIRECT HDL-C 3RD
GENERATION

Test ID

Test Status

Done 

Reported Text Result

57

Reported Numeric Result

57

Reference Range low

29

Reference Range high

62

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: 1202**

Folder: Day 30

Form: Risk Markers(CCLS) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:51:59

Generated On: 20 Jul 2016 20:43:03

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: 1202**

Folder: Day 30

Form: Risk Markers(CCLS) (2)

Data signed: (hfarmer1) 27 Mar 2015 14:51:59

Generated On: 20 Jul 2016 20:43:03

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	1202
----------------------	------

Subject Sex	M
-------------	---

Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	DAY30
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	V969071
--------------	---------

Actual Collection Date	2014 04 15
------------------------	------------

Actual Collection Time	06:40
------------------------	-------

Specimen Condition	
--------------------	--

Battery ID	SC3249
------------	--------

Battery Name	HS-CRP
--------------	--------

Lab Test ID	SCT1528
-------------	---------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 30

Form: Risk Markers(CCLS) (2)

Data signed: (hfarmer1) 27 Mar 2015 14:51:59


Generated On: 20 Jul 2016 20:43:03

Lab Test Name

C-REACTIVE PROTEIN (N
HS)-QT

Test ID

Test Status

Done 

Reported Text Result

0.098

Reported Numeric Result

0.098

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: 1202**

Folder: Day 30

Form: Risk Markers(CCLS) (2)

Data signed: (hfarmer1) 27 Mar 2015 14:51:59

Generated On: 20 Jul 2016 20:43:03

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: 1202**

Folder: Day 30

Form: Risk Markers(CCLS) (3)

Data signed: (hfarmer1) 27 Mar 2015 14:51:59

Generated On: 20 Jul 2016 20:43:03

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	1202
----------------------	------

Subject Sex	M
-------------	---

Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	DAY30
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	V969071
--------------	---------

Actual Collection Date	2014 04 15
------------------------	------------

Actual Collection Time	06:40
------------------------	-------

Specimen Condition	
--------------------	--

Battery ID	CG267
------------	-------

Battery Name	FIBRINOGEN
--------------	------------

Lab Test ID	CGT285
-------------	--------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 30

Form: Risk Markers(CCLS) (3)

Data signed: (hfarmer1) 27 Mar 2015 14:51:59

Generated On: 20 Jul 2016 20:43:03

Lab Test Name	FIBRINOGEN
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	315
Reported Numeric Result	315
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: 1202**

Folder: Day 30

Form: Risk Markers(CCLS) (3)

Data signed: (hfarmer1) 27 Mar 2015 14:51:59

Generated On: 20 Jul 2016 20:43:03

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: 1202**

Folder: Day 30

Form: Risk Markers(CCLS) (4)

Data signed: (hfarmer1) 27 Mar 2015 14:51:59

Generated On: 20 Jul 2016 20:43:03

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	1202
----------------------	------

Subject Sex	M
-------------	---

Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	DAY30
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	V969071
--------------	---------

Actual Collection Date	2014 04 15
------------------------	------------

Actual Collection Time	06:40
------------------------	-------

Specimen Condition	
--------------------	--

Battery ID	CN236
------------	-------

Battery Name	HOMOCYSTEINE
--------------	--------------

Lab Test ID	CNT145
-------------	--------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 30

Form: Risk Markers(CCLS) (4)

Data signed: (hfarmer1) 27 Mar 2015 14:51:59

Generated On: 20 Jul 2016 20:43:03

Lab Test Name	HOMOCYSTEINE, EDTAPL
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	9.11
Reported Numeric Result	9.11
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: 1202**

Folder: Day 30

Form: Risk Markers(CCLS) (4)

Data signed: (hfarmer1) 27 Mar 2015 14:51:59

Generated On: 20 Jul 2016 20:43:03

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: 1202

Folder: Day 30

Form: Risk Markers(CCLS) (5)

Data signed: (hfarmer1) 27 Mar 2015 14:51:59

Generated On: 20 Jul 2016 20:43:03

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	1202
----------------------	------

Subject Sex	M
-------------	---

Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	DAY30
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	V969071
--------------	---------

Actual Collection Date	2014 04 15
------------------------	------------

Actual Collection Time	06:40
------------------------	-------

Specimen Condition	
--------------------	--

Battery ID	IM2293
------------	--------

Battery Name	SICAM-1
--------------	---------

Lab Test ID	IMT1768
-------------	---------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 30

Form: Risk Markers(CCLS) (5)

Data signed: (hfarmer1) 27 Mar 2015 14:51:59

Generated On: 20 Jul 2016 20:43:03

Lab Test Name	SICAM-1-RUO
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	131.9
Reported Numeric Result	131.9
Reference Range low	98.8
Reference Range high	320.0
Range Units	NG/ML
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 30

Form: Risk Markers(CCLS) (5)

Data signed: (hfarmer1) 27 Mar 2015 14:51:59

Generated On: 20 Jul 2016 20:43:03

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: 1202**

Folder: Day 30

Form: Risk Markers(CCLS) (6)

Data signed: (hfarmer1) 27 Mar 2015 14:51:59

Generated On: 20 Jul 2016 20:43:03

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	1202
----------------------	------

Subject Sex	M
-------------	---

Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	DAY30
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	V969071
--------------	---------

Actual Collection Date	2014 04 15
------------------------	------------

Actual Collection Time	06:40
------------------------	-------

Specimen Condition	
--------------------	--

Battery ID	RC9267
------------	--------

Battery Name	LDL
--------------	-----

Lab Test ID	RCT2394
-------------	---------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 30

Form: Risk Markers(CCLS) (6)

Data signed: (hfarmer1) 27 Mar 2015 14:51:59

Generated On: 20 Jul 2016 20:43:03

Lab Test Name	DIRECT LDL-C 2ND GEN (-70)
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Test ID	<hr/>
---------	-------

Test Status	Done 
-------------	--

Reported Text Result	127
----------------------	-----

Reported Numeric Result	127
-------------------------	-----

Reference Range low	81
---------------------	----

Reference Range high	189
----------------------	-----

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: 1202**

Folder: Day 30

Form: Risk Markers(CCLS) (6)

Data signed: (hfarmer1) 27 Mar 2015 14:51:59

Generated On: 20 Jul 2016 20:43:03

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: 1202**

Folder: Day 30

Form: Biomarker-Urine (CEMA, HPMA, HBMA)

Data signed: (hfarmer1) 27 Mar 2015 14:52:17

Generated On: 20 Jul 2016 20:43:03

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 30

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:52:17

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05112450002283
Analyte	HPMA
Sample type	URINE
Result	.
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	30
Celerion Study Number	AA99128-03
Date of Collection	2014-APR-14
Timepoint-minutes	
Urine Start Day	30

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 30

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:52:17

Generated On: 20 Jul 2016 20:43:03

Urine End Day

31

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 30

Form: Biomarker-Urine (CEMA, HPMa, HBMA) (2)

Data signed: (hfarmer1) 27 Mar 2015 14:52:17

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05112450002283
Analyte	CEMA
Sample type	URINE
Result	.
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	30
Celerion Study Number	AA99128-03
Date of Collection	2014-APR-14
Timepoint-minutes	
Urine Start Day	30

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 30

Form: Biomarker-Urine (CEMA, HPMa, HBMA) (2)

Data signed: (hfarmer1) 27 Mar 2015 14:52:17

Generated On: 20 Jul 2016 20:43:03

Urine End Day

31

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 30

Form: Biomarker-Urine (CEMA, HPMa, HBMA) (3)

Data signed: (hfarmer1) 27 Mar 2015 14:52:17

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05112450002283
----------------	----------------

Analyte	HBMA
---------	------

Sample type	URINE
-------------	-------

Result	.
--------	---

Result Unit	NG/ML
-------------	-------

Lab Status	OTHER
------------	-------

Sample comment	ANALYSIS NOT REQUIRED
----------------	-----------------------

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	30
--------------	----

Celerion Study Number	AA99128-03
-----------------------	------------

Date of Collection	2014-APR-14
--------------------	-------------

Timepoint-minutes	
-------------------	--

Urine Start Day	30
-----------------	----

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 30

Form: Biomarker-Urine (CEMA, HPMa, HBMA) (3)

Data signed: (hfarmer1) 27 Mar 2015 14:52:17

Generated On: 20 Jul 2016 20:43:03

Urine End Day

31

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 30

Form: Biomarker-Urine (NNN, NNAL)

Data signed: (hfarmer1) 27 Mar 2015 14:52:17

Generated On: 20 Jul 2016 20:43:03

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 30

Form: Biomarker-Urine (NNN, NNAL) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:52:17

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05112460002726
Analyte	NNAL
Sample type	URINE
Result	.
Result Unit	PG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	30
Celerion Study Number	AA99128-04
Date of Collection	2014-APR-14
Timepoint-minutes	
Urine Start Day	30

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 30

Form: Biomarker-Urine (NNN, NNAL) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:52:17

Generated On: 20 Jul 2016 20:43:03

Urine End Day

31

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 30

Form: Biomarker-Urine (NNN, NNAL) (2)

Data signed: (hfarmer1) 27 Mar 2015 14:52:17

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05112460002726
Analyte	NNN
Sample type	URINE
Result	.
Result Unit	PG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	30
Celerion Study Number	AA99128-04
Date of Collection	2014-APR-14
Timepoint-minutes	
Urine Start Day	30

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 30

Form: Biomarker-Urine (NNN, NNAL) (2)

Data signed: (hfarmer1) 27 Mar 2015 14:52:17

Generated On: 20 Jul 2016 20:43:03

Urine End Day

31

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 30

Form: Biomarker-Urine (HEMA)

Data signed: (hfarmer1) 27 Mar 2015 14:52:17

Generated On: 20 Jul 2016 20:43:03

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 30

Form: Biomarker-Urine (HEMA) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:52:17

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05112470001362
Analyte	HEMA
Sample type	URINE
Result	1.04
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	30
Celerion Study Number	AA99128-05
Date of Collection	2014-APR-14
Timepoint-minutes	
Urine Start Day	30

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 30

Form: Biomarker-Urine (HEMA) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:52:17

Generated On: 20 Jul 2016 20:43:03

Urine End Day

31

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 30

Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)

Data signed: (hfarmer1) 27 Mar 2015 14:52:17

Generated On: 20 Jul 2016 20:43:03

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 30

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(1)**

Data signed: (hfarmer1) 27 Mar 2015 14:52:17

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05112550000262
Analyte	COT
Sample type	URINE
Result	41.2
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	30
Celerion Study Number	AA99128-13
Date of Collection	2014-APR-14
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 30

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(1)**

Data signed: (hfarmer1) 27 Mar 2015 14:52:17

Generated On: 20 Jul 2016 20:43:03

Urine Start Day	30
<hr/>	
Urine End Day	31
<hr/>	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 30

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(2)**

Data signed: (hfarmer1) 27 Mar 2015 14:52:17

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05112550000262
Analyte	COT-GLUC
Sample type	URINE
Result	117
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	30
Celerion Study Number	AA99128-13
Date of Collection	2014-APR-14
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 30

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(2)**

Data signed: (hfarmer1) 27 Mar 2015 14:52:17

Generated On: 20 Jul 2016 20:43:03

Urine Start Day	30
<hr/>	
Urine End Day	31
<hr/>	

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1202

Folder: Day 30

Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc) (3)

Data signed: (hfarmer1) 27 Mar 2015 14:52:17

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05112550000262
Analyte	NIC
Sample type	URINE
Result	BLQ<(10.0)
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	30
Celerion Study Number	AA99128-13
Date of Collection	2014-APR-14
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 30

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(3)**

Data signed: (hfarmer1) 27 Mar 2015 14:52:17

Generated On: 20 Jul 2016 20:43:03

Urine Start Day	30
<hr/>	
Urine End Day	31
<hr/>	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 30

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(4)**

Data signed: (hfarmer1) 27 Mar 2015 14:52:17

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05112550000262
----------------	----------------

Analyte	NIC-GLUC
---------	----------

Sample type	URINE
-------------	-------

Result	BLQ<(10.0)
--------	------------

Result Unit	NG/ML
-------------	-------

Lab Status	OTHER
------------	-------

Sample comment	ANALYZED IN ERROR
----------------	-------------------

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	30
--------------	----

Celerion Study Number	AA99128-13
-----------------------	------------

Date of Collection	2014-APR-14
--------------------	-------------

Timepoint-minutes	
-------------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 30

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(4)**

Data signed: (hfarmer1) 27 Mar 2015 14:52:17

Generated On: 20 Jul 2016 20:43:03

Urine Start Day	30
<hr/>	
Urine End Day	31
<hr/>	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 30

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(5)**

Data signed: (hfarmer1) 27 Mar 2015 14:52:17

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05112550000262
Analyte	THCOT
Sample type	URINE
Result	123
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	30
Celerion Study Number	AA99128-13
Date of Collection	2014-APR-14
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 30

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(5)**

Data signed: (hfarmer1) 27 Mar 2015 14:52:17

Generated On: 20 Jul 2016 20:43:03

Urine Start Day	30
-----------------	----

Urine End Day	31
---------------	----

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 30

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(6)**

Data signed: (hfarmer1) 27 Mar 2015 14:52:17

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05112550000262
Analyte	THCOT-GLUC
Sample type	URINE
Result	60.4
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	30
Celerion Study Number	AA99128-13
Date of Collection	2014-APR-14
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 30

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(6)**

Data signed: (hfarmer1) 27 Mar 2015 14:52:17

Generated On: 20 Jul 2016 20:43:03

Urine Start Day	30
<hr/>	
Urine End Day	31
<hr/>	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 30

Form: Biomarker-Urine (3-OH BaP)

Data signed: (hfarmer1) 27 Mar 2015 14:52:18

Generated On: 20 Jul 2016 20:43:03

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 30

Form: Biomarker-Urine (3-OH BaP) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:52:18

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05112490001362
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Analyte	3-OH BAP
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Sample type	URINE
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Result	.
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Result Unit	FG/ML
-------------	-------

Lab Status	OTHER
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Sample comment	ANALYSIS NOT REQUIRED
----------------	-----------------------

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	30
--------------	----

Celerion Study Number	AA99128-07
-----------------------	------------

Date of Collection	2014-APR-14
--------------------	-------------

Timepoint-minutes	
-------------------	--

Urine Start Day	30
-----------------	----

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 30

Form: Biomarker-Urine (3-OH BaP) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:52:18

Generated On: 20 Jul 2016 20:43:03

Urine End Day

31

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 30

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP)

Data signed: (hfarmer1) 27 Mar 2015 14:52:18

Generated On: 20 Jul 2016 20:43:03

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 30

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:52:18

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05112510001384
Analyte	1-NA
Sample type	URINE
Result	6.10
Result Unit	PG/ML
Lab Status	OTHER
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	30
Celerion Study Number	AA99128-09
Date of Collection	2014-APR-14
Timepoint-minutes	
Urine Start Day	30

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 30

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:52:18

Generated On: 20 Jul 2016 20:43:03

Urine End Day

31

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 30

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (2)

Data signed: (hfarmer1) 27 Mar 2015 14:52:18

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05112510001384
Analyte	2-NA
Sample type	URINE
Result	BLQ<(2.50)
Result Unit	PG/ML
Lab Status	OTHER
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	30
Celerion Study Number	AA99128-09
Date of Collection	2014-APR-14
Timepoint-minutes	
Urine Start Day	30

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 30

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (2)

Data signed: (hfarmer1) 27 Mar 2015 14:52:18

Generated On: 20 Jul 2016 20:43:03

Urine End Day

31

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 30

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (3)

Data signed: (hfarmer1) 27 Mar 2015 14:52:18

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05112510001384
Analyte	4-ABP
Sample type	URINE
Result	BLQ<(1.50)
Result Unit	PG/ML
Lab Status	OTHER
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	30
Celerion Study Number	AA99128-09
Date of Collection	2014-APR-14
Timepoint-minutes	
Urine Start Day	30

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 30

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (3)

Data signed: (hfarmer1) 27 Mar 2015 14:52:18

Generated On: 20 Jul 2016 20:43:03

Urine End Day

31

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 30

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (4)

Data signed: (hfarmer1) 27 Mar 2015 14:52:18

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05112510001384
Analyte	O-TOL
Sample type	URINE
Result	BLQ<(50.0)
Result Unit	PG/ML
Lab Status	OTHER
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	30
Celerion Study Number	AA99128-09
Date of Collection	2014-APR-14
Timepoint-minutes	
Urine Start Day	30

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 30

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (4)

Data signed: (hfarmer1) 27 Mar 2015 14:52:18

Generated On: 20 Jul 2016 20:43:03

Urine End Day

31

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 30

Form: Biomarker-Urine (11-dTXb2)

Data signed: (hfarmer1) 27 Mar 2015 14:52:17

Generated On: 20 Jul 2016 20:43:03

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 30

Form: Biomarker-Urine (11-dTXb2) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:52:17

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05112530000432
Analyte	11-DTXB2
Sample type	URINE
Result	.
Result Unit	PG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	30
Celerion Study Number	AA99128-11
Date of Collection	2014-APR-14
Timepoint-minutes	
Urine Start Day	30

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 30

Form: Biomarker-Urine (11-dTXb2) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:52:17

Generated On: 20 Jul 2016 20:43:03

Urine End Day

31

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 30

Form: Biomarker-Urine (iPF2a-III)

Data signed: (hfarmer1) 27 Mar 2015 14:52:17

Generated On: 20 Jul 2016 20:43:03

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 30

Form: Biomarker-Urine (iPF2a-III) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:52:17

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05112540000425
Analyte	IPF2A-III
Sample type	URINE
Result	163
Result Unit	PG/ML
Lab Status	OTHER
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	30
Celerion Study Number	AA99128-12
Date of Collection	2014-APR-14
Timepoint-minutes	
Urine Start Day	30

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 30

Form: Biomarker-Urine (iPF2a-III) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:52:17

Generated On: 20 Jul 2016 20:43:03

Urine End Day

31

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 30

Form: Biomarker-Urine (1-OHP)

Data signed: (hfarmer1) 27 Mar 2015 14:52:18

Generated On: 20 Jul 2016 20:43:03

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 30

Form: Biomarker-Urine (1-OHP) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:52:18

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05115190001615
Analyte	1-OHP
Sample type	URINE
Result	.
Result Unit	PG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	30
Celerion Study Number	AA99598-03
Date of Collection	2014-APR-14
Timepoint-minutes	
Urine Start Day	30

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 30

Form: Biomarker-Urine (1-OHP) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:52:18

Generated On: 20 Jul 2016 20:43:03

Urine End Day

31

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 30

Form: Biomarker-Urine (SPMA, SBMA)

Data signed: (hfarmer1) 27 Mar 2015 14:52:17

Generated On: 20 Jul 2016 20:43:03

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 30

Form: Biomarker-Urine (SPMA, SBMA) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:52:17

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05115170001593
Analyte	SBMA
Sample type	URINE
Result	.
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	30
Celerion Study Number	AA99598-01
Date of Collection	2014-APR-14
Timepoint-minutes	
Urine Start Day	30

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 30

Form: Biomarker-Urine (SPMA, SBMA) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:52:17

Generated On: 20 Jul 2016 20:43:03

Urine End Day

31

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 30

Form: Biomarker-Urine (SPMA, SBMA) (2)

Data signed: (hfarmer1) 27 Mar 2015 14:52:17

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05115170001593
Analyte	SPMA
Sample type	URINE
Result	.
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	30
Celerion Study Number	AA99598-01
Date of Collection	2014-APR-14
Timepoint-minutes	
Urine Start Day	30

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 30

Form: Biomarker-Urine (SPMA, SBMA) (2)

Data signed: (hfarmer1) 27 Mar 2015 14:52:17

Generated On: 20 Jul 2016 20:43:03

Urine End Day

31

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 30

Form: Biomarker-Urine (MHBMA)

Data signed: (hfarmer1) 27 Mar 2015 14:52:17

Generated On: 20 Jul 2016 20:43:03

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 30

Form: Biomarker-Urine (MHBMA) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:52:17

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05115180001615
Analyte	MHBMA
Sample type	URINE
Result	.
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	30
Celerion Study Number	AA99598-02
Date of Collection	2014-APR-14
Timepoint-minutes	
Urine Start Day	30

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 30

Form: Biomarker-Urine (MHBMA) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:52:17

Generated On: 20 Jul 2016 20:43:03

Urine End Day

31

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 30

Form: Biomarker-Urine (Creatinine)

Data signed: (hfarmer1) 27 Mar 2015 14:52:18

Generated On: 20 Jul 2016 20:43:03

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 30

Form: Biomarker-Urine (Creatinine) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:52:18

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05115160001362
Analyte	CREATININE
Sample type	URINE
Result	.
Result Unit	MG/DL
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	SPECTROPHOTOMETRIC
Planned time point (Hour)	0
Day of Visit	30
Celerion Study Number	AA99128-14
Date of Collection	2014-APR-14
Timepoint-minutes	
Urine Start Day	30

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 30

Form: Biomarker-Urine (Creatinine) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:52:18

Generated On: 20 Jul 2016 20:43:03

Urine End Day

31

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 30

Form: Biomarker-Plasma (Nic, Cot, tHCot)

Data signed: (hfarmer1) 27 Mar 2015 14:52:17

Generated On: 20 Jul 2016 20:43:03

Sample type

PLASMA

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 30

Form: Biomarker-Plasma (Nic, Cot, tHCot) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:52:17

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05112440000238
Analyte	COT
Sample type	PLASMA
Result	8.03
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	30
Celerion Study Number	AA99128-02
Date of Collection	2014-APR-14
Timepoint-minutes	0
Urine Start Day	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 30

Form: Biomarker-Plasma (Nic, Cot, tHCot) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:52:17

Generated On: 20 Jul 2016 20:43:03

Urine End Day

30

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 30

Form: Biomarker-Plasma (Nic, Cot, tHCot) (2)

Data signed: (hfarmer1) 27 Mar 2015 14:52:17

Generated On: 20 Jul 2016 20:43:03

Sample Barcode	05112440000238
Analyte	NIC
Sample type	PLASMA
Result	0.234
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	30
Celerion Study Number	AA99128-02
Date of Collection	2014-APR-14
Timepoint-minutes	0
Urine Start Day	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 30

Form: Biomarker-Plasma (Nic, Cot, tHCot) (2)

Data signed: (hfarmer1) 27 Mar 2015 14:52:17

Generated On: 20 Jul 2016 20:43:03

Urine End Day

30

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Day 60

Form: Date of Visit

Data signed: (hcoleman1) 18 Jun 2015 21:10:24

Generated On: 20 Jul 2016 20:43:03

Visit Not Done	True
----------------	------

If Not Done, Specify Reason

SUBJECT DID NOT RETURN
FOR DAY 60 VISIT SITE MADE
NUMEROUS ATTEMPTS TO
CONTACT SUBJECT HE
COMPLETED AN EARLY TERM
VISIT ON 12-JUN-2014

Date of Visit	
---------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Discharge (Ambulatory)

Form: Date of Discharge

Data signed: (hfarmer1) 27 Mar 2015 14:52:26

Generated On: 20 Jul 2016 20:43:03

Date of Visit

12 JUN 2014
DD/MMM/YYYY

Discharge Time

13:32
hour:min 24-hour clock

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Discharge (Ambulatory)

Form: Vital Signs

Data signed: (hfarmer1) 27 Mar 2015 14:52:26

Generated On: 20 Jul 2016 20:43:03

Were Vitals Signs assessed? Yes ☒

If No, please specify the reason: _____

Has the subject smoked within 15 minutes prior to assessment Yes ☒

Date of assessment 12 JUN 2014
DD/MMM/YYYY

Time of assessment 13:06
hour:min 24-hour clock

Pulse rate 90
beats per minute

Respiratory rate 18
breaths per minute

Blood Pressure (systolic) 139
mmHg

Blood Pressure (diastolic) 85
mmHg

Vital Signs Position of Subject Supine ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Discharge (Ambulatory)

Form: Advice on the risk of smoking and debriefing

Data signed: (hfarmer1) 27 Mar 2015 14:52:26

Generated On: 20 Jul 2016 20:43:03

Date	12 JUN 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: 1202**

Folder: Discharge (Ambulatory)

Form: Physical Examination

Data signed: (hfarmer1) 27 Mar 2015 14:52:23

Generated On: 20 Jul 2016 20:43:03

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of Assessment

12 JUN 2014
DD/MMM/YYYY

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Discharge (Ambulatory)

Form: Physical Examination (1)

Data signed: (hfarmer1) 27 Mar 2015 14:52:23

Generated On: 20 Jul 2016 20:43:03

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of Assessment 12 JUN 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: 1202**

Folder: Discharge (Ambulatory)

Form: Physical Examination (2)

Data signed: (hfarmer1) 27 Mar 2015 14:52:23

Generated On: 20 Jul 2016 20:43:03

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of Assessment

12 JUN 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: 1202**

Folder: Discharge (Ambulatory)

Form: Physical Examination (3)

Data signed: (hfarmer1) 27 Mar 2015 14:52:23

Generated On: 20 Jul 2016 20:43:03

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of Assessment 12 JUN 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: 1202**

Folder: Discharge (Ambulatory)

Form: Physical Examination (4)

Data signed: (hfarmer1) 27 Mar 2015 14:52:23

Generated On: 20 Jul 2016 20:43:03

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of Assessment 12 JUN 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: 1202**

Folder: Discharge (Ambulatory)

Form: Physical Examination (5)

Data signed: (hfarmer1) 27 Mar 2015 14:52:23

Generated On: 20 Jul 2016 20:43:03

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of Assessment 12 JUN 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: 1202**

Folder: Discharge (Ambulatory)

Form: Physical Examination (6)

Data signed: (hfarmer1) 27 Mar 2015 14:52:23

Generated On: 20 Jul 2016 20:43:03

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of Assessment 12 JUN 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: 1202**

Folder: Discharge (Ambulatory)

Form: Physical Examination (7)

Data signed: (hfarmer1) 27 Mar 2015 14:52:23

Generated On: 20 Jul 2016 20:43:03

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of Assessment 12 JUN 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: 1202**

Folder: Discharge (Ambulatory)

Form: Physical Examination (8)

Data signed: (hfarmer1) 27 Mar 2015 14:52:23

Generated On: 20 Jul 2016 20:43:03

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of Assessment 12 JUN 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: 1202**

Folder: Discharge (Ambulatory)

Form: Physical Examination (9)

Data signed: (hfarmer1) 27 Mar 2015 14:52:23

Generated On: 20 Jul 2016 20:43:03

Was the physical examination performed? Yes ☐

If No, please specify the reason: _____

Date of Assessment 12 JUN 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: 1202**

Folder: Discharge (Ambulatory)

Form: Physical Examination (10)

Data signed: (hfarmer1) 27 Mar 2015 14:52:23

Generated On: 20 Jul 2016 20:43:03

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of Assessment 12 JUN 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: 1202**

Folder: Discharge (Ambulatory)

Form: Physical Examination (11)

Data signed: (hfarmer1) 27 Mar 2015 14:52:23

Generated On: 20 Jul 2016 20:43:03

Was the physical examination performed? Yes ☐

If No, please specify the reason: _____

Date of Assessment 12 JUN 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: 1202**

Folder: Discharge (Ambulatory)

Form: Physical Examination (12)

Data signed: (hfarmer1) 27 Mar 2015 14:52:23

Generated On: 20 Jul 2016 20:43:03

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of Assessment 12 JUN 2014
DD/MMM/YYYY

System Musculoskeletal ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Discharge (Ambulatory)

Form: Physical Examination (13)

Data signed: (hfarmer1) 27 Mar 2015 14:52:23

Generated On: 20 Jul 2016 20:43:03

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of Assessment 12 JUN 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: 1202**

Folder: Discharge (Ambulatory)

Form: Physical Examination (14)

Data signed: (hfarmer1) 27 Mar 2015 14:52:23

Generated On: 20 Jul 2016 20:43:03

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of Assessment 12 JUN 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: 1202**

Folder: Discharge (Ambulatory)

Form: Physical Examination (15)

Data signed: (hfarmer1) 27 Mar 2015 14:52:23

Generated On: 20 Jul 2016 20:43:03

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of Assessment

12 JUN 2014
DD/MMM/YYYY

System

Other ☒

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: 1202**

Folder: Discharge (Ambulatory)

Form: Physical Examination (16)

Data signed: (hfarmer1) 27 Mar 2015 14:52:23

Generated On: 20 Jul 2016 20:43:03

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of Assessment

12 JUN 2014
DD/MMM/YYYY

System

Other ☒

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: 1202**

Folder: Discharge (Ambulatory)

Form: Physical Examination (17)

Data signed: (hfarmer1) 27 Mar 2015 14:52:23

Generated On: 20 Jul 2016 20:43:03

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of Assessment 12 JUN 2014
DD/MMM/YYYY

System Other ☒

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: 1202**

Folder: Discharge (Ambulatory)

Form: Physical Examination (18)

Data signed: (hfarmer1) 27 Mar 2015 14:52:23

Generated On: 20 Jul 2016 20:43:03

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of Assessment

12 JUN 2014
DD/MMM/YYYY

System

Other ☒

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: 1202**

Folder: Discharge (Ambulatory)

Form: Physical Examination (19)

Data signed: (hfarmer1) 27 Mar 2015 14:52:23

Generated On: 20 Jul 2016 20:43:03

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of Assessment

12 JUN 2014
DD/MMM/YYYY

System

Other ☒

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: 1202**

Folder: Discharge (Ambulatory)

Form: Weight

Data signed: (hfarmer1) 27 Mar 2015 14:52:26

Generated On: 20 Jul 2016 20:43:03

Measurement(s) assessed?

Yes ☒

If No, please specify the reason: _____

Date of Assessment

12 JUN 2014
DD/MMM/YYYY

Time of assessment

13:09
hour:min 24-hour clock

Weight

69.4
kg

Waist circumference _____

BMI

22.9

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Discharge (Ambulatory)

Form: ECG (12-Lead Standard)

Data signed: (hfarmer1) 27 Mar 2015 14:52:23

Generated On: 20 Jul 2016 20:43:03

Was the ECG performed?

Yes ☒

If No, please specify the reason: _____

Date of Assessment

12 JUN 2014
DD/MMM/YYYY

Position

Supine ☒

Heart Rate

95
beats per minute

QRS Interval

100
msec

QT Interval

365
msec

QTcB Interval

460
msec

PR Interval

139
msec

QTcF Interval

426
msec

Interpretation

Normal ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Discharge (Ambulatory)

Form: ECG (12-Lead Standard)

Data signed: (hfarmer1) 27 Mar 2015 14:52:23

Generated On: 20 Jul 2016 20:43:03

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: 1202**

Folder: Discharge (Ambulatory)

Form: Gas Transfer

Data signed: (hcoleman1) 18 Jun 2015 21:10:24

Generated On: 20 Jul 2016 20:43:03

Was the Gas Transfer performed?

No ☒

If No, please specify the reason:

TEST PERFORMED BUT THEY
WERE NOT RESULTED

Category

Position

SITTING

Date of assessment
DD/MMM/YYYY

Time of assessment

DLCO value

KCO value

DLCO/VA value

Interpretation

If Abnormal, Clinical Significance

If Not Clinically Significant or Clinically Significant, Please
specify the finding(s)

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Discharge (Ambulatory)

Form: Lung Volume Measurements

Data signed: (hcoleman1) 18 Jun 2015 21:10:24

Generated On: 20 Jul 2016 20:43:03

Were the Lung Volume Measurements performed?

No ☒

If No, please specify the reason:

TEST PERFORMED BUT THEY
WERE NOT RESULTED

Category

Position

SITTING

Date of assessment
DD/MMM/YYYY

Time of assessment

VC value

TLC value

IC value

FRC value

Interpretation

If Abnormal, Clinical Significance

If Not Clinically Significant or Clinically Significant, Please
specify the finding(s)

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1202

Folder: Discharge (Ambulatory)

Form: Spirometry with a short-acting bronchodilator

Data signed: (hcoleman1) 18 Jun 2015 21:10:25

Generated On: 20 Jul 2016 20:43:03

Was the Spirometry with a short-acting bronchodilator performed?

No ☒

If No, please specify the reason:

TEST PERFORMED BUT THEY WERE NOT RESULTED

Category

With short-acting bronchodilator ☒

Position

SITTING

Date of assessment
DD/MMM/YYYY

Time of assessment

Name of bronchodilator

Dose

Predicted FVC value

Best measured FVC value

Percent of predicted FVC value

Best measured FEV1 value

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Discharge (Ambulatory)

Form: Spirometry with a short-acting bronchodilator

Data signed: (hcoleman1) 18 Jun 2015 21:10:25

Generated On: 20 Jul 2016 20:43:03

Predicted FEV1 value

Percent of predicted FEV1 value

Calculated ratio between FEV1/FVC

MEF 25/75 value

Interpretation

If Abnormal, Clinical Significance

If Not Clinically Significant or Clinically Significant, Please
specify the finding(s)

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Discharge (Ambulatory)

Form: Haematology

Data signed: (hfarmer1) 27 Mar 2015 14:52:23

Generated On: 20 Jul 2016 20:43:03

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: 1202**

Folder: Discharge (Ambulatory)

Form: Clinical Chemistry

Data signed: (hfarmer1) 27 Mar 2015 14:52:23

Generated On: 20 Jul 2016 20:43:03

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: 1202**

Folder: Discharge (Ambulatory)

Form: Urine analysis

Data signed: (hfarmer1) 27 Mar 2015 14:52:23

Generated On: 20 Jul 2016 20:43:03

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: 1202**

Folder: Discharge (Ambulatory)

Form: CoHb Blood Sample <prior to gas transfer and product>

Data signed: (hfarmer1) 27 Mar 2015 14:52:23

Generated On: 20 Jul 2016 20:43:03

Not Done	True
----------	------

If Not Done, please specify the reason:	NOT NEEDED FOR EARLY TERMINATION VISIT PER PROTOCOL
---	---

Date DD/MMM/YYYY	
---------------------	--

Timepoint	Prior to gas transfer <input checked="" type="radio"/> assessment and prior to product use
-----------	--

Time hour:min 24-hour clock	
--------------------------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (1)

Data signed: (hfarmer1) 27 Mar 2015 14:52:26

Generated On: 20 Jul 2016 20:43:03

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	M
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Subject Date of Birth	(b) (6)
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	X759342
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Actual Collection Date	2014 06 12
------------------------	------------

Actual Collection Time	13:22
------------------------	-------

Specimen Condition	<hr/>
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Battery ID	RC1029
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Battery Name	TRIGLYCERIDES
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Lab Test ID	RCT19
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1202

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (1)

Data signed: (hfarmer1) 27 Mar 2015 14:52:26

Generated On: 20 Jul 2016 20:43:03

Lab Test Name	TRIGLYCERIDES (GPO)
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	76
Reported Numeric Result	76
Reference Range low	50
Reference Range high	321
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: 1202**

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (1)

Data signed: (hfarmer1) 27 Mar 2015 14:52:26

Generated On: 20 Jul 2016 20:43:03

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (2)

Data signed: (hfarmer1) 27 Mar 2015 14:52:26

Generated On: 20 Jul 2016 20:43:03

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6)

Visit Name _____

Visit Type Scheduled ☒

Accession ID X759342

Actual Collection Date 2014 06 12

Actual Collection Time 13:22

Specimen Condition _____

Battery ID RC1092

Battery Name FASTING GLUCOSE

Lab Test ID RCT142

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1202

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (2)

Data signed: (hfarmer1) 27 Mar 2015 14:52:26

Generated On: 20 Jul 2016 20:43:03

Lab Test Name	FASTING GLUCOSE
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	100
Reported Numeric Result	100
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: 1202**

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (2)

Data signed: (hfarmer1) 27 Mar 2015 14:52:26

Generated On: 20 Jul 2016 20:43:03

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (3)

Data signed: (hfarmer1) 27 Mar 2015 14:52:26

Generated On: 20 Jul 2016 20:43:03

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6)

Visit Name _____

Visit Type Scheduled ☒

Accession ID X759342

Actual Collection Date 2014 06 12

Actual Collection Time 13:22

Specimen Condition _____

Battery ID RC272

Battery Name TOTAL CHOLESTEROL

Lab Test ID RCT20

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (3)

Data signed: (hfarmer1) 27 Mar 2015 14:52:26


Generated On: 20 Jul 2016 20:43:03

Lab Test Name

CHOLESTEROL (HIGH
PERFORMANCE)

Test ID

Test Status

Done 

Reported Text Result

210

Reported Numeric Result

210

Reference Range low

150

Reference Range high

264

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: 1202**

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (3)

Data signed: (hfarmer1) 27 Mar 2015 14:52:26

Generated On: 20 Jul 2016 20:43:03

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: 1202**

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (4)

Data signed: (hfarmer1) 27 Mar 2015 14:52:26

Generated On: 20 Jul 2016 20:43:03

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	M
-------------	---

Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	X759342
--------------	---------

Actual Collection Date	2014 06 12
------------------------	------------

Actual Collection Time	13:22
------------------------	-------

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: 1202**

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (4)

Data signed: (hfarmer1) 27 Mar 2015 14:52:26

Generated On: 20 Jul 2016 20:43:03

Lab Test Name	TOTAL BILIRUBIN
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	1.6
Reported Numeric Result	1.6
Reference Range low	0.2
Reference Range high	1.2
Range Units	MG/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (4)

Data signed: (hfarmer1) 27 Mar 2015 14:52:26

Generated On: 20 Jul 2016 20:43:03

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: 1202**

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (5)

Data signed: (hfarmer1) 27 Mar 2015 14:52:26

Generated On: 20 Jul 2016 20:43:03

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
----------------------	-------

Subject Sex	M
-------------	---

Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	X759342
--------------	---------

Actual Collection Date	2014 06 12
------------------------	------------

Actual Collection Time	13:22
------------------------	-------

Specimen Condition	<hr/>
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Battery ID	RC9255
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Battery Name	CHEMISTRY PANEL
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Lab Test ID	RCT12
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1202

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (5)

Data signed: (hfarmer1) 27 Mar 2015 14:52:26

Generated On: 20 Jul 2016 20:43:03

Lab Test Name	TOTAL PROTEIN
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	7.5
Reported Numeric Result	7.5
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: 1202**

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (5)

Data signed: (hfarmer1) 27 Mar 2015 14:52:26

Generated On: 20 Jul 2016 20:43:03

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (6)

Data signed: (hfarmer1) 27 Mar 2015 14:52:26

Generated On: 20 Jul 2016 20:43:03

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	<hr/>
----------------------	-------

Subject Sex	M
-------------	---

Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	X759342
--------------	---------

Actual Collection Date	2014 06 12
------------------------	------------

Actual Collection Time	13:22
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	RC9255
------------	--------

Battery Name	CHEMISTRY PANEL
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Lab Test ID	RCT13
-------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (6)

Data signed: (hfarmer1) 27 Mar 2015 14:52:26

Generated On: 20 Jul 2016 20:43:03

Lab Test Name	ALBUMIN
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	4.6
Reported Numeric Result	4.6
Reference Range low	3.3
Reference Range high	4.9
Range Units	G/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (6)

Data signed: (hfarmer1) 27 Mar 2015 14:52:26

Generated On: 20 Jul 2016 20:43:03

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (7)

Data signed: (hfarmer1) 27 Mar 2015 14:52:26

Generated On: 20 Jul 2016 20:43:03

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6)

Visit Name _____

Visit Type Scheduled ☒

Accession ID X759342

Actual Collection Date 2014 06 12

Actual Collection Time 13:22

Specimen Condition _____

Battery ID RC9255

Battery Name CHEMISTRY PANEL

Lab Test ID RCT1407

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1202

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (7)

Data signed: (hfarmer1) 27 Mar 2015 14:52:26

Generated On: 20 Jul 2016 20:43:03

Lab Test Name	ALKALINE PHOSPHATASE
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	77
Reported Numeric Result	77
Reference Range low	31
Reference Range high	129
Range Units	U/L
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (7)

Data signed: (hfarmer1) 27 Mar 2015 14:52:26

Generated On: 20 Jul 2016 20:43:03

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (8)

Data signed: (hfarmer1) 27 Mar 2015 14:52:26

Generated On: 20 Jul 2016 20:43:03

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	<hr/>
----------------------	-------

Subject Sex	M
-------------	---

Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	X759342
--------------	---------

Actual Collection Date	2014 06 12
------------------------	------------

Actual Collection Time	13:22
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	RC9255
------------	--------

Battery Name	CHEMISTRY PANEL
--------------	-----------------

Lab Test ID	RCT1408
-------------	---------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1202

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (8)

Data signed: (hfarmer1) 27 Mar 2015 14:52:26

Generated On: 20 Jul 2016 20:43:03

Lab Test Name	LDH
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	130
Reported Numeric Result	130
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: 1202**

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (8)

Data signed: (hfarmer1) 27 Mar 2015 14:52:26

Generated On: 20 Jul 2016 20:43:03

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (9)

Data signed: (hfarmer1) 27 Mar 2015 14:52:26

Generated On: 20 Jul 2016 20:43:03

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	<hr/>
----------------------	-------

Subject Sex	M
-------------	---

Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	X759342
--------------	---------

Actual Collection Date	2014 06 12
------------------------	------------

Actual Collection Time	13:22
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	RC9255
------------	--------

Battery Name	CHEMISTRY PANEL
--------------	-----------------

Lab Test ID	RCT15
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1202

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (9)

Data signed: (hfarmer1) 27 Mar 2015 14:52:26

Generated On: 20 Jul 2016 20:43:03

Lab Test Name	SERUM SODIUM
Test ID	
Test Status	Done <input checked="" type="radio"/>
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: 1202**

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (9)

Data signed: (hfarmer1) 27 Mar 2015 14:52:26

Generated On: 20 Jul 2016 20:43:03

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (10)

Data signed: (hfarmer1) 27 Mar 2015 14:52:26

Generated On: 20 Jul 2016 20:43:03

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	M
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Subject Date of Birth	(b) (6)
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	X759342
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Actual Collection Date	2014 06 12
------------------------	------------

Actual Collection Time	13:22
------------------------	-------

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: 1202**

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (10)

Data signed: (hfarmer1) 27 Mar 2015 14:52:26

Generated On: 20 Jul 2016 20:43:03

Lab Test Name	SERUM POTASSIUM
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	4.1
Reported Numeric Result	4.1
Reference Range low	3.4
Reference Range high	5.4
Range Units	MEQ/L
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (10)

Data signed: (hfarmer1) 27 Mar 2015 14:52:26

Generated On: 20 Jul 2016 20:43:03

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (11)

Data signed: (hfarmer1) 27 Mar 2015 14:52:26

Generated On: 20 Jul 2016 20:43:03

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	M
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Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	X759342
--------------	---------

Actual Collection Date	2014 06 12
------------------------	------------

Actual Collection Time	13:22
------------------------	-------

Specimen Condition	<hr/>
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Battery ID	RC9255
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Battery Name	CHEMISTRY PANEL
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Lab Test ID	RCT29
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1202

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (11)

Data signed: (hfarmer1) 27 Mar 2015 14:52:26

Generated On: 20 Jul 2016 20:43:03

Lab Test Name	DIRECT BILIRUBIN
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	0.3
Reported Numeric Result	0.3
Reference Range low	0.0
Reference Range high	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: 1202**

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (11)

Data signed: (hfarmer1) 27 Mar 2015 14:52:26

Generated On: 20 Jul 2016 20:43:03

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (12)

Data signed: (hfarmer1) 27 Mar 2015 14:52:26

Generated On: 20 Jul 2016 20:43:03

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	M
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Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	X759342
--------------	---------

Actual Collection Date	2014 06 12
------------------------	------------

Actual Collection Time	13:22
------------------------	-------

Specimen Condition	<hr/>
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Battery ID	RC9255
------------	--------

Battery Name	CHEMISTRY PANEL
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Lab Test ID	RCT3
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1202

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (12)

Data signed: (hfarmer1) 27 Mar 2015 14:52:26

Generated On: 20 Jul 2016 20:43:03

Lab Test Name	GGT
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	29
Reported Numeric Result	29
Reference Range low	10
Reference Range high	61
Range Units	U/L
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (12)

Data signed: (hfarmer1) 27 Mar 2015 14:52:26

Generated On: 20 Jul 2016 20:43:03

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (13)

Data signed: (hfarmer1) 27 Mar 2015 14:52:26

Generated On: 20 Jul 2016 20:43:03

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	M
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Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	X759342
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Actual Collection Date	2014 06 12
------------------------	------------

Actual Collection Time	13:22
------------------------	-------

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: 1202**

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (13)

Data signed: (hfarmer1) 27 Mar 2015 14:52:26

Generated On: 20 Jul 2016 20:43:03

Lab Test Name	CREATININE (RATE BLANKED)
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Test ID	<hr/>
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Test Status	Done <input checked="" type="radio"/>
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Reported Text Result	1.0
----------------------	-----

Reported Numeric Result	1.0
-------------------------	-----

Reference Range low	0.5
---------------------	-----

Reference Range high	1.2
----------------------	-----

Range Units	MG/DL
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Conventional Text Result	<hr/>
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Conventional Numeric Result	<hr/>
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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: 1202**

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (13)

Data signed: (hfarmer1) 27 Mar 2015 14:52:26

Generated On: 20 Jul 2016 20:43:03

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (14)

Data signed: (hfarmer1) 27 Mar 2015 14:52:26

Generated On: 20 Jul 2016 20:43:03

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	M
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Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	X759342
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Actual Collection Date	2014 06 12
------------------------	------------

Actual Collection Time	13:22
------------------------	-------

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: 1202

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (14)

Data signed: (hfarmer1) 27 Mar 2015 14:52:26

Generated On: 20 Jul 2016 20:43:03

Lab Test Name	ALT (SGPT)
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	20
Reported Numeric Result	20
Reference Range low	6
Reference Range high	43
Range Units	U/L
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (14)

Data signed: (hfarmer1) 27 Mar 2015 14:52:26

Generated On: 20 Jul 2016 20:43:03

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (15)

Data signed: (hfarmer1) 27 Mar 2015 14:52:26

Generated On: 20 Jul 2016 20:43:03

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
----------------------	-------

Subject Sex	M
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Subject Date of Birth	(b) (6)
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	X759342
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Actual Collection Date	2014 06 12
------------------------	------------

Actual Collection Time	13:22
------------------------	-------

Specimen Condition	<hr/>
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Battery ID	RC9255
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Battery Name	CHEMISTRY PANEL
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Lab Test ID	RCT5
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1202

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (15)

Data signed: (hfarmer1) 27 Mar 2015 14:52:26

Generated On: 20 Jul 2016 20:43:03

Lab Test Name	AST (SGOT)
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	24
Reported Numeric Result	24
Reference Range low	11
Reference Range high	36
Range Units	U/L
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (15)

Data signed: (hfarmer1) 27 Mar 2015 14:52:26

Generated On: 20 Jul 2016 20:43:03

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (16)

Data signed: (hfarmer1) 27 Mar 2015 14:52:26

Generated On: 20 Jul 2016 20:43:03

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	M
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Subject Date of Birth	(b) (6)
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	X759342
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Actual Collection Date	2014 06 12
------------------------	------------

Actual Collection Time	13:22
------------------------	-------

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: 1202

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (16)

Data signed: (hfarmer1) 27 Mar 2015 14:52:26

Generated On: 20 Jul 2016 20:43:03

Lab Test Name	UREA NITROGEN
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	13
Reported Numeric Result	13
Reference Range low	4
Reference Range high	24
Range Units	MG/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (16)

Data signed: (hfarmer1) 27 Mar 2015 14:52:26

Generated On: 20 Jul 2016 20:43:03

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (17)

Data signed: (hfarmer1) 27 Mar 2015 14:52:26

Generated On: 20 Jul 2016 20:43:03

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	M
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Subject Date of Birth	(b) (6)
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	X759342
--------------	---------

Actual Collection Date	2014 06 12
------------------------	------------

Actual Collection Time	13:22
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Specimen Condition	<hr/>
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Battery ID	HM1604
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Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
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Lab Test ID	HMT10
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1202

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (17)

Data signed: (hfarmer1) 27 Mar 2015 14:52:26

Generated On: 20 Jul 2016 20:43:03

Lab Test Name	MONOCYTES
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	0.85
Reported Numeric Result	0.85
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: 1202**

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (17)

Data signed: (hfarmer1) 27 Mar 2015 14:52:26

Generated On: 20 Jul 2016 20:43:03

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (18)

Data signed: (hfarmer1) 27 Mar 2015 14:52:26

Generated On: 20 Jul 2016 20:43:03

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	M
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Subject Date of Birth	(b) (6)
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	X759342
--------------	---------

Actual Collection Date	2014 06 12
------------------------	------------

Actual Collection Time	13:22
------------------------	-------

Specimen Condition	<hr/>
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Battery ID	HM1604
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Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
--------------	-----------------------------------

Lab Test ID	HMT100
-------------	--------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1202

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (18)

Data signed: (hfarmer1) 27 Mar 2015 14:52:26

Generated On: 20 Jul 2016 20:43:03

Lab Test Name	MCH
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	27
Reported Numeric Result	27
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: 1202**

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (18)

Data signed: (hfarmer1) 27 Mar 2015 14:52:26

Generated On: 20 Jul 2016 20:43:03

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1202

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (19)

Data signed: (hfarmer1) 27 Mar 2015 14:52:26

Generated On: 20 Jul 2016 20:43:03

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
----------------------	-------

Subject Sex	M
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Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	X759342
--------------	---------

Actual Collection Date	2014 06 12
------------------------	------------

Actual Collection Time	13:22
------------------------	-------

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: 1202

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (19)

Data signed: (hfarmer1) 27 Mar 2015 14:52:26

Generated On: 20 Jul 2016 20:43:03

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: 1202**

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (19)

Data signed: (hfarmer1) 27 Mar 2015 14:52:26

Generated On: 20 Jul 2016 20:43:03

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1202

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (20)

Data signed: (hfarmer1) 27 Mar 2015 14:52:26

Generated On: 20 Jul 2016 20:43:03

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	M
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Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	X759342
--------------	---------

Actual Collection Date	2014 06 12
------------------------	------------

Actual Collection Time	13:22
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	HM1604
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Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
--------------	-----------------------------------

Lab Test ID	HMT11
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (20)

Data signed: (hfarmer1) 27 Mar 2015 14:52:26

Generated On: 20 Jul 2016 20:43:03

Lab Test Name	EOSINOPHILS
Test ID	
Test Status	Done <input type="checkbox"/>
Reported Text Result	0.11
Reported Numeric Result	0.11
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: 1202**

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (20)

Data signed: (hfarmer1) 27 Mar 2015 14:52:26

Generated On: 20 Jul 2016 20:43:03

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1202

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (21)

Data signed: (hfarmer1) 27 Mar 2015 14:52:26

Generated On: 20 Jul 2016 20:43:03

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	M
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Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	X759342
--------------	---------

Actual Collection Date	2014 06 12
------------------------	------------

Actual Collection Time	13:22
------------------------	-------

Specimen Condition	<hr/>
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Battery ID	HM1604
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Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
--------------	-----------------------------------

Lab Test ID	HMT12
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1202

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (21)

Data signed: (hfarmer1) 27 Mar 2015 14:52:26

Generated On: 20 Jul 2016 20:43:03

Lab Test Name	BASOPHILS
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	0.03
Reported Numeric Result	0.03
Reference Range low	0.00
Reference Range high	0.20
Range Units	X10^3/UL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (21)

Data signed: (hfarmer1) 27 Mar 2015 14:52:26

Generated On: 20 Jul 2016 20:43:03

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1202

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (22)

Data signed: (hfarmer1) 27 Mar 2015 14:52:26

Generated On: 20 Jul 2016 20:43:03

Transmission Type Cumulative ☒

Subject ID or Number

Subject Sex M

Subject Date of Birth (b) (6)

Visit Name

Visit Type Scheduled ☒

Accession ID X759342

Actual Collection Date 2014 06 12

Actual Collection Time 13:22

Specimen Condition

Battery ID HM1604

Battery Name HEMATOLOGY
&DIFFERENTIAL PANEL

Lab Test ID HMT13

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1202

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (22)

Data signed: (hfarmer1) 27 Mar 2015 14:52:26

Generated On: 20 Jul 2016 20:43:03

Lab Test Name	PLATELETS
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	302
Reported Numeric Result	302
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: 1202**

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (22)

Data signed: (hfarmer1) 27 Mar 2015 14:52:26

Generated On: 20 Jul 2016 20:43:03

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (23)

Data signed: (hfarmer1) 27 Mar 2015 14:52:26

Generated On: 20 Jul 2016 20:43:03

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	M
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Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	X759342
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Actual Collection Date	2014 06 12
------------------------	------------

Actual Collection Time	13:22
------------------------	-------

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: 1202

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (23)

Data signed: (hfarmer1) 27 Mar 2015 14:52:26

Generated On: 20 Jul 2016 20:43:03

Lab Test Name	NEUTROPHILS (%)
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	61.3
Reported Numeric Result	61.3
Reference Range low	40.5
Reference Range high	75.0
Range Units	%
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (23)

Data signed: (hfarmer1) 27 Mar 2015 14:52:26

Generated On: 20 Jul 2016 20:43:03

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (24)

Data signed: (hfarmer1) 27 Mar 2015 14:52:26

Generated On: 20 Jul 2016 20:43:03

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	M
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Subject Date of Birth	(b) (6)
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	X759342
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Actual Collection Date	2014 06 12
------------------------	------------

Actual Collection Time	13:22
------------------------	-------

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: 1202

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (24)

Data signed: (hfarmer1) 27 Mar 2015 14:52:26

Generated On: 20 Jul 2016 20:43:03

Lab Test Name	LYMPHOCYTES (%)
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	29.0
Reported Numeric Result	29.0
Reference Range low	15.4
Reference Range high	48.5
Range Units	%
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (24)

Data signed: (hfarmer1) 27 Mar 2015 14:52:26

Generated On: 20 Jul 2016 20:43:03

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (25)

Data signed: (hfarmer1) 27 Mar 2015 14:52:26

Generated On: 20 Jul 2016 20:43:03

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	M
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Subject Date of Birth	(b) (6)
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	X759342
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Actual Collection Date	2014 06 12
------------------------	------------

Actual Collection Time	13:22
------------------------	-------

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: 1202

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (25)

Data signed: (hfarmer1) 27 Mar 2015 14:52:26

Generated On: 20 Jul 2016 20:43:03

Lab Test Name	MONOCYTES (%)
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	8.4
Reported Numeric Result	8.4
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: 1202**

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (25)

Data signed: (hfarmer1) 27 Mar 2015 14:52:26

Generated On: 20 Jul 2016 20:43:03

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (26)

Data signed: (hfarmer1) 27 Mar 2015 14:52:26

Generated On: 20 Jul 2016 20:43:03

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	M
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Subject Date of Birth	(b) (6)
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	X759342
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Actual Collection Date	2014 06 12
------------------------	------------

Actual Collection Time	13:22
------------------------	-------

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: 1202

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (26)

Data signed: (hfarmer1) 27 Mar 2015 14:52:26

Generated On: 20 Jul 2016 20:43:03

Lab Test Name	EOSINOPHILS (%)
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	1.1
Reported Numeric Result	1.1
Reference Range low	0.0
Reference Range high	6.8
Range Units	%
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (26)

Data signed: (hfarmer1) 27 Mar 2015 14:52:26

Generated On: 20 Jul 2016 20:43:03

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1202

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (27)

Data signed: (hfarmer1) 27 Mar 2015 14:52:26

Generated On: 20 Jul 2016 20:43:03

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	M
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Subject Date of Birth	(b) (6)
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	X759342
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Actual Collection Date	2014 06 12
------------------------	------------

Actual Collection Time	13:22
------------------------	-------

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: 1202

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (27)

Data signed: (hfarmer1) 27 Mar 2015 14:52:26

Generated On: 20 Jul 2016 20:43:03

Lab Test Name	BASOPHILS (%)
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	0.3
Reported Numeric Result	0.3
Reference Range low	0.0
Reference Range high	2.0
Range Units	%
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (27)

Data signed: (hfarmer1) 27 Mar 2015 14:52:26

Generated On: 20 Jul 2016 20:43:03

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (28)

Data signed: (hfarmer1) 27 Mar 2015 14:52:26

Generated On: 20 Jul 2016 20:43:03

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	M
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Subject Date of Birth	(b) (6)
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	X759342
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Actual Collection Date	2014 06 12
------------------------	------------

Actual Collection Time	13:22
------------------------	-------

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: 1202

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (28)

Data signed: (hfarmer1) 27 Mar 2015 14:52:26

Generated On: 20 Jul 2016 20:43:03

Lab Test Name	HEMATOCRIT
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	46
Reported Numeric Result	46
Reference Range low	39
Reference Range high	54
Range Units	%
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (28)

Data signed: (hfarmer1) 27 Mar 2015 14:52:26

Generated On: 20 Jul 2016 20:43:03

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (29)

Data signed: (hfarmer1) 27 Mar 2015 14:52:26

Generated On: 20 Jul 2016 20:43:03

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	M
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Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	X759342
--------------	---------

Actual Collection Date	2014 06 12
------------------------	------------

Actual Collection Time	13:22
------------------------	-------

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: 1202

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (29)

Data signed: (hfarmer1) 27 Mar 2015 14:52:26

Generated On: 20 Jul 2016 20:43:03

Lab Test Name	RBC
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	5.7
Reported Numeric Result	5.7
Reference Range low	4.5
Reference Range high	6.4
Range Units	X10^6/UL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (29)

Data signed: (hfarmer1) 27 Mar 2015 14:52:26

Generated On: 20 Jul 2016 20:43:03

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (30)

Data signed: (hfarmer1) 27 Mar 2015 14:52:26

Generated On: 20 Jul 2016 20:43:03

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	M
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Subject Date of Birth	(b) (6)
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	X759342
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Actual Collection Date	2014 06 12
------------------------	------------

Actual Collection Time	13:22
------------------------	-------

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: 1202**

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (30)

Data signed: (hfarmer1) 27 Mar 2015 14:52:26

Generated On: 20 Jul 2016 20:43:03

Lab Test Name	MCV
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	81
Reported Numeric Result	81
Reference Range low	79
Reference Range high	96
Range Units	FL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (30)

Data signed: (hfarmer1) 27 Mar 2015 14:52:26

Generated On: 20 Jul 2016 20:43:03

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1202

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (31)

Data signed: (hfarmer1) 27 Mar 2015 14:52:26

Generated On: 20 Jul 2016 20:43:03

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	M
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Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	X759342
--------------	---------

Actual Collection Date	2014 06 12
------------------------	------------

Actual Collection Time	13:22
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	HM1604
------------	--------

Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
--------------	-----------------------------------

Lab Test ID	HMT40
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (31)

Data signed: (hfarmer1) 27 Mar 2015 14:52:26

Generated On: 20 Jul 2016 20:43:03

Lab Test Name	HEMOGLOBIN
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	15.1
Reported Numeric Result	15.1
Reference Range low	12.7
Reference Range high	18.1
Range Units	G/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (31)

Data signed: (hfarmer1) 27 Mar 2015 14:52:26

Generated On: 20 Jul 2016 20:43:03

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (32)

Data signed: (hfarmer1) 27 Mar 2015 14:52:26

Generated On: 20 Jul 2016 20:43:03

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
----------------------	-------

Subject Sex	M
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Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	X759342
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Actual Collection Date	2014 06 12
------------------------	------------

Actual Collection Time	13:22
------------------------	-------

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: 1202**

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (32)

Data signed: (hfarmer1) 27 Mar 2015 14:52:26

Generated On: 20 Jul 2016 20:43:03

Lab Test Name	WBC
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	10.16
Reported Numeric Result	10.16
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: 1202**

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (32)

Data signed: (hfarmer1) 27 Mar 2015 14:52:26

Generated On: 20 Jul 2016 20:43:03

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (33)

Data signed: (hfarmer1) 27 Mar 2015 14:52:26

Generated On: 20 Jul 2016 20:43:03

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	<hr/>
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Subject Sex	M
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Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	X759342
--------------	---------

Actual Collection Date	2014 06 12
------------------------	------------

Actual Collection Time	13:22
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Specimen Condition	<hr/>
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Battery ID	HM1604
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Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
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Lab Test ID	HMT71
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1202

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (33)

Data signed: (hfarmer1) 27 Mar 2015 14:52:26


Generated On: 20 Jul 2016 20:43:03

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: 1202**

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (33)

Data signed: (hfarmer1) 27 Mar 2015 14:52:26

Generated On: 20 Jul 2016 20:43:03

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1202

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (34)

Data signed: (hfarmer1) 27 Mar 2015 14:52:26

Generated On: 20 Jul 2016 20:43:03

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	M
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Subject Date of Birth	(b) (6)
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	X759342
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Actual Collection Date	2014 06 12
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Actual Collection Time	13:22
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Specimen Condition	<hr/>
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Battery ID	HM1604
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Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
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Lab Test ID	HMT8
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1202

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (34)

Data signed: (hfarmer1) 27 Mar 2015 14:52:26

Generated On: 20 Jul 2016 20:43:03

Lab Test Name	NEUTROPHILS
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	6.23
Reported Numeric Result	6.23
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: 1202**

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (34)

Data signed: (hfarmer1) 27 Mar 2015 14:52:26

Generated On: 20 Jul 2016 20:43:03

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1202

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (35)

Data signed: (hfarmer1) 27 Mar 2015 14:52:26

Generated On: 20 Jul 2016 20:43:03

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	
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Subject Sex	M
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Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	
------------	--

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	X759342
--------------	---------

Actual Collection Date	2014 06 12
------------------------	------------

Actual Collection Time	13:22
------------------------	-------

Specimen Condition	
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Battery ID	HM1604
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Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
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Lab Test ID	HMT9
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (35)

Data signed: (hfarmer1) 27 Mar 2015 14:52:26

Generated On: 20 Jul 2016 20:43:03

Lab Test Name	LYMPHOCYTES
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	2.95
Reported Numeric Result	2.95
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: 1202**

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (35)

Data signed: (hfarmer1) 27 Mar 2015 14:52:26

Generated On: 20 Jul 2016 20:43:03

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (36)

Data signed: (hfarmer1) 27 Mar 2015 14:52:26

Generated On: 20 Jul 2016 20:43:03

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	M
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Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	X759342
--------------	---------

Actual Collection Date	2014 06 12
------------------------	------------

Actual Collection Time	13:22
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	UA1538
------------	--------

Battery Name	URINE MACRO PANEL
--------------	-------------------

Lab Test ID	UAT10
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (36)

Data signed: (hfarmer1) 27 Mar 2015 14:52:26


Generated On: 20 Jul 2016 20:43:03

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: 1202**

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (36)

Data signed: (hfarmer1) 27 Mar 2015 14:52:26

Generated On: 20 Jul 2016 20:43:03

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (37)

Data signed: (hfarmer1) 27 Mar 2015 14:52:26

Generated On: 20 Jul 2016 20:43:03

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	<hr/>
----------------------	-------

Subject Sex	M
-------------	---

Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	X759342
--------------	---------

Actual Collection Date	2014 06 12
------------------------	------------

Actual Collection Time	13:22
------------------------	-------

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: 1202

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (37)

Data signed: (hfarmer1) 27 Mar 2015 14:52:26

Generated On: 20 Jul 2016 20:43:03

Lab Test Name	UR SPECIFIC GRAVITY
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	1.022
Reported Numeric Result	1.022
Reference Range low	1.003
Reference Range high	1.035
Range Units	
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (37)

Data signed: (hfarmer1) 27 Mar 2015 14:52:26

Generated On: 20 Jul 2016 20:43:03

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (38)

Data signed: (hfarmer1) 27 Mar 2015 14:52:26

Generated On: 20 Jul 2016 20:43:03

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	<hr/>
----------------------	-------

Subject Sex	M
-------------	---

Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	X759342
--------------	---------

Actual Collection Date	2014 06 12
------------------------	------------

Actual Collection Time	13:22
------------------------	-------

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: 1202**

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (38)

Data signed: (hfarmer1) 27 Mar 2015 14:52:26

Generated On: 20 Jul 2016 20:43:03

Lab Test Name	UR PH
Test ID	
Test Status	Done <input type="checkbox"/>
Reported Text Result	5.5
Reported Numeric Result	5.5
Reference Range low	5.0
Reference Range high	8.0
Range Units	
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (38)

Data signed: (hfarmer1) 27 Mar 2015 14:52:26

Generated On: 20 Jul 2016 20:43:03

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (39)

Data signed: (hfarmer1) 27 Mar 2015 14:52:26

Generated On: 20 Jul 2016 20:43:03

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	<hr/>
----------------------	-------

Subject Sex	M
-------------	---

Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	X759342
--------------	---------

Actual Collection Date	2014 06 12
------------------------	------------

Actual Collection Time	13:22
------------------------	-------

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: 1202**

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (39)

Data signed: (hfarmer1) 27 Mar 2015 14:52:26


Generated On: 20 Jul 2016 20:43:03

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: 1202**

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (39)

Data signed: (hfarmer1) 27 Mar 2015 14:52:26

Generated On: 20 Jul 2016 20:43:03

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (40)

Data signed: (hfarmer1) 27 Mar 2015 14:52:26

Generated On: 20 Jul 2016 20:43:03

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	<hr/>
----------------------	-------

Subject Sex	M
-------------	---

Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	X759342
--------------	---------

Actual Collection Date	2014 06 12
------------------------	------------

Actual Collection Time	13:22
------------------------	-------

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: 1202**

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (40)

Data signed: (hfarmer1) 27 Mar 2015 14:52:26


Generated On: 20 Jul 2016 20:43:03

Lab Test Name

UR PROTEIN

Test ID

Test Status

Done 

Reported Text Result

TRACE

Reported Numeric Result

Reference Range low

Reference Range high

Range Units

Conventional Text Result

Conventional Numeric Result

Conventional Reference Range Low

Conventional Reference Range High

Conventional Units

SI Text Result

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (40)

Data signed: (hfarmer1) 27 Mar 2015 14:52:26

Generated On: 20 Jul 2016 20:43:03

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: 1202**

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (41)

Data signed: (hfarmer1) 27 Mar 2015 14:52:26

Generated On: 20 Jul 2016 20:43:03

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	<hr/>
----------------------	-------

Subject Sex	M
-------------	---

Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	X759342
--------------	---------

Actual Collection Date	2014 06 12
------------------------	------------

Actual Collection Time	13:22
------------------------	-------

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: 1202**

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (41)

Data signed: (hfarmer1) 27 Mar 2015 14:52:26


Generated On: 20 Jul 2016 20:43:03

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: 1202**

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (41)

Data signed: (hfarmer1) 27 Mar 2015 14:52:26

Generated On: 20 Jul 2016 20:43:03

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (42)

Data signed: (hfarmer1) 27 Mar 2015 14:52:26

Generated On: 20 Jul 2016 20:43:03

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	<hr/>
----------------------	-------

Subject Sex	M
-------------	---

Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	X759342
--------------	---------

Actual Collection Date	2014 06 12
------------------------	------------

Actual Collection Time	13:22
------------------------	-------

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: 1202

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (42)

Data signed: (hfarmer1) 27 Mar 2015 14:52:26


Generated On: 20 Jul 2016 20:43:03

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: 1202**

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (42)

Data signed: (hfarmer1) 27 Mar 2015 14:52:26

Generated On: 20 Jul 2016 20:43:03

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Product Use

Form: Product administration-mCC

Data signed: (hfarmer1) 27 Mar 2015 14:52:46

Generated On: 20 Jul 2016 20:43:03

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1202

Folder: Product Use

Form: Product administration-mCC (1)

Data signed: (hfarmer1) 27 Mar 2015 14:52:46

Generated On: 20 Jul 2016 20:43:03

Date of product use DD/MMM/YYYY	12 MAR 2014
------------------------------------	-------------

Visit	Day -1 <input checked="" type="radio"/>
-------	---

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	07:06
----------------------	-------

Time of butt return	07:14
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1202

Folder: Product Use

Form: Product administration-mCC (1)

Data signed: (hfarmer1) 27 Mar 2015 14:52:46

Generated On: 20 Jul 2016 20:43:03

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1202

Folder: Product Use

Form: Product administration-mCC (2)

Data signed: (hfarmer1) 27 Mar 2015 14:52:46

Generated On: 20 Jul 2016 20:43:03

Date of product use DD/MMM/YYYY	12 MAR 2014
------------------------------------	-------------

Visit	Day -1 <input checked="" type="radio"/>
-------	---

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	08:36
----------------------	-------

Time of butt return	08:45
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1202

Folder: Product Use

Form: Product administration-mCC (2)

Data signed: (hfarmer1) 27 Mar 2015 14:52:46

Generated On: 20 Jul 2016 20:43:03

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Product Use

Form: Product administration-mCC (3)

Data signed: (hfarmer1) 27 Mar 2015 14:52:46

Generated On: 20 Jul 2016 20:43:03

Date of product use DD/MMM/YYYY	12 MAR 2014
------------------------------------	-------------

Visit	Day -1 <input checked="" type="radio"/>
-------	---

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	10:49
----------------------	-------

Time of butt return	10:57
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1202

Folder: Product Use

Form: Product administration-mCC (3)

Data signed: (hfarmer1) 27 Mar 2015 14:52:46

Generated On: 20 Jul 2016 20:43:03

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Product Use

Form: Product administration-mCC (4)

Data signed: (hfarmer1) 27 Mar 2015 14:52:46

Generated On: 20 Jul 2016 20:43:03

Date of product use DD/MMM/YYYY	12 MAR 2014
------------------------------------	-------------

Visit	Day -1 <input checked="" type="radio"/>
-------	---

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	12:39
----------------------	-------

Time of butt return	12:47
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1202

Folder: Product Use

Form: Product administration-mCC (4)

Data signed: (hfarmer1) 27 Mar 2015 14:52:46

Generated On: 20 Jul 2016 20:43:03

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Product Use

Form: Product administration-mCC (5)

Data signed: (hfarmer1) 27 Mar 2015 14:52:46

Generated On: 20 Jul 2016 20:43:03

Date of product use DD/MMM/YYYY	12 MAR 2014
------------------------------------	-------------

Visit	Day -1 <input checked="" type="radio"/>
-------	---

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	13:54
----------------------	-------

Time of butt return	14:04
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1202

Folder: Product Use

Form: Product administration-mCC (5)

Data signed: (hfarmer1) 27 Mar 2015 14:52:46

Generated On: 20 Jul 2016 20:43:03

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1202

Folder: Product Use

Form: Product administration-mCC (6)

Data signed: (hfarmer1) 27 Mar 2015 14:52:46

Generated On: 20 Jul 2016 20:43:03

Date of product use DD/MMM/YYYY	12 MAR 2014
------------------------------------	-------------

Visit	Day -1 <input checked="" type="radio"/>
-------	---

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	15:10
----------------------	-------

Time of butt return	15:20
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1202

Folder: Product Use

Form: Product administration-mCC (6)

Data signed: (hfarmer1) 27 Mar 2015 14:52:46

Generated On: 20 Jul 2016 20:43:03

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1202

Folder: Product Use

Form: Product administration-mCC (7)

Data signed: (hfarmer1) 27 Mar 2015 14:52:46

Generated On: 20 Jul 2016 20:43:03

Date of product use DD/MMM/YYYY	12 MAR 2014
------------------------------------	-------------

Visit	Day -1 <input checked="" type="radio"/>
-------	---

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	16:38
----------------------	-------

Time of butt return	16:51
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1202

Folder: Product Use

Form: Product administration-mCC (7)

Data signed: (hfarmer1) 27 Mar 2015 14:52:46

Generated On: 20 Jul 2016 20:43:03

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1202

Folder: Product Use

Form: Product administration-mCC (8)

Data signed: (hfarmer1) 27 Mar 2015 14:52:46

Generated On: 20 Jul 2016 20:43:03

Date of product use DD/MMM/YYYY	12 MAR 2014
------------------------------------	-------------

Visit	Day -1 <input checked="" type="radio"/>
-------	---

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	17:56
----------------------	-------

Time of butt return	18:06
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1202

Folder: Product Use

Form: Product administration-mCC (8)

Data signed: (hfarmer1) 27 Mar 2015 14:52:46

Generated On: 20 Jul 2016 20:43:03

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1202

Folder: Product Use

Form: Product administration-mCC (9)

Data signed: (hfarmer1) 27 Mar 2015 14:52:46

Generated On: 20 Jul 2016 20:43:03

Date of product use DD/MMM/YYYY	12 MAR 2014
------------------------------------	-------------

Visit	Day -1 <input checked="" type="radio"/>
-------	---

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	19:39
----------------------	-------

Time of butt return	19:50
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1202

Folder: Product Use

Form: Product administration-mCC (9)

Data signed: (hfarmer1) 27 Mar 2015 14:52:46

Generated On: 20 Jul 2016 20:43:03

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Product Use

Form: Product administration-mCC (10)

Data signed: (hfarmer1) 27 Mar 2015 14:52:46

Generated On: 20 Jul 2016 20:43:03

Date of product use DD/MMM/YYYY	12 MAR 2014
------------------------------------	-------------

Visit	Day -1 <input checked="" type="radio"/>
-------	---

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	21:09
----------------------	-------

Time of butt return	21:15
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1202

Folder: Product Use

Form: Product administration-mCC (10)

Data signed: (hfarmer1) 27 Mar 2015 14:52:46

Generated On: 20 Jul 2016 20:43:03

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Product Use

Form: Product administration-mCC (11)

Data signed: (hfarmer1) 27 Mar 2015 14:52:46

Generated On: 20 Jul 2016 20:43:03

Date of product use DD/MMM/YYYY	12 MAR 2014
------------------------------------	-------------

Visit	Day -1 <input checked="" type="radio"/>
-------	---

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	22:02
----------------------	-------

Time of butt return	22:13
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1202

Folder: Product Use

Form: Product administration-mCC (11)

Data signed: (hfarmer1) 27 Mar 2015 14:52:46

Generated On: 20 Jul 2016 20:43:03

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Product Use

Form: Product administration-mCC (12)

Data signed: (hfarmer1) 27 Mar 2015 14:52:46

Generated On: 20 Jul 2016 20:43:03

Date of product use DD/MMM/YYYY	13 MAR 2014
------------------------------------	-------------

Visit	Day 0 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	07:57
----------------------	-------

Time of butt return	08:07
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	149
---------------------	-----

SODIM sample holder number	0201
----------------------------	------

SODIM file number	08DY0149COHJ10201001
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1202

Folder: Product Use

Form: Product administration-mCC (12)

Data signed: (hfarmer1) 27 Mar 2015 14:52:46

Generated On: 20 Jul 2016 20:43:03

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1202

Folder: Product Use

Form: Product administration-mCC (13)

Data signed: (hfarmer1) 27 Mar 2015 14:52:46

Generated On: 20 Jul 2016 20:43:03

Date of product use DD/MMM/YYYY	13 MAR 2014
------------------------------------	-------------

Visit	Day 0 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	10:19
----------------------	-------

Time of butt return	10:30
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	149
---------------------	-----

SODIM sample holder number	0201
----------------------------	------

SODIM file number	08DY0149COHJ10201001
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1202

Folder: Product Use

Form: Product administration-mCC (13)

Data signed: (hfarmer1) 27 Mar 2015 14:52:46

Generated On: 20 Jul 2016 20:43:03

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Product Use

Form: Product administration-mCC (14)

Data signed: (hfarmer1) 27 Mar 2015 14:52:46

Generated On: 20 Jul 2016 20:43:03

Date of product use DD/MMM/YYYY	13 MAR 2014
------------------------------------	-------------

Visit	Day 0 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	12:19
----------------------	-------

Time of butt return	12:33
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	164
---------------------	-----

SODIM sample holder number	0207
----------------------------	------

SODIM file number	08DY0164COHJ10207001
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1202

Folder: Product Use

Form: Product administration-mCC (14)

Data signed: (hfarmer1) 27 Mar 2015 14:52:46

Generated On: 20 Jul 2016 20:43:03

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1202

Folder: Product Use

Form: Product administration-mCC (15)

Data signed: (hfarmer1) 27 Mar 2015 14:52:46

Generated On: 20 Jul 2016 20:43:03

Date of product use DD/MMM/YYYY	13 MAR 2014
------------------------------------	-------------

Visit	Day 0 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	13:32
----------------------	-------

Time of butt return	13:40
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	164
---------------------	-----

SODIM sample holder number	0207
----------------------------	------

SODIM file number	08DY0164COHJ10207003
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1202

Folder: Product Use

Form: Product administration-mCC (15)

Data signed: (hfarmer1) 27 Mar 2015 14:52:46

Generated On: 20 Jul 2016 20:43:03

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Product Use

Form: Product administration-mCC (16)

Data signed: (hfarmer1) 27 Mar 2015 14:52:46

Generated On: 20 Jul 2016 20:43:03

Date of product use DD/MMM/YYYY	13 MAR 2014
------------------------------------	-------------

Visit	Day 0 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	14:40
----------------------	-------

Time of butt return	14:47
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	164
---------------------	-----

SODIM sample holder number	0207
----------------------------	------

SODIM file number	08DY0164COHJ10207004
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1202

Folder: Product Use

Form: Product administration-mCC (16)

Data signed: (hfarmer1) 27 Mar 2015 14:52:46

Generated On: 20 Jul 2016 20:43:03

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Product Use

Form: Product administration-mCC (17)

Data signed: (hfarmer1) 27 Mar 2015 14:52:46

Generated On: 20 Jul 2016 20:43:03

Date of product use DD/MMM/YYYY	13 MAR 2014
------------------------------------	-------------

Visit	Day 0 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	16:06
----------------------	-------

Time of butt return	16:18
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	164
---------------------	-----

SODIM sample holder number	0207
----------------------------	------

SODIM file number	08DY0164COHJ10207005
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1202

Folder: Product Use

Form: Product administration-mCC (17)

Data signed: (hfarmer1) 27 Mar 2015 14:52:46

Generated On: 20 Jul 2016 20:43:03

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Product Use

Form: Product administration-mCC (18)

Data signed: (hfarmer1) 27 Mar 2015 14:52:46

Generated On: 20 Jul 2016 20:43:03

Date of product use DD/MMM/YYYY	13 MAR 2014
------------------------------------	-------------

Visit	Day 0 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	17:26
----------------------	-------

Time of butt return	17:37
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	164
---------------------	-----

SODIM sample holder number	0207
----------------------------	------

SODIM file number	08DY0164COHJ10207006
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1202

Folder: Product Use

Form: Product administration-mCC (18)

Data signed: (hfarmer1) 27 Mar 2015 14:52:46

Generated On: 20 Jul 2016 20:43:03

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Product Use

Form: Product administration-mCC (19)

Data signed: (hfarmer1) 27 Mar 2015 14:52:46

Generated On: 20 Jul 2016 20:43:03

Date of product use DD/MMM/YYYY	13 MAR 2014
------------------------------------	-------------

Visit	Day 0 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	18:34
----------------------	-------

Time of butt return	18:41
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	164
---------------------	-----

SODIM sample holder number	0207
----------------------------	------

SODIM file number	08DY0164COHJ10207007
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1202

Folder: Product Use

Form: Product administration-mCC (19)

Data signed: (hfarmer1) 27 Mar 2015 14:52:46

Generated On: 20 Jul 2016 20:43:03

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Product Use

Form: Product administration-mCC (20)

Data signed: (hfarmer1) 27 Mar 2015 14:52:46

Generated On: 20 Jul 2016 20:43:03

Date of product use DD/MMM/YYYY	13 MAR 2014
------------------------------------	-------------

Visit	Day 0 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	19:29
----------------------	-------

Time of butt return	19:40
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	164
---------------------	-----

SODIM sample holder number	0207
----------------------------	------

SODIM file number	08DY0164COHJ10207008
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1202

Folder: Product Use

Form: Product administration-mCC (20)

Data signed: (hfarmer1) 27 Mar 2015 14:52:46

Generated On: 20 Jul 2016 20:43:03

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1202

Folder: Product Use

Form: Product administration-mCC (21)

Data signed: (hfarmer1) 27 Mar 2015 14:52:46

Generated On: 20 Jul 2016 20:43:03

Date of product use DD/MMM/YYYY	13 MAR 2014
------------------------------------	-------------

Visit	Day 0 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	21:25
----------------------	-------

Time of butt return	21:42
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	164
---------------------	-----

SODIM sample holder number	0207
----------------------------	------

SODIM file number	08DY0164COHJ10207009
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1202

Folder: Product Use

Form: Product administration-mCC (21)

Data signed: (hfarmer1) 27 Mar 2015 14:52:46

Generated On: 20 Jul 2016 20:43:03

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Product Use

Form: Product administration-mCC (22)

Data signed: (hfarmer1) 27 Mar 2015 14:52:46

Generated On: 20 Jul 2016 20:43:03

Date of product use DD/MMM/YYYY	13 MAR 2014
------------------------------------	-------------

Visit	Day 0 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	22:36
----------------------	-------

Time of butt return	22:46
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	164
---------------------	-----

SODIM sample holder number	0207
----------------------------	------

SODIM file number	08DY0164COHJ10207010
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1202

Folder: Product Use

Form: Product administration-mCC (22)

Data signed: (hfarmer1) 27 Mar 2015 14:52:46

Generated On: 20 Jul 2016 20:43:03

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Product Use

Form: Product administration-THS menthol

Data signed: (hfarmer1) 27 Mar 2015 14:52:51

Generated On: 20 Jul 2016 20:43:03

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: 1202**

Folder: Product Use

Form: Product administration-THS menthol (1)

Data signed: (hfarmer1) 27 Mar 2015 14:52:51

Generated On: 20 Jul 2016 20:43:03

Date of product use DD/MMM/YYYY	11 MAR 2014
------------------------------------	-------------

Visit	Day -2 <input type="radio"/>
-------	------------------------------

Type of Product Use	THS 2.2 Menthol <input type="radio"/>
---------------------	---------------------------------------

If type of Product Use different from the randomization please explain PRODUCT TEST

Time of distribution	15:52
----------------------	-------

Time of product return	<hr/>
------------------------	-------

SODIM device number	<hr/>
---------------------	-------

SODIM sample holder number	<hr/>
----------------------------	-------

Tobacco plug kit number	<hr/>
-------------------------	-------

Tobacco plug vial number	<hr/>
--------------------------	-------

SODIM file number	<hr/>
-------------------	-------

Comment	<hr/>
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Batch Number	B08545
--------------	--------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1202

Folder: Product Use

Form: Product administration-THS menthol (1)

Data signed: (hfarmer1) 27 Mar 2015 14:52:51

Generated On: 20 Jul 2016 20:43:03

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: 1202**

Folder: Product Use

Form: HST 4 hours (1)

Data signed: (hfarmer1) 27 Mar 2015 14:52:52

Generated On: 20 Jul 2016 20:43:03

Visit

Day 30 ☒

Not Done

True

If Not Done, please specify

SUBJECT IN S.A. ARM

Date
DD/MMM/YYYY

SODIM device distribution time
hour:min 24-hour clock

SODIM device collection time

hour:min 24-hour clock

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Product Use

Form: HST 4 hours (2)

Data signed: (hfarmer1) 27 Mar 2015 14:52:52

Generated On: 20 Jul 2016 20:43:03

Visit	Day 60 <input checked="" type="radio"/>
-------	---

Not Done	True
----------	------

If Not Done, please specify	SUBJECT IN S.A. ARM
-----------------------------	---------------------

Date DD/MMM/YYYY	<hr/>
---------------------	-------

SODIM device distribution time hour:min 24-hour clock	<hr/>
--	-------

SODIM device collection time hour:min 24-hour clock	<hr/>
--	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Product Use

Form: HST 4 hours (3)

Data signed: (hfarmer1) 27 Mar 2015 14:52:52

Generated On: 20 Jul 2016 20:43:03

Visit

Day 90 ☒

Not Done

True

If Not Done, please specify

SUBJECT IN S.A. ARM

Date
DD/MMM/YYYY

SODIM device distribution time
hour:min 24-hour clock

SODIM device collection time
hour:min 24-hour clock

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Product Use

Form: Topography files status for mCC (1)

Generated On: 20 Jul 2016 20:43:03

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: 1202**

Folder: Product Use

Form: Topography files status for mCC (2)

Generated On: 20 Jul 2016 20:43:03

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: 1202**

Folder: Product Use

Form: Topography files status for mCC (3)

Generated On: 20 Jul 2016 20:43:03

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: 1202**

Folder: Product Use

Form: Topography files status for mCC (4)

Generated On: 20 Jul 2016 20:43:03

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: 1202**

Folder: Product Use

Form: Topography files status for mCC (5)

Generated On: 20 Jul 2016 20:43:03

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: 1202**

Folder: Product Use

Form: Topography files status for mCC (6)

Generated On: 20 Jul 2016 20:43:03

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: 1202**

Folder: Product Use

Form: Topography files status for mCC (7)

Generated On: 20 Jul 2016 20:43:03

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: 1202**

Folder: Product Use

Form: Topography files status for mCC (8)

Generated On: 20 Jul 2016 20:43:03

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: 1202**

Folder: Product Use

Form: Topography files status for mCC (9)

Generated On: 20 Jul 2016 20:43:03

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: 1202**

Folder: Product Use

Form: Topography files status for mCC (10)

Generated On: 20 Jul 2016 20:43:03

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: 1202**

Folder: Product Use

Form: Topography files status for mCC (11)

Generated On: 20 Jul 2016 20:43:03

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: 1202**

Folder: Product Use

Form: Topography files status for mCC (12)

Generated On: 20 Jul 2016 20:43:03

SODIM file number	08DY0149COHJ10201001
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File Status	Error 
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Rejection / Error reason	DATA INCOMPATIBLE
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Date of analysis DD/MMM/YYYY	19 JAN 2015
---------------------------------	-------------

Operator	Anthony Bruchet 
----------	---

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: 1202**

Folder: Product Use

Form: Topography files status for mCC (15)

Generated On: 20 Jul 2016 20:43:03

SODIM file number	08DY0164COHJ10207003
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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	05 SEP 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: 1202**

Folder: Product Use

Form: Topography files status for mCC (16)

Generated On: 20 Jul 2016 20:43:03

SODIM file number	08DY0164COHJ10207004
-------------------	----------------------

File Status	Accepted 
-------------	--

Rejection / Error reason	<hr/>
--------------------------	-------

Date of analysis DD/MMM/YYYY	05 SEP 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: 1202**

Folder: Product Use

Form: Topography files status for mCC (17)

Generated On: 20 Jul 2016 20:43:03

SODIM file number	08DY0164COHJ10207005
-------------------	----------------------

File Status	Accepted 
-------------	--

Rejection / Error reason	<hr/>
--------------------------	-------

Date of analysis DD/MMM/YYYY	05 SEP 2014
---------------------------------	-------------

Operator	Thierry Bachmann 
----------	--

Comment	<hr/>
---------	-------

Modified File Number	<hr/>
----------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Product Use

Form: Topography files status for mCC (18)

Generated On: 20 Jul 2016 20:43:03

SODIM file number	08DY0164COHJ10207006
-------------------	----------------------

File Status	Accepted <input checked="" type="radio"/>
-------------	---

Rejection / Error reason	
--------------------------	--

Date of analysis DD/MMM/YYYY	05 SEP 2014
---------------------------------	-------------

Operator	Thierry Bachmann <input checked="" type="radio"/>
----------	---

Comment	
---------	--

Modified File Number	
----------------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Product Use

Form: Topography files status for mCC (19)

Generated On: 20 Jul 2016 20:43:03

SODIM file number	08DY0164COHJ10207007
-------------------	----------------------

File Status	Accepted <input checked="" type="radio"/>
-------------	---

Rejection / Error reason	
--------------------------	--

Date of analysis DD/MMM/YYYY	05 SEP 2014
---------------------------------	-------------

Operator	Thierry Bachmann <input checked="" type="radio"/>
----------	---

Comment	
---------	--

Modified File Number	
----------------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Product Use

Form: Topography files status for mCC (20)

Generated On: 20 Jul 2016 20:43:03

SODIM file number	08DY0164COHJ10207008
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File Status	Accepted 
-------------	--

Rejection / Error reason	<hr/>
--------------------------	-------

Date of analysis DD/MMM/YYYY	05 SEP 2014
---------------------------------	-------------

Operator	Thierry Bachmann 
----------	--

Comment	<hr/>
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Modified File Number	<hr/>
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Product Use

Form: Topography files status for mCC (21)

Generated On: 20 Jul 2016 20:43:03

SODIM file number	08DY0164COHJ10207009
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File Status	Accepted <input checked="" type="radio"/>
-------------	---

Rejection / Error reason	
--------------------------	--

Date of analysis DD/MMM/YYYY	05 SEP 2014
---------------------------------	-------------

Operator	Thierry Bachmann <input checked="" type="radio"/>
----------	---

Comment	
---------	--

Modified File Number	
----------------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Product Use

Form: Topography files status for mCC (22)

Generated On: 20 Jul 2016 20:43:03

SODIM file number	08DY0164COHJ10207010
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File Status	Accepted 
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Rejection / Error reason	<hr/>
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Date of analysis DD/MMM/YYYY	05 SEP 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: 1202**

Folder: Product Use

Form: Product use diary(Paper)

Data signed: (hfarmer1) 27 Mar 2015 14:52:52

Generated On: 20 Jul 2016 20:43:03

Was paper questionnaire used?

No ☒

Reason not done

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Product Use

Form: Product use diary(Paper) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:52:52

Generated On: 20 Jul 2016 20:43:03

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: 1202**

Folder: Product Use

Form: Product use diary(Paper) (1)

Data signed: (hfarmer1) 27 Mar 2015 14:52:52

Generated On: 20 Jul 2016 20:43:03

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: 1202**

Folder: Adverse Events

Form: Adverse Events Y/N

Data signed: (hfarmer1) 27 Mar 2015 14:52:53

Generated On: 20 Jul 2016 20:43:03

Was there any Adverse Event for this subject?

Yes ☒

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1202

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (hfarmer1) 27 Mar 2015 14:52:53

Generated On: 20 Jul 2016 20:43:03

AE Identifier	1
---------------	---

Adverse Event	STRAINED BACK MUSCLE
---------------	----------------------

Start Date	14 MAR 2014
------------	-------------

DD/MMM/YYYY

End Date	17 MAR 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: 1202**

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (hfarmer1) 27 Mar 2015 14:52:53

Generated On: 20 Jul 2016 20:43:03

Action taken with study product

Not Applicable ☒

Other action taken

Outcome

Recovered or Resolved ☒

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1202

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (hfarmer1) 27 Mar 2015 14:52:53

Generated On: 20 Jul 2016 20:43:03

AE Identifier	2
---------------	---

Adverse Event	FEVERISH
---------------	----------

Start Date	11 APR 2014
------------	-------------

DD/MMM/YYYY

End Date	12 APR 2014
----------	-------------

DD/MMM/YYYY

Ongoing at final contact	No <input type="radio"/>
--------------------------	--------------------------

Severity	Mild Adverse Event <input type="radio"/>
----------	--

Serious AE	No <input type="radio"/>
------------	--------------------------

Seriousness Criteria

Treatment given	Yes <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: 1202**

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (hfarmer1) 27 Mar 2015 14:52:53

Generated On: 20 Jul 2016 20:43:03

Action taken with study product

Not Applicable ☒

Other action taken

Outcome

Recovered or Resolved ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Previous and Concomitant Medication

Form: Previous and Concomitant Medication Y/N

Data signed: (hfarmer1) 27 Mar 2015 14:52:53

Generated On: 20 Jul 2016 20:43:03

Has the subject taken previous or concomitant
medication?

Yes ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Previous and Concomitant Medication

Form: Previous and Concomitant Medication (1)

Data signed: (hfarmer1) 27 Mar 2015 14:52:53

Generated On: 20 Jul 2016 20:43:03

Brand Name	MINOCYCLINE
Start Date DD/MMM/YYYY	UN UNK 2011
Stop Date DD/MMM/YYYY	27 FEB 2014
Ongoing at final contact	False
Total Daily dose - Dose	100
Total Daily dose - Unit	Milligram <input checked="" type="radio"/>
Route	Oral Route of Administration <input checked="" type="radio"/>
Indication	ACNE
Concomitant Disease Number	1
AE Number	
Other	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Folder: Previous and Concomitant Medication

Form: Previous and Concomitant Medication (2)

Data signed: (hfarmer1) 27 Mar 2015 14:52:53

Generated On: 20 Jul 2016 20:43:03

Brand Name	ACETAMINOPHEN
Start Date DD/MMM/YYYY	11 APR 2014
Stop Date DD/MMM/YYYY	11 APR 2014
Ongoing at final contact	False
Total Daily dose - Dose	500
Total Daily dose - Unit	Milligram <input checked="" type="radio"/>
Route	Oral Route of Administration <input checked="" type="radio"/>
Indication	FEVERISH
Concomitant Disease Number	
AE Number	2
Other	

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1202

Form: Product use diary (1)

Data signed: (hfarmer1) 27 Mar 2015 14:49:36

Generated On: 20 Jul 2016 20:43:03

Date of Birth

(b) (6)

Date of completion
DD/MMM/YYYY

2014 MAR 19

Time of completion
hh:mm

21:01

Date the questionnaire was completed for
DD/MMM/YYYY

2014 MAR 19

Assessment Status

Completed ☒

What tobacco/nicotine product did you use today?

None of the above ☒

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 ☒

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: 1202

Form: Product use diary (1)

Data signed: (hfarmer1) 27 Mar 2015 14:49:36

Generated On: 20 Jul 2016 20:43:03

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: 1202

Form: Product use diary (2)

Data signed: (hfarmer1) 27 Mar 2015 14:49:36

Generated On: 20 Jul 2016 20:43:03

Date of Birth	(b) (6)
Date of completion DD/MMM/YYYY	2014 MAR 20
Time of completion hh:mm	20:00
Date the questionnaire was completed for DD/MMM/YYYY	2014 MAR 20
Assessment Status	Completed <input checked="" type="radio"/>
What tobacco/nicotine product did you use today?	None of the above <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: 1202

Form: Product use diary (2)

Data signed: (hfarmer1) 27 Mar 2015 14:49:36

Generated On: 20 Jul 2016 20:43:03

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: 1202

Form: Product use diary (3)

Data signed: (hfarmer1) 27 Mar 2015 14:49:36

Generated On: 20 Jul 2016 20:43:03

Date of Birth

(b) (6)

Date of completion
DD/MMM/YYYY

2014 MAR 21

Time of completion
hh:mm

20:01

Date the questionnaire was completed for
DD/MMM/YYYY

2014 MAR 21

Assessment Status

Completed ☒

What tobacco/nicotine product did you use today?

None of the above ☒

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 ☒

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: 1202

Form: Product use diary (3)

Data signed: (hfarmer1) 27 Mar 2015 14:49:36

Generated On: 20 Jul 2016 20:43:03

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: 1202

Form: Product use diary (4)

Data signed: (hfarmer1) 27 Mar 2015 14:49:36

Generated On: 20 Jul 2016 20:43:03

Date of Birth

(b) (6)

Date of completion
DD/MMM/YYYY

2014 MAR 22

Time of completion
hh:mm

20:00

Date the questionnaire was completed for
DD/MMM/YYYY

2014 MAR 22

Assessment Status

Completed ☒

What tobacco/nicotine product did you use today?

None of the above ☒

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 ☒

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: 1202

Form: Product use diary (4)

Data signed: (hfarmer1) 27 Mar 2015 14:49:36

Generated On: 20 Jul 2016 20:43:03

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: 1202

Form: Product use diary (5)

Data signed: (hfarmer1) 27 Mar 2015 14:49:36

Generated On: 20 Jul 2016 20:43:03

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?

None of the above ☒

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 ☒

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: 1202

Form: Product use diary (5)

Data signed: (hfarmer1) 27 Mar 2015 14:49:36

Generated On: 20 Jul 2016 20:43:03

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: 1202

Form: Product use diary (6)

Data signed: (hfarmer1) 27 Mar 2015 14:49:36

Generated On: 20 Jul 2016 20:43:03

Date of Birth

(b) (6)

Date of completion
DD/MMM/YYYY

2014 MAR 24

Time of completion
hh:mm

20:39

Date the questionnaire was completed for
DD/MMM/YYYY

2014 MAR 24

Assessment Status

Completed ☒

What tobacco/nicotine product did you use today?

None of the above ☒

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 ☒

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: 1202

Form: Product use diary (6)

Data signed: (hfarmer1) 27 Mar 2015 14:49:36

Generated On: 20 Jul 2016 20:43:03

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: 1202

Form: Product use diary (7)

Data signed: (hfarmer1) 27 Mar 2015 14:49:36

Generated On: 20 Jul 2016 20:43:03

Date of Birth	(b) (6)
Date of completion DD/MMM/YYYY	2014 MAR 25
Time of completion hh:mm	19:31
Date the questionnaire was completed for DD/MMM/YYYY	2014 MAR 25
Assessment Status	Completed <input checked="" type="radio"/>
What tobacco/nicotine product did you use today?	None of the above <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: 1202

Form: Product use diary (7)

Data signed: (hfarmer1) 27 Mar 2015 14:49:36

Generated On: 20 Jul 2016 20:43:03

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: 1202

Form: Product use diary (8)

Data signed: (hfarmer1) 27 Mar 2015 14:49:36

Generated On: 20 Jul 2016 20:43:03

Date of Birth

(b) (6)

Date of completion
DD/MMM/YYYY

2014 MAR 26

Time of completion
hh:mm

19:51

Date the questionnaire was completed for
DD/MMM/YYYY

2014 MAR 26

Assessment Status

Completed ☒

What tobacco/nicotine product did you use today?

None of the above ☒

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 ☒

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: 1202

Form: Product use diary (8)

Data signed: (hfarmer1) 27 Mar 2015 14:49:36

Generated On: 20 Jul 2016 20:43:03

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: 1202

Form: Product use diary (9)

Data signed: (hfarmer1) 27 Mar 2015 14:49:36

Generated On: 20 Jul 2016 20:43:03

Date of Birth

(b) (6)

Date of completion
DD/MMM/YYYY

2014 MAR 27

Time of completion
hh:mm

21:55

Date the questionnaire was completed for
DD/MMM/YYYY

2014 MAR 27

Assessment Status

Completed ☒

What tobacco/nicotine product did you use today?

None of the above ☒

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 ☒

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: 1202

Form: Product use diary (9)

Data signed: (hfarmer1) 27 Mar 2015 14:49:36

Generated On: 20 Jul 2016 20:43:03

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: 1202

Form: Product use diary (10)

Data signed: (hfarmer1) 27 Mar 2015 14:49:36

Generated On: 20 Jul 2016 20:43:03

Date of Birth

(b) (6)

Date of completion
DD/MMM/YYYY

2014 MAR 28

Time of completion
hh:mm

20:01

Date the questionnaire was completed for
DD/MMM/YYYY

2014 MAR 28

Assessment Status

Completed ☒

What tobacco/nicotine product did you use today?

None of the above ☒

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 ☒

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: 1202

Form: Product use diary (10)

Data signed: (hfarmer1) 27 Mar 2015 14:49:36

Generated On: 20 Jul 2016 20:43:03

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: 1202

Form: Product use diary (11)

Data signed: (hfarmer1) 27 Mar 2015 14:49:36

Generated On: 20 Jul 2016 20:43:03

Date of Birth

(b) (6)

Date of completion
DD/MMM/YYYY

2014 MAR 29

Time of completion
hh:mm

21:41

Date the questionnaire was completed for
DD/MMM/YYYY

2014 MAR 29

Assessment Status

Completed ☒

What tobacco/nicotine product did you use today?

None of the above ☒

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 ☒

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: 1202

Form: Product use diary (11)

Data signed: (hfarmer1) 27 Mar 2015 14:49:36

Generated On: 20 Jul 2016 20:43:03

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: 1202

Form: Product use diary (12)

Data signed: (hfarmer1) 27 Mar 2015 14:49:36

Generated On: 20 Jul 2016 20:43:03

Date of Birth

(b) (6)

Date of completion
DD/MMM/YYYY

2014 MAR 30

Time of completion
hh:mm

20:55

Date the questionnaire was completed for
DD/MMM/YYYY

2014 MAR 30

Assessment Status

Completed ☒

What tobacco/nicotine product did you use today?

None of the above ☒

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 ☒

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: 1202

Form: Product use diary (12)

Data signed: (hfarmer1) 27 Mar 2015 14:49:36

Generated On: 20 Jul 2016 20:43:03

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: 1202

Form: Product use diary (13)

Data signed: (hfarmer1) 27 Mar 2015 14:49:36

Generated On: 20 Jul 2016 20:43:03

Date of Birth

(b) (6)

Date of completion
DD/MMM/YYYY

2014 APR 01

Time of completion
hh:mm

09:01

Date the questionnaire was completed for
DD/MMM/YYYY

2014 MAR 31

Assessment Status

Completed ☒

What tobacco/nicotine product did you use today?

None of the above ☒

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 ☒

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: 1202

Form: Product use diary (13)

Data signed: (hfarmer1) 27 Mar 2015 14:49:36

Generated On: 20 Jul 2016 20:43:03

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: 1202

Form: Product use diary (14)

Data signed: (hfarmer1) 27 Mar 2015 14:49:36

Generated On: 20 Jul 2016 20:43:03

Date of Birth

(b) (6)

Date of completion
DD/MMM/YYYY

2014 APR 01

Time of completion
hh:mm

20:07

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?

5

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: 1202

Form: Product use diary (14)

Data signed: (hfarmer1) 27 Mar 2015 14:49:36

Generated On: 20 Jul 2016 20:43:03

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: 1202

Form: Product use diary (15)

Data signed: (hfarmer1) 27 Mar 2015 14:49:36

Generated On: 20 Jul 2016 20:43:03

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 ☒

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?

6

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: 1202

Form: Product use diary (15)

Data signed: (hfarmer1) 27 Mar 2015 14:49:36

Generated On: 20 Jul 2016 20:43:03

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: 1202

Form: Product use diary (16)

Data signed: (hfarmer1) 27 Mar 2015 14:49:36

Generated On: 20 Jul 2016 20:43:03

Date of Birth	(b) (6)
Date of completion DD/MMM/YYYY	2014 APR 03
Time of completion hh:mm	20:00
Date the questionnaire was completed for DD/MMM/YYYY	2014 APR 03
Assessment Status	Completed <input checked="" type="radio"/>
What tobacco/nicotine product did you use today?	CC <input checked="" type="radio"/>
How many THS 2.2 tobacco sticks did you use today?	-9
How many CC/ roll-your-own did you smoke today?	5
What NRT product did you used today?	Not Applicable <input checked="" type="radio"/>
How many times did you use an inhaler today?	-9
How many times did you use a nasal spray today?	-9
How many gums did you use today?	-9
How many lozenges did you use today?	-9

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1202

Form: Product use diary (16)

Data signed: (hfarmer1) 27 Mar 2015 14:49:36

Generated On: 20 Jul 2016 20:43:03

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: 1202

Form: Product use diary (17)

Data signed: (hfarmer1) 27 Mar 2015 14:49:36

Generated On: 20 Jul 2016 20:43:03

Date of Birth

(b) (6)

Date of completion
DD/MMM/YYYY

2014 APR 04

Time of completion
hh:mm

20:02

Date the questionnaire was completed for
DD/MMM/YYYY

2014 APR 04

Assessment Status

Completed ☒

What tobacco/nicotine product did you use today?

CC ☒

How many THS 2.2 tobacco sticks did you use today?

-9

How many CC/ roll-your-own did you smoke today?

4

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: 1202

Form: Product use diary (17)

Data signed: (hfarmer1) 27 Mar 2015 14:49:36

Generated On: 20 Jul 2016 20:43:03

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: 1202

Form: Product use diary (18)

Data signed: (hfarmer1) 27 Mar 2015 14:49:36

Generated On: 20 Jul 2016 20:43:03

Date of Birth

(b) (6)

Date of completion
DD/MMM/YYYY

2014 APR 05

Time of completion
hh:mm

20:00

Date the questionnaire was completed for
DD/MMM/YYYY

2014 APR 05

Assessment Status

Completed ☒

What tobacco/nicotine product did you use today?

CC ☒

How many THS 2.2 tobacco sticks did you use today?

-9

How many CC/ roll-your-own did you smoke today?

7

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: 1202

Form: Product use diary (18)

Data signed: (hfarmer1) 27 Mar 2015 14:49:36

Generated On: 20 Jul 2016 20:43:03

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: 1202

Form: Product use diary (19)

Data signed: (hfarmer1) 27 Mar 2015 14:49:36

Generated On: 20 Jul 2016 20:43:03

Date of Birth

(b) (6)

Date of completion
DD/MMM/YYYY

2014 APR 06

Time of completion
hh:mm

22:00

Date the questionnaire was completed for
DD/MMM/YYYY

2014 APR 06

Assessment Status

Completed ☒

What tobacco/nicotine product did you use today?

None of the above ☒

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 ☒

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: 1202

Form: Product use diary (19)

Data signed: (hfarmer1) 27 Mar 2015 14:49:36

Generated On: 20 Jul 2016 20:43:03

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: 1202

Form: Product use diary (20)

Data signed: (hfarmer1) 27 Mar 2015 14:49:36

Generated On: 20 Jul 2016 20:43:03

Date of Birth

(b) (6)

Date of completion
DD/MMM/YYYY

2014 APR 07

Time of completion
hh:mm

20:00

Date the questionnaire was completed for
DD/MMM/YYYY

2014 APR 07

Assessment Status

Completed ☒

What tobacco/nicotine product did you use today?

None of the above ☒

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 ☒

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: 1202

Form: Product use diary (20)

Data signed: (hfarmer1) 27 Mar 2015 14:49:36

Generated On: 20 Jul 2016 20:43:03

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: 1202

Form: Product use diary (21)

Data signed: (hfarmer1) 27 Mar 2015 14:49:36

Generated On: 20 Jul 2016 20:43:03

Date of Birth	(b) (6)
Date of completion DD/MMM/YYYY	2014 APR 08
Time of completion hh:mm	20:01
Date the questionnaire was completed for DD/MMM/YYYY	2014 APR 08
Assessment Status	Completed <input checked="" type="radio"/>
What tobacco/nicotine product did you use today?	None of the above <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: 1202

Form: Product use diary (21)

Data signed: (hfarmer1) 27 Mar 2015 14:49:36

Generated On: 20 Jul 2016 20:43:03

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: 1202

Form: Product use diary (22)

Data signed: (hfarmer1) 27 Mar 2015 14:49:36

Generated On: 20 Jul 2016 20:43:03

Date of Birth

(b) (6)

Date of completion
DD/MMM/YYYY

2014 APR 09

Time of completion
hh:mm

20:00

Date the questionnaire was completed for
DD/MMM/YYYY

2014 APR 09

Assessment Status

Completed ☒

What tobacco/nicotine product did you use today?

None of the above ☒

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 ☒

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: 1202

Form: Product use diary (22)

Data signed: (hfarmer1) 27 Mar 2015 14:49:36

Generated On: 20 Jul 2016 20:43:03

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: 1202

Form: Product use diary (23)

Data signed: (hfarmer1) 27 Mar 2015 14:49:36

Generated On: 20 Jul 2016 20:43:03

Date of Birth

(b) (6)

Date of completion
DD/MMM/YYYY

2014 APR 10

Time of completion
hh:mm

22:57

Date the questionnaire was completed for
DD/MMM/YYYY

2014 APR 10

Assessment Status

Completed ☒

What tobacco/nicotine product did you use today?

None of the above ☒

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 ☒

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: 1202

Form: Product use diary (23)

Data signed: (hfarmer1) 27 Mar 2015 14:49:36

Generated On: 20 Jul 2016 20:43:03

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: 1202

Form: Product use diary (24)

Data signed: (hfarmer1) 27 Mar 2015 14:49:36

Generated On: 20 Jul 2016 20:43:03

Date of Birth

(b) (6)

Date of completion
DD/MMM/YYYY

2014 APR 11

Time of completion
hh:mm

21:01

Date the questionnaire was completed for
DD/MMM/YYYY

2014 APR 11

Assessment Status

Completed ☒

What tobacco/nicotine product did you use today?

None of the above ☒

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 ☒

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: 1202

Form: Product use diary (24)

Data signed: (hfarmer1) 27 Mar 2015 14:49:36

Generated On: 20 Jul 2016 20:43:03

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: 1202

Form: Product use diary (25)

Data signed: (hfarmer1) 27 Mar 2015 14:49:36

Generated On: 20 Jul 2016 20:43:03

Date of Birth	(b) (6)
Date of completion DD/MMM/YYYY	2014 APR 12
Time of completion hh:mm	20:00
Date the questionnaire was completed for DD/MMM/YYYY	2014 APR 12
Assessment Status	Completed <input checked="" type="radio"/>
What tobacco/nicotine product did you use today?	CC <input checked="" type="radio"/>
How many THS 2.2 tobacco sticks did you use today?	-9
How many CC/ roll-your-own did you smoke today?	7
What NRT product did you used today?	Not Applicable <input checked="" type="radio"/>
How many times did you use an inhaler today?	-9
How many times did you use a nasal spray today?	-9
How many gums did you use today?	-9
How many lozenges did you use today?	-9

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1202

Form: Product use diary (25)

Data signed: (hfarmer1) 27 Mar 2015 14:49:36

Generated On: 20 Jul 2016 20:43:03

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: 1202

Form: Product use diary (26)

Data signed: (hfarmer1) 27 Mar 2015 14:49:36

Generated On: 20 Jul 2016 20:43:03

Date of Birth	(b) (6)
Date of completion DD/MMM/YYYY	2014 APR 13
Time of completion hh:mm	20:03
Date the questionnaire was completed for DD/MMM/YYYY	2014 APR 13
Assessment Status	Completed <input checked="" type="radio"/>
What tobacco/nicotine product did you use today?	None of the above <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: 1202

Form: Product use diary (26)

Data signed: (hfarmer1) 27 Mar 2015 14:49:36

Generated On: 20 Jul 2016 20:43:03

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: 1202

Form: Product use diary (27)

Data signed: (hfarmer1) 27 Mar 2015 14:49:36

Generated On: 20 Jul 2016 20:43:03

Date of Birth

(b) (6)

Date of completion
DD/MMM/YYYY

2014 APR 14

Time of completion
hh:mm

19:56

Date the questionnaire was completed for
DD/MMM/YYYY

2014 APR 14

Assessment Status

Completed ☒

What tobacco/nicotine product did you use today?

None of the above ☒

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 ☒

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: 1202

Form: Product use diary (27)

Data signed: (hfarmer1) 27 Mar 2015 14:49:36

Generated On: 20 Jul 2016 20:43:03

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: 1202

Form: Product use diary (28)

Data signed: (hfarmer1) 27 Mar 2015 14:49:36

Generated On: 20 Jul 2016 20:43:03

Date of Birth

(b) (6)

Date of completion
DD/MMM/YYYY

2014 APR 15

Time of completion
hh:mm

20:00

Date the questionnaire was completed for
DD/MMM/YYYY

2014 APR 15

Assessment Status

Completed ☒

What tobacco/nicotine product did you use today?

None of the above ☒

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 ☒

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: 1202

Form: Product use diary (28)

Data signed: (hfarmer1) 27 Mar 2015 14:49:36

Generated On: 20 Jul 2016 20:43:03

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: 1202

Form: Product use diary (29)

Data signed: (hfarmer1) 27 Mar 2015 14:49:36

Generated On: 20 Jul 2016 20:43:03

Date of Birth

(b) (6)

Date of completion
DD/MMM/YYYY

2014 APR 16

Time of completion
hh:mm

20:00

Date the questionnaire was completed for
DD/MMM/YYYY

2014 APR 16

Assessment Status

Completed ☒

What tobacco/nicotine product did you use today?

None of the above ☒

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 ☒

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: 1202

Form: Product use diary (29)

Data signed: (hfarmer1) 27 Mar 2015 14:49:36

Generated On: 20 Jul 2016 20:43:03

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: 1202

Form: Product use diary (30)

Data signed: (hfarmer1) 27 Mar 2015 14:49:36

Generated On: 20 Jul 2016 20:43:03

Date of Birth

(b) (6)

Date of completion
DD/MMM/YYYY

2014 APR 17

Time of completion
hh:mm

20:00

Date the questionnaire was completed for
DD/MMM/YYYY

2014 APR 17

Assessment Status

Completed ☒

What tobacco/nicotine product did you use today?

None of the above ☒

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 ☒

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: 1202

Form: Product use diary (30)

Data signed: (hfarmer1) 27 Mar 2015 14:49:36

Generated On: 20 Jul 2016 20:43:03

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: 1202

Form: Product use diary (31)

Data signed: (hfarmer1) 27 Mar 2015 14:49:36

Generated On: 20 Jul 2016 20:43:03

Date of Birth

(b) (6)

Date of completion
DD/MMM/YYYY

2014 APR 18

Time of completion
hh:mm

20:00

Date the questionnaire was completed for
DD/MMM/YYYY

2014 APR 18

Assessment Status

Completed ☒

What tobacco/nicotine product did you use today?

None of the above ☒

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 ☒

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: 1202

Form: Product use diary (31)

Data signed: (hfarmer1) 27 Mar 2015 14:49:36

Generated On: 20 Jul 2016 20:43:03

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: 1202

Form: Product use diary (32)

Data signed: (hfarmer1) 27 Mar 2015 14:49:36

Generated On: 20 Jul 2016 20:43:03

Date of Birth	(b) (6)
Date of completion DD/MMM/YYYY	2014 APR 19
Time of completion hh:mm	20:00
Date the questionnaire was completed for DD/MMM/YYYY	2014 APR 19
Assessment Status	Completed <input checked="" type="radio"/>
What tobacco/nicotine product did you use today?	None of the above <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: 1202

Form: Product use diary (32)

Data signed: (hfarmer1) 27 Mar 2015 14:49:36

Generated On: 20 Jul 2016 20:43:03

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: 1202

Form: Product use diary (33)

Data signed: (hfarmer1) 27 Mar 2015 14:49:36

Generated On: 20 Jul 2016 20:43:03

Date of Birth	(b) (6)
Date of completion DD/MMM/YYYY	2014 APR 22
Time of completion hh:mm	21:00
Date the questionnaire was completed for DD/MMM/YYYY	2014 APR 22
Assessment Status	Completed <input checked="" type="radio"/>
What tobacco/nicotine product did you use today?	None of the above <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: 1202

Form: Product use diary (33)

Data signed: (hfarmer1) 27 Mar 2015 14:49:36

Generated On: 20 Jul 2016 20:43:03

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 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: 1202

Form: Product use diary (34)

Data signed: (hfarmer1) 27 Mar 2015 14:49:36

Generated On: 20 Jul 2016 20:43:03

Date of Birth

(b) (6)

Date of completion
DD/MMM/YYYY

2014 APR 23

Time of completion
hh:mm

20:00

Date the questionnaire was completed for
DD/MMM/YYYY

2014 APR 23

Assessment Status

Completed ☒

What tobacco/nicotine product did you use today?

None of the above ☒

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 ☒

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: 1202

Form: Product use diary (34)

Data signed: (hfarmer1) 27 Mar 2015 14:49:36

Generated On: 20 Jul 2016 20:43:03

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: 1202

Form: Product use diary (35)

Data signed: (hfarmer1) 27 Mar 2015 14:49:36

Generated On: 20 Jul 2016 20:43:03

Date of Birth

(b) (6)

Date of completion
DD/MMM/YYYY

2014 APR 24

Time of completion
hh:mm

20:00

Date the questionnaire was completed for
DD/MMM/YYYY

2014 APR 24

Assessment Status

Completed ☒

What tobacco/nicotine product did you use today?

None of the above ☒

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 ☒

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: 1202

Form: Product use diary (35)

Data signed: (hfarmer1) 27 Mar 2015 14:49:36

Generated On: 20 Jul 2016 20:43:03

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: 1202

Form: Product use diary (36)

Data signed: (hfarmer1) 27 Mar 2015 14:49:36

Generated On: 20 Jul 2016 20:43:03

Date of Birth

(b) (6)

Date of completion
DD/MMM/YYYY

2014 APR 26

Time of completion
hh:mm

23:20

Date the questionnaire was completed for
DD/MMM/YYYY

2014 APR 26

Assessment Status

Completed ☒

What tobacco/nicotine product did you use today?

None of the above ☒

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 ☒

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: 1202

Form: Product use diary (36)

Data signed: (hfarmer1) 27 Mar 2015 14:49:36

Generated On: 20 Jul 2016 20:43:03

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: 1202

Form: Product use diary (37)

Data signed: (hfarmer1) 27 Mar 2015 14:49:36

Generated On: 20 Jul 2016 20:43:03

Date of Birth

(b) (6)

Date of completion
DD/MMM/YYYY

2014 APR 27

Time of completion
hh:mm

20:01

Date the questionnaire was completed for
DD/MMM/YYYY

2014 APR 27

Assessment Status

Completed ☒

What tobacco/nicotine product did you use today?

None of the above ☒

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 ☒

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: 1202

Form: Product use diary (37)

Data signed: (hfarmer1) 27 Mar 2015 14:49:36

Generated On: 20 Jul 2016 20:43:03

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: 1202

Form: Product use diary (38)

Data signed: (hfarmer1) 27 Mar 2015 14:49:36

Generated On: 20 Jul 2016 20:43:03

Date of Birth

(b) (6)

Date of completion
DD/MMM/YYYY

2014 APR 28

Time of completion
hh:mm

20:00

Date the questionnaire was completed for
DD/MMM/YYYY

2014 APR 28

Assessment Status

Completed ☒

What tobacco/nicotine product did you use today?

None of the above ☒

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 ☒

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: 1202

Form: Product use diary (38)

Data signed: (hfarmer1) 27 Mar 2015 14:49:36

Generated On: 20 Jul 2016 20:43:03

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: 1202

Form: Product use diary (39)

Data signed: (hfarmer1) 27 Mar 2015 14:49:36

Generated On: 20 Jul 2016 20:43:03

Date of Birth

(b) (6)

Date of completion
DD/MMM/YYYY

2014 APR 30

Time of completion
hh:mm

09:00

Date the questionnaire was completed for
DD/MMM/YYYY

2014 APR 29

Assessment Status

Completed ☒

What tobacco/nicotine product did you use today?

None of the above ☒

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 ☒

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: 1202

Form: Product use diary (39)

Data signed: (hfarmer1) 27 Mar 2015 14:49:36

Generated On: 20 Jul 2016 20:43:03

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: 1202

Form: Product use diary (40)

Data signed: (hfarmer1) 27 Mar 2015 14:49:36

Generated On: 20 Jul 2016 20:43:03

Date of Birth

(b) (6)

Date of completion
DD/MMM/YYYY

2014 APR 30

Time of completion
hh:mm

20:01

Date the questionnaire was completed for
DD/MMM/YYYY

2014 APR 30

Assessment Status

Completed ☒

What tobacco/nicotine product did you use today?

None of the above ☒

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 ☒

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: 1202

Form: Product use diary (40)

Data signed: (hfarmer1) 27 Mar 2015 14:49:36

Generated On: 20 Jul 2016 20:43:03

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: 1202

Form: Product use diary (41)

Data signed: (hfarmer1) 27 Mar 2015 14:49:36

Generated On: 20 Jul 2016 20:43:03

Date of Birth

(b) (6)

Date of completion
DD/MMM/YYYY

2014 MAY 01

Time of completion
hh:mm

20:13

Date the questionnaire was completed for
DD/MMM/YYYY

2014 MAY 01

Assessment Status

Completed ☒

What tobacco/nicotine product did you use today?

None of the above ☒

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 ☒

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: 1202

Form: Product use diary (41)

Data signed: (hfarmer1) 27 Mar 2015 14:49:36

Generated On: 20 Jul 2016 20:43:03

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: 1202

Form: Product use diary (42)

Data signed: (hfarmer1) 27 Mar 2015 14:49:36

Generated On: 20 Jul 2016 20:43:03

Date of Birth

(b) (6)

Date of completion
DD/MMM/YYYY

2014 MAY 02

Time of completion
hh:mm

20:00

Date the questionnaire was completed for
DD/MMM/YYYY

2014 MAY 02

Assessment Status

Completed ☒

What tobacco/nicotine product did you use today?

None of the above ☒

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 ☒

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: 1202

Form: Product use diary (42)

Data signed: (hfarmer1) 27 Mar 2015 14:49:36

Generated On: 20 Jul 2016 20:43:03

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: 1202

Form: Product use diary (43)

Data signed: (hfarmer1) 27 Mar 2015 14:49:36

Generated On: 20 Jul 2016 20:43:03

Date of Birth

(b) (6)

Date of completion
DD/MMM/YYYY

2014 MAY 03

Time of completion
hh:mm

20:04

Date the questionnaire was completed for
DD/MMM/YYYY

2014 MAY 03

Assessment Status

Completed ☒

What tobacco/nicotine product did you use today?

None of the above ☒

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 ☒

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: 1202

Form: Product use diary (43)

Data signed: (hfarmer1) 27 Mar 2015 14:49:36

Generated On: 20 Jul 2016 20:43:03

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: 1202

Form: Product use diary (44)

Data signed: (hfarmer1) 27 Mar 2015 14:49:36

Generated On: 20 Jul 2016 20:43:03

Date of Birth

(b) (6)

Date of completion
DD/MMM/YYYY

2014 MAY 04

Time of completion
hh:mm

20:00

Date the questionnaire was completed for
DD/MMM/YYYY

2014 MAY 04

Assessment Status

Completed ☒

What tobacco/nicotine product did you use today?

None of the above ☒

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 ☒

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: 1202

Form: Product use diary (44)

Data signed: (hfarmer1) 27 Mar 2015 14:49:36

Generated On: 20 Jul 2016 20:43:03

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: 1202

Form: Product use diary (45)

Data signed: (hfarmer1) 27 Mar 2015 14:49:36

Generated On: 20 Jul 2016 20:43:03

Date of Birth	(b) (6)
Date of completion DD/MMM/YYYY	2014 MAY 05
Time of completion hh:mm	20:00
Date the questionnaire was completed for DD/MMM/YYYY	2014 MAY 05
Assessment Status	Completed <input checked="" type="radio"/>
What tobacco/nicotine product did you use today?	None of the above <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: 1202

Form: Product use diary (45)

Data signed: (hfarmer1) 27 Mar 2015 14:49:36

Generated On: 20 Jul 2016 20:43:03

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: 1202

Form: Product use diary (46)

Data signed: (hfarmer1) 27 Mar 2015 14:49:36

Generated On: 20 Jul 2016 20:43:03

Date of Birth

(b) (6)

Date of completion
DD/MMM/YYYY

2014 MAY 06

Time of completion
hh:mm

20:00

Date the questionnaire was completed for
DD/MMM/YYYY

2014 MAY 06

Assessment Status

Completed ☒

What tobacco/nicotine product did you use today?

None of the above ☒

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 ☒

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: 1202

Form: Product use diary (46)

Data signed: (hfarmer1) 27 Mar 2015 14:49:36

Generated On: 20 Jul 2016 20:43:03

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: 1202

Form: Product use diary (47)

Data signed: (hfarmer1) 27 Mar 2015 14:49:36

Generated On: 20 Jul 2016 20:43:03

Date of Birth	(b) (6)
Date of completion DD/MMM/YYYY	2014 MAY 07
Time of completion hh:mm	20:00
Date the questionnaire was completed for DD/MMM/YYYY	2014 MAY 07
Assessment Status	Completed <input checked="" type="radio"/>
What tobacco/nicotine product did you use today?	None of the above <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: 1202

Form: Product use diary (47)

Data signed: (hfarmer1) 27 Mar 2015 14:49:36

Generated On: 20 Jul 2016 20:43:03

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: 1202

Form: Product use diary (48)

Data signed: (hfarmer1) 27 Mar 2015 14:49:36

Generated On: 20 Jul 2016 20:43:03

Date of Birth

(b) (6)

Date of completion
DD/MMM/YYYY

2014 MAY 08

Time of completion
hh:mm

21:57

Date the questionnaire was completed for
DD/MMM/YYYY

2014 MAY 08

Assessment Status

Completed ☒

What tobacco/nicotine product did you use today?

None of the above ☒

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 ☒

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: 1202

Form: Product use diary (48)

Data signed: (hfarmer1) 27 Mar 2015 14:49:36

Generated On: 20 Jul 2016 20:43:03

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: 1202

Form: Product use diary (49)

Data signed: (hfarmer1) 27 Mar 2015 14:49:36

Generated On: 20 Jul 2016 20:43:03

Date of Birth

(b) (6)

Date of completion
DD/MMM/YYYY

2014 MAY 12

Time of completion
hh:mm

09:03

Date the questionnaire was completed for
DD/MMM/YYYY

2014 MAY 11

Assessment Status

Completed ☒

What tobacco/nicotine product did you use today?

None of the above ☒

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 ☒

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: 1202

Form: Product use diary (49)

Data signed: (hfarmer1) 27 Mar 2015 14:49:36

Generated On: 20 Jul 2016 20:43:03

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: 1202

Form: Product use diary (50)

Data signed: (hfarmer1) 27 Mar 2015 14:49:36

Generated On: 20 Jul 2016 20:43:03

Date of Birth	(b) (6)
Date of completion DD/MMM/YYYY	2014 MAY 12
Time of completion hh:mm	20:00
Date the questionnaire was completed for DD/MMM/YYYY	2014 MAY 12
Assessment Status	Completed <input checked="" type="radio"/>
What tobacco/nicotine product did you use today?	None of the above <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: 1202

Form: Product use diary (50)

Data signed: (hfarmer1) 27 Mar 2015 14:49:36

Generated On: 20 Jul 2016 20:43:03

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: 1202

Form: Product use diary (51)

Data signed: (hfarmer1) 27 Mar 2015 14:49:36

Generated On: 20 Jul 2016 20:43:03

Date of Birth

(b) (6)

Date of completion
DD/MMM/YYYY

2014 MAY 13

Time of completion
hh:mm

20:00

Date the questionnaire was completed for
DD/MMM/YYYY

2014 MAY 13

Assessment Status

Completed ☒

What tobacco/nicotine product did you use today?

None of the above ☒

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 ☒

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: 1202

Form: Product use diary (51)

Data signed: (hfarmer1) 27 Mar 2015 14:49:36

Generated On: 20 Jul 2016 20:43:03

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: 1202

Form: Product use diary (52)

Data signed: (hfarmer1) 27 Mar 2015 14:49:36

Generated On: 20 Jul 2016 20:43:03

Date of Birth	(b) (6)
Date of completion DD/MMM/YYYY	2014 MAY 14
Time of completion hh:mm	20:00
Date the questionnaire was completed for DD/MMM/YYYY	2014 MAY 14
Assessment Status	Completed <input checked="" type="radio"/>
What tobacco/nicotine product did you use today?	None of the above <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: 1202

Form: Product use diary (52)

Data signed: (hfarmer1) 27 Mar 2015 14:49:36

Generated On: 20 Jul 2016 20:43:03

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: 1202

Form: Product use diary (53)

Data signed: (hfarmer1) 27 Mar 2015 14:49:36

Generated On: 20 Jul 2016 20:43:03

Date of Birth

(b) (6)

Date of completion
DD/MMM/YYYY

2014 MAY 16

Time of completion
hh:mm

11:00

Date the questionnaire was completed for
DD/MMM/YYYY

2014 MAY 15

Assessment Status

Completed ☒

What tobacco/nicotine product did you use today?

None of the above ☒

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 ☒

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: 1202

Form: Product use diary (53)

Data signed: (hfarmer1) 27 Mar 2015 14:49:36

Generated On: 20 Jul 2016 20:43:03

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: 1202

Form: Product use diary (54)

Data signed: (hfarmer1) 27 Mar 2015 14:49:36

Generated On: 20 Jul 2016 20:43:03

Date of Birth

(b) (6)

Date of completion
DD/MMM/YYYY

2014 MAY 16

Time of completion
hh:mm

22:01

Date the questionnaire was completed for
DD/MMM/YYYY

2014 MAY 16

Assessment Status

Completed ☒

What tobacco/nicotine product did you use today?

None of the above ☒

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 ☒

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: 1202

Form: Product use diary (54)

Data signed: (hfarmer1) 27 Mar 2015 14:49:36

Generated On: 20 Jul 2016 20:43:03

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: 1202

Form: Product use diary (55)

Data signed: (hfarmer1) 27 Mar 2015 14:49:36

Generated On: 20 Jul 2016 20:43:03

Date of Birth	(b) (6)
Date of completion DD/MMM/YYYY	2014 MAY 17
Time of completion hh:mm	20:00
Date the questionnaire was completed for DD/MMM/YYYY	2014 MAY 17
Assessment Status	Completed <input checked="" type="radio"/>
What tobacco/nicotine product did you use today?	None of the above <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: 1202

Form: Product use diary (55)

Data signed: (hfarmer1) 27 Mar 2015 14:49:36

Generated On: 20 Jul 2016 20:43:03

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: 1202

Form: Product use diary (57)

Data signed: (hfarmer1) 27 Mar 2015 14:49:36

Generated On: 20 Jul 2016 20:43:03

Date of Birth

(b) (6)

Date of completion
DD/MMM/YYYY

2014 MAY 18

Time of completion
hh:mm

20:02

Date the questionnaire was completed for
DD/MMM/YYYY

2014 MAY 18

Assessment Status

Completed ☒

What tobacco/nicotine product did you use today?

None of the above ☒

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 ☒

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: 1202

Form: Product use diary (57)

Data signed: (hfarmer1) 27 Mar 2015 14:49:36

Generated On: 20 Jul 2016 20:43:03

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: 1202

Form: Product use diary (58)

Data signed: (hfarmer1) 27 Mar 2015 14:49:36

Generated On: 20 Jul 2016 20:43:03

Date of Birth

(b) (6)

Date of completion
DD/MMM/YYYY

2014 MAY 19

Time of completion
hh:mm

20:00

Date the questionnaire was completed for
DD/MMM/YYYY

2014 MAY 19

Assessment Status

Completed ☒

What tobacco/nicotine product did you use today?

None of the above ☒

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 ☒

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: 1202

Form: Product use diary (58)

Data signed: (hfarmer1) 27 Mar 2015 14:49:36

Generated On: 20 Jul 2016 20:43:03

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: 1202

Form: Product use diary (59)

Data signed: (hfarmer1) 27 Mar 2015 14:49:36

Generated On: 20 Jul 2016 20:43:03

Date of Birth

(b) (6)

Date of completion
DD/MMM/YYYY

2014 MAY 20

Time of completion
hh:mm

21:00

Date the questionnaire was completed for
DD/MMM/YYYY

2014 MAY 20

Assessment Status

Completed ☒

What tobacco/nicotine product did you use today?

None of the above ☒

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 ☒

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: 1202

Form: Product use diary (59)

Data signed: (hfarmer1) 27 Mar 2015 14:49:36

Generated On: 20 Jul 2016 20:43:03

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: 1202

Form: Product use diary (60)

Data signed: (hfarmer1) 27 Mar 2015 14:49:36

Generated On: 20 Jul 2016 20:43:03

Date of Birth

(b) (6)

Date of completion
DD/MMM/YYYY

2014 MAY 21

Time of completion
hh:mm

20:03

Date the questionnaire was completed for
DD/MMM/YYYY

2014 MAY 21

Assessment Status

Completed ☒

What tobacco/nicotine product did you use today?

None of the above ☒

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 ☒

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: 1202

Form: Product use diary (60)

Data signed: (hfarmer1) 27 Mar 2015 14:49:36

Generated On: 20 Jul 2016 20:43:03

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: 1202

Form: Product use diary (61)

Data signed: (hfarmer1) 27 Mar 2015 14:49:36

Generated On: 20 Jul 2016 20:43:03

Date of Birth

(b) (6)

Date of completion
DD/MMM/YYYY

2014 MAY 22

Time of completion
hh:mm

20:00

Date the questionnaire was completed for
DD/MMM/YYYY

2014 MAY 22

Assessment Status

Completed ☒

What tobacco/nicotine product did you use today?

None of the above ☒

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 ☒

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: 1202

Form: Product use diary (61)

Data signed: (hfarmer1) 27 Mar 2015 14:49:36

Generated On: 20 Jul 2016 20:43:03

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: 1202

Form: Product use diary (62)

Data signed: (hfarmer1) 27 Mar 2015 14:49:36

Generated On: 20 Jul 2016 20:43:03

Date of Birth

(b) (6)

Date of completion
DD/MMM/YYYY

2014 MAY 23

Time of completion
hh:mm

20:02

Date the questionnaire was completed for
DD/MMM/YYYY

2014 MAY 23

Assessment Status

Completed ☒

What tobacco/nicotine product did you use today?

None of the above ☒

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 ☒

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: 1202**

Form: Product use diary (62)

Data signed: (hfarmer1) 27 Mar 2015 14:49:36

Generated On: 20 Jul 2016 20:43:03

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: 1202

Form: Product use diary (63)

Data signed: (hfarmer1) 27 Mar 2015 14:49:36

Generated On: 20 Jul 2016 20:43:03

Date of Birth

(b) (6)

Date of completion
DD/MMM/YYYY

2014 MAY 24

Time of completion
hh:mm

20:00

Date the questionnaire was completed for
DD/MMM/YYYY

2014 MAY 24

Assessment Status

Completed ☒

What tobacco/nicotine product did you use today?

None of the above ☒

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 ☒

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: 1202

Form: Product use diary (63)

Data signed: (hfarmer1) 27 Mar 2015 14:49:36

Generated On: 20 Jul 2016 20:43:03

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: 1202

Form: Product use diary (64)

Data signed: (hfarmer1) 27 Mar 2015 14:49:36

Generated On: 20 Jul 2016 20:43:03

Date of Birth	(b) (6)
Date of completion DD/MMM/YYYY	2014 MAY 25
Time of completion hh:mm	20:00
Date the questionnaire was completed for DD/MMM/YYYY	2014 MAY 25
Assessment Status	Completed <input checked="" type="radio"/>
What tobacco/nicotine product did you use today?	None of the above <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: 1202

Form: Product use diary (64)

Data signed: (hfarmer1) 27 Mar 2015 14:49:36

Generated On: 20 Jul 2016 20:43:03

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: 1202

Form: Product use diary (65)

Data signed: (hfarmer1) 27 Mar 2015 14:49:36

Generated On: 20 Jul 2016 20:43:03

Date of Birth

(b) (6)

Date of completion
DD/MMM/YYYY

2014 MAY 26

Time of completion
hh:mm

21:00

Date the questionnaire was completed for
DD/MMM/YYYY

2014 MAY 26

Assessment Status

Completed ☒

What tobacco/nicotine product did you use today?

None of the above ☒

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 ☒

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: 1202

Form: Product use diary (65)

Data signed: (hfarmer1) 27 Mar 2015 14:49:36

Generated On: 20 Jul 2016 20:43:03

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: 1202

Form: Product use diary (67)

Data signed: (hfarmer1) 27 Mar 2015 14:49:36

Generated On: 20 Jul 2016 20:43:03

Date of Birth

(b) (6)

Date of completion
DD/MMM/YYYY

2014 MAY 27

Time of completion
hh:mm

20:00

Date the questionnaire was completed for
DD/MMM/YYYY

2014 MAY 27

Assessment Status

Completed ☒

What tobacco/nicotine product did you use today?

None of the above ☒

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 ☒

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: 1202

Form: Product use diary (67)

Data signed: (hfarmer1) 27 Mar 2015 14:49:36

Generated On: 20 Jul 2016 20:43:03

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: 1202

Form: Product use diary (68)

Data signed: (hfarmer1) 27 Mar 2015 14:49:36

Generated On: 20 Jul 2016 20:43:03

Date of Birth

(b) (6)

Date of completion
DD/MMM/YYYY

2014 MAY 29

Time of completion
hh:mm

11:01

Date the questionnaire was completed for
DD/MMM/YYYY

2014 MAY 28

Assessment Status

Completed ☒

What tobacco/nicotine product did you use today?

None of the above ☒

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 ☒

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: 1202

Form: Product use diary (68)

Data signed: (hfarmer1) 27 Mar 2015 14:49:36

Generated On: 20 Jul 2016 20:43:03

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: 1202

Form: Product use diary (69)

Data signed: (hfarmer1) 27 Mar 2015 14:49:36

Generated On: 20 Jul 2016 20:43:03

Date of Birth

(b) (6)

Date of completion
DD/MMM/YYYY

2014 MAY 29

Time of completion
hh:mm

20:00

Date the questionnaire was completed for
DD/MMM/YYYY

2014 MAY 29

Assessment Status

Completed ☒

What tobacco/nicotine product did you use today?

None of the above ☒

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 ☒

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: 1202

Form: Product use diary (69)

Data signed: (hfarmer1) 27 Mar 2015 14:49:36

Generated On: 20 Jul 2016 20:43:03

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: 1202

Form: Product use diary (70)

Data signed: (hfarmer1) 27 Mar 2015 14:49:36

Generated On: 20 Jul 2016 20:43:03

Date of Birth

(b) (6)

Date of completion
DD/MMM/YYYY

2014 MAY 30

Time of completion
hh:mm

20:01

Date the questionnaire was completed for
DD/MMM/YYYY

2014 MAY 30

Assessment Status

Completed ☒

What tobacco/nicotine product did you use today?

None of the above ☒

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 ☒

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: 1202

Form: Product use diary (70)

Data signed: (hfarmer1) 27 Mar 2015 14:49:36

Generated On: 20 Jul 2016 20:43:03

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: 1202

Form: Product use diary (71)

Data signed: (hfarmer1) 27 Mar 2015 14:49:36

Generated On: 20 Jul 2016 20:43:03

Date of Birth	(b) (6)
Date of completion DD/MMM/YYYY	2014 MAY 31
Time of completion hh:mm	20:00
Date the questionnaire was completed for DD/MMM/YYYY	2014 MAY 31
Assessment Status	Completed <input checked="" type="radio"/>
What tobacco/nicotine product did you use today?	None of the above <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: 1202

Form: Product use diary (71)

Data signed: (hfarmer1) 27 Mar 2015 14:49:36

Generated On: 20 Jul 2016 20:43:03

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: 1202**

Form: End of study

Data signed: (hfarmer1) 27 Mar 2015 14:49:36

Generated On: 20 Jul 2016 20:43:03

End of study date

10 JUL 2014
DD/MMM/YYYY

Has the subject completed the study ?

No ☒

If No, please specify the reason:

Withdrawal by Subject ☒

Details:

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1202**

Form: Consent Withdrawal

Data signed: (hfarmer1) 27 Mar 2015 14:49:36

Generated On: 20 Jul 2016 20:43:03

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: 1202**

Form: Withdrawal

Data signed: (hfarmer1) 27 Mar 2015 14:49:36

Generated On: 20 Jul 2016 20:43:03

Date of withdrawal	12 JUN 2014 DD/MMM/YYYY
--------------------	-------------------------

Did the subject withdraw it's consent from the main study?	Yes <input type="radio"/>
--	---------------------------

If available, please provide details	SUBJECT WITHDREW FROM THE STUDY
--------------------------------------	---------------------------------

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?	No <input type="radio"/>
--	--------------------------
