

Subject Case Report Forms

1062 (Prod: Covance Clinical Development Services, Daytona Beach, Florida)

Generated On: 20 Jul 2016 12:09:14

All time stamps listed in this document are displayed in GMT

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Form: Subject

Data signed: (hfarmer1) 26 Mar 2015 14:17:53

Generated On: 20 Jul 2016 12:09:14

Screening number	1062
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Site number	DAY
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Subject Status

Form: Subject Status

Data signed: (hfarmer1) 26 Mar 2015 14:17:55

Generated On: 20 Jul 2016 12:09:14

Date of 'Screen Failed' Event

Date of 'Discontinued From
Enrollment' Event

Randomization Date

19 JAN 2014
DD/MMM/YYYY

Randomization Time

10:55
hour:min 24-hour clock

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Screening

Form: Date of Visit

Data signed: (hfarmer1) 26 Mar 2015 14:18:06

Generated On: 20 Jul 2016 12:09:14

Date of Visit

15 JAN 2014
DD/MMM/YYYY

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Screening

Form: Additional Informed Consent

Data signed: (hfarmer1) 26 Mar 2015 14:17:56

Generated On: 20 Jul 2016 12:09:14

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

Yes ☒

Consent Date

15 JAN 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

15 JAN 2014
DD/MMM/YYYY

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Screening

Form: Inclusion Criteria

Data signed: (hfarmer1) 26 Mar 2015 14:17:57

Generated On: 20 Jul 2016 12:09:14

*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: 1062**

Folder: Screening

Form: Inclusion Criteria (1)

Data signed: (hfarmer1) 26 Mar 2015 14:17:57

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Screening

Form: Inclusion Criteria (2)

Data signed: (hfarmer1) 26 Mar 2015 14:17:57

Generated On: 20 Jul 2016 12:09:14

Inclusion Criterion Number	2
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Inclusion Criterion	Subject is at a minimum 22 years of age(inclusive).	<input checked="" type="radio"/>
---------------------	--	----------------------------------

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

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1062

Folder: Screening

Form: Inclusion Criteria (3)

Data signed: (hfarmer1) 26 Mar 2015 14:17:57

Generated On: 20 Jul 2016 12:09:14

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: 1062

Folder: Screening

Form: Inclusion Criteria (4)

Data signed: (hfarmer1) 26 Mar 2015 14:17:57

Generated On: 20 Jul 2016 12:09:14

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

*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: 1062**

Folder: Screening

Form: Inclusion Criteria (5)

Data signed: (hfarmer1) 26 Mar 2015 14:17:57

Generated On: 20 Jul 2016 12:09:14

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Screening

Form: Inclusion Criteria (6)

Data signed: (hfarmer1) 26 Mar 2015 14:17:57

Generated On: 20 Jul 2016 12:09:14

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

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Screening

Form: Exclusion Criteria

Data signed: (hfarmer1) 26 Mar 2015 14:17:56

Generated On: 20 Jul 2016 12:09:14

*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: 1062**

Folder: Screening

Form: Exclusion Criteria (1)

Data signed: (hfarmer1) 26 Mar 2015 14:17:56

Generated On: 20 Jul 2016 12:09:14

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: 1062

Folder: Screening

Form: Exclusion Criteria (2)

Data signed: (hfarmer1) 26 Mar 2015 14:17:56

Generated On: 20 Jul 2016 12:09:14

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

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

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1062

Folder: Screening

Form: Exclusion Criteria (3)

Data signed: (hfarmer1) 26 Mar 2015 14:17:56

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Screening

Form: Exclusion Criteria (4)

Data signed: (hfarmer1) 26 Mar 2015 14:17:56

Generated On: 20 Jul 2016 12:09:14

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

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

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

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1062

Folder: Screening

Form: Exclusion Criteria (5)

Data signed: (hfarmer1) 26 Mar 2015 14:17:56

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Screening

Form: Exclusion Criteria (6)

Data signed: (hfarmer1) 26 Mar 2015 14:17:56

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Screening

Form: Exclusion Criteria (7)

Data signed: (hfarmer1) 26 Mar 2015 14:17:56

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Screening

Form: Exclusion Criteria (8)

Data signed: (hfarmer1) 26 Mar 2015 14:17:56

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Screening

Form: Exclusion Criteria (9)

Data signed: (hfarmer1) 26 Mar 2015 14:17:56

Generated On: 20 Jul 2016 12:09:14

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

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

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1062

Folder: Screening

Form: Exclusion Criteria (10)

Data signed: (hfarmer1) 26 Mar 2015 14:17:56

Generated On: 20 Jul 2016 12:09:14

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

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1062

Folder: Screening

Form: Exclusion Criteria (11)

Data signed: (hfarmer1) 26 Mar 2015 14:17:56

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Screening

Form: Exclusion Criteria (12)

Data signed: (hfarmer1) 26 Mar 2015 14:17:56

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Screening

Form: Exclusion Criteria (13)

Data signed: (hfarmer1) 26 Mar 2015 14:17:56

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Screening

Form: Exclusion Criteria (14)

Data signed: (hfarmer1) 26 Mar 2015 14:17:56

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Screening

Form: Exclusion Criteria (15)

Data signed: (hfarmer1) 26 Mar 2015 14:17:56

Generated On: 20 Jul 2016 12:09:14

Exclusion Criterion Number	16
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Exclusion Criterion	Positive serology test for human immunodeficiency virus (HIV)1/2, hepatitis B or hepatitis C.
---------------------	--

Result	No
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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: 1062**

Folder: Screening

Form: Exclusion Criteria (16)

Data signed: (hfarmer1) 26 Mar 2015 14:17:56

Generated On: 20 Jul 2016 12:09:14

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

Result	No	<input 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: 1062**

Folder: Screening

Form: Exclusion Criteria (17)

Data signed: (hfarmer1) 26 Mar 2015 14:17:56

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Screening

Form: Exclusion Criteria (18)

Data signed: (hfarmer1) 26 Mar 2015 14:17:56

Generated On: 20 Jul 2016 12:09:14

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

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

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

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Screening

Form: Exclusion Criteria (19)

Data signed: (hfarmer1) 26 Mar 2015 14:17:56

Generated On: 20 Jul 2016 12:09:14

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

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Screening

Form: Exclusion Criteria (20)

Data signed: (hfarmer1) 26 Mar 2015 14:17:56

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Screening

Form: Exclusion Criteria (21)

Data signed: (hfarmer1) 26 Mar 2015 14:17:56

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Screening

Form: Demographics

Data signed: (hfarmer1) 26 Mar 2015 14:17:55

Generated On: 20 Jul 2016 12:09:14

Date of Birth

(b) (6)

Sex

Male ☒

Race

White ☒

Other, specify _____

Ethnicity

Not Hispanic ☒

Date the Subject signed the Informed Consent

15 JAN 2014
DD/MMM/YYYY

Time the Subject signed the Informed Consent

08:48
hour:min 24-hour clock

Age(Derived)

49

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Screening

Form: Medical History/Concomitant Disease

Data signed: (hfarmer1) 26 Mar 2015 14:17:58

Generated On: 20 Jul 2016 12:09:14

Date of collection

15 JAN 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: 1062**

Folder: Screening

Form: Medical History/Concomitant Disease (1)

Data signed: (hfarmer1) 26 Mar 2015 14:17:58

Generated On: 20 Jul 2016 12:09:14

Date of collection	15 JAN 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	TATTOOS RIGHT ARM
-----------------------	-------------------

Onset Date DD/MMM/YYYY	UN UNK 1987
---------------------------	-------------

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

Ongoing?	True
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Screening

Form: Medical History/Concomitant Disease (2)

Data signed: (hfarmer1) 26 Mar 2015 14:17:58

Generated On: 20 Jul 2016 12:09:14

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

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

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

Diagnosis Description	PRESBYOPIA
-----------------------	------------

Onset Date DD/MMM/YYYY	UN UNK 2011
---------------------------	-------------

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

Ongoing?	True
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Screening

Form: Vital Signs<Screening/<

Data signed: (hfarmer1) 26 Mar 2015 14:18:06

Generated On: 20 Jul 2016 12:09:14

Were Vitals Signs assessed?

Yes ☒

If No, please specify the reason: _____

Has the subject smoked within 15 minutes prior to
assessment

No ☒

Date of assessment

15 JAN 2014
DD/MMM/YYYY

Time of assessment

09:44
hour:min 24-hour clock

Pulse rate

56
beats per minute

Respiratory rate

14
breaths per minute

Blood Pressure (systolic)

123
mmHg

Blood Pressure (diastolic)

81
mmHg

Vital Signs Position of Subject

Supine ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Screening

Form: Physical Examination

Data signed: (hfarmer1) 26 Mar 2015 14:17:59

Generated On: 20 Jul 2016 12:09:14

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

15 JAN 2014
DD/MMM/YYYY

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Screening

Form: Physical Examination (1)

Data signed: (hfarmer1) 26 Mar 2015 14:17:59

Generated On: 20 Jul 2016 12:09:14

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of assessment 15 JAN 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: 1062**

Folder: Screening

Form: Physical Examination (2)

Data signed: (hfarmer1) 26 Mar 2015 14:17:59

Generated On: 20 Jul 2016 12:09:14

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of assessment 15 JAN 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: 1062**

Folder: Screening

Form: Physical Examination (3)

Data signed: (hfarmer1) 26 Mar 2015 14:17:59

Generated On: 20 Jul 2016 12:09:14

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of assessment 15 JAN 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: 1062**

Folder: Screening

Form: Physical Examination (4)

Data signed: (hfarmer1) 26 Mar 2015 14:17:59

Generated On: 20 Jul 2016 12:09:14

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

15 JAN 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: 1062**

Folder: Screening

Form: Physical Examination (5)

Data signed: (hfarmer1) 26 Mar 2015 14:17:59

Generated On: 20 Jul 2016 12:09:14

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of assessment 15 JAN 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: 1062**

Folder: Screening

Form: Physical Examination (6)

Data signed: (hfarmer1) 26 Mar 2015 14:17:59

Generated On: 20 Jul 2016 12:09:14

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

15 JAN 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: 1062**

Folder: Screening

Form: Physical Examination (7)

Data signed: (hfarmer1) 26 Mar 2015 14:17:59

Generated On: 20 Jul 2016 12:09:14

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

15 JAN 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: 1062**

Folder: Screening

Form: Physical Examination (8)

Data signed: (hfarmer1) 26 Mar 2015 14:17:59

Generated On: 20 Jul 2016 12:09:14

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of assessment 15 JAN 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: 1062**

Folder: Screening

Form: Physical Examination (9)

Data signed: (hfarmer1) 26 Mar 2015 14:17:59

Generated On: 20 Jul 2016 12:09:14

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of assessment 15 JAN 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: 1062**

Folder: Screening

Form: Physical Examination (10)

Data signed: (hfarmer1) 26 Mar 2015 14:17:59

Generated On: 20 Jul 2016 12:09:14

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of assessment 15 JAN 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: 1062**

Folder: Screening

Form: Physical Examination (11)

Data signed: (hfarmer1) 26 Mar 2015 14:17:59

Generated On: 20 Jul 2016 12:09:14

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of assessment 15 JAN 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: 1062**

Folder: Screening

Form: Physical Examination (12)

Data signed: (hfarmer1) 26 Mar 2015 14:17:59

Generated On: 20 Jul 2016 12:09:14

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of assessment 15 JAN 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: 1062**

Folder: Screening

Form: Physical Examination (13)

Data signed: (hfarmer1) 26 Mar 2015 14:17:59

Generated On: 20 Jul 2016 12:09:14

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of assessment 15 JAN 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: 1062**

Folder: Screening

Form: Physical Examination (14)

Data signed: (hfarmer1) 26 Mar 2015 14:17:59

Generated On: 20 Jul 2016 12:09:14

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of assessment 15 JAN 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: 1062**

Folder: Screening

Form: Physical Examination (15)

Data signed: (hfarmer1) 26 Mar 2015 14:17:59

Generated On: 20 Jul 2016 12:09:14

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

15 JAN 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: 1062**

Folder: Screening

Form: Physical Examination (16)

Data signed: (hfarmer1) 26 Mar 2015 14:17:59

Generated On: 20 Jul 2016 12:09:14

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

15 JAN 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: 1062**

Folder: Screening

Form: Physical Examination (17)

Data signed: (hfarmer1) 26 Mar 2015 14:17:59

Generated On: 20 Jul 2016 12:09:14

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

15 JAN 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: 1062**

Folder: Screening

Form: Physical Examination (18)

Data signed: (hfarmer1) 26 Mar 2015 14:17:59

Generated On: 20 Jul 2016 12:09:14

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

15 JAN 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: 1062**

Folder: Screening

Form: Physical Examination (19)

Data signed: (hfarmer1) 26 Mar 2015 14:17:59

Generated On: 20 Jul 2016 12:09:14

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

15 JAN 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: 1062**

Folder: Screening

Form: Advice on the risk of smoking and debriefing

Data signed: (hfarmer1) 26 Mar 2015 14:18:06

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Screening

Form: Identification of Current Cigarette Brand

Data signed: (hfarmer1) 26 Mar 2015 14:18:05

Generated On: 20 Jul 2016 12:09:14

Date

15 JAN 2014
DD/MMM/YYYY

Brand name

NEWPORT 100'S

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Screening

Form: THS 2.2 menthol product demonstration

Data signed: (hfarmer1) 26 Mar 2015 14:18:06

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Screening

Form: Smoking History

Data signed: (hfarmer1) 26 Mar 2015 14:18:05

Generated On: 20 Jul 2016 12:09:14

Date of Assessment

15 JAN 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: 1062**

Folder: Screening

Form: Weight and Height

Data signed: (hfarmer1) 26 Mar 2015 14:18:06

Generated On: 20 Jul 2016 12:09:14

Measurement(s) assessed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

15 JAN 2014
DD/MMM/YYYY

Weight

76.2
kg

Height

179.7
cm

BMI (Derived)

23.6
kg/m2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Screening

Form: ECG (12-Lead Standard)

Data signed: (hfarmer1) 26 Mar 2015 14:17:56

Generated On: 20 Jul 2016 12:09:14

Was the ECG performed? Yes ☒

If No, please specify the reason: _____

Date of assessment: 15 JAN 2014
DD/MMM/YYYY

Position Supine ☒

Heart Rate 54
beats per minute

QRS Interval 100
msec

QT Interval 379
msec

QTcB Interval 361
msec

QTcF Interval 367
msec

PR Interval 136
msec

Interpretation Normal ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Screening

Form: ECG (12-Lead Standard)

Data signed: (hfarmer1) 26 Mar 2015 14:17:56

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Screening

Form: Spirometry (1)

Data signed: (hcoleman1) 18 Jun 2015 19:58:06

Generated On: 20 Jul 2016 12:09:14

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 15 JAN 2014
DD/MMM/YYYY

Time of assessment 10:40

Predicted FVC value 5.23
L

Best measured FVC value 5.75
L

Percent of predicted FVC value 110
%

Best measured FEV1 value 4.26
L

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Screening

Form: Spirometry (1)

Data signed: (hcoleman1) 18 Jun 2015 19:58:06

Generated On: 20 Jul 2016 12:09:14

Predicted FEV1 value	4.07 L
Percent of predicted FEV1 value	105 %
Calculated ratio between FEV1/FVC	0.74
MEF 25/75 value	3.09 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: 1062**

Folder: Screening

Form: Spirometry (2)

Data signed: (hcoleman1) 18 Jun 2015 19:58:06

Generated On: 20 Jul 2016 12:09:14

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 15 JAN 2014
DD/MMM/YYYY

Time of assessment 11:24

Name of bronchodilator ALBUTEROL SULFATE

Dose 180 MCG

Predicted FVC value 5.23
L

Best measured FVC value 4.70
L

Percent of predicted FVC value 90
%

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Screening

Form: Spirometry (2)

Data signed: (hcoleman1) 18 Jun 2015 19:58:06

Generated On: 20 Jul 2016 12:09:14

Best measured FEV1 value	3.92 L
Predicted FEV1 value	4.07 L
Percent of predicted FEV1 value	96 %
Calculated ratio between FEV1/FVC	0.83
MEF 25/75 value	4.11 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: 1062**

Folder: Screening

Form: Chest X-Ray

Data signed: (hfarmer1) 26 Mar 2015 14:18:06

Generated On: 20 Jul 2016 12:09:14

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

Yes ☒

If No, please specify the reason: _____

Date of assessment

15 JAN 2014
DD/MMM/YYYY

System

Chest ☒

Interpretation

Normal ☒

Clinically significant _____

Abnormal, please specify: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Screening

Form: Haematology

Data signed: (hfarmer1) 26 Mar 2015 14:17:58

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Screening

Form: Clinical Chemistry

Data signed: (hfarmer1) 26 Mar 2015 14:17:57

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Screening

Form: Urine analysis

Data signed: (hfarmer1) 26 Mar 2015 14:17:58

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Screening

Form: Serology for HIV and Hepatitis B and C

Data signed: (hfarmer1) 26 Mar 2015 14:17:58

Generated On: 20 Jul 2016 12:09:14

Category

Serology ☒

Not Done

False

If Not Done, please specify the reason:

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1062

Folder: Screening

Form: Urine Drug Screen

Data signed: (hfarmer1) 26 Mar 2015 14:17:58

Generated On: 20 Jul 2016 12:09:14

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

If Not Done, please specify the reason: _____

Date of sample collection	15 JAN 2014 DD/MMM/YYYY
---------------------------	----------------------------

Time of sample collection	09:30 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: 1062

Folder: Screening

Form: Urine Drug Screen (4)

Data signed: (hfarmer1) 26 Mar 2015 14:17:58

Generated On: 20 Jul 2016 12:09:14

Drug type	Result
Cannabinoids	Negative
Cocaine	Negative
Opiates	Negative

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Screening

Form: Alcohol Test

Data signed: (hfarmer1) 26 Mar 2015 14:17:57

Generated On: 20 Jul 2016 12:09:14

Was the alcohol test performed? Yes ☒

If No, please specify the reason: _____

Method used Breath test ☒

Date of assessment 15 JAN 2014
DD/MMM/YYYY

Time of assessment 09:48
hour:min 24-hour clock

Result Negative ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Screening

Form: Urine Cotinine Test

Data signed: (hfarmer1) 26 Mar 2015 14:17:58

Generated On: 20 Jul 2016 12:09:14

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

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

If Not Done, please specify the reason: _____

Date of Sample Collection	15 JAN 2014 DD/MMM/YYYY
---------------------------	----------------------------

Time of Sample Collection	09:30 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: 1062**

Folder: Screening

Form: Lab-BU-LabCorp CHEMISTRY(15 JAN 2014)

Data signed: (hfarmer1) 26 Mar 2015 14:18:06

Generated On: 20 Jul 2016 12:09:14

Experiment Type

CHEMISTRY

Date of Sample Collection
YYYY/MM/DD

15 JAN 2014

Please document clinically relevant abnormalities in the AE form

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Screening

Form: Lab-BU-LabCorp CHEMISTRY(15 JAN 2014)

Data signed: (hfarmer1) 26 Mar 2015 14:18:06

Generated On: 20 Jul 2016 12:09:14

Experiment Type	CHEMISTRY
Date of Sample Collection YYYY/MM/DD	15 JAN 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Male <input checked="" type="radio"/>
Time of Sample Collection	10:25
Analyte Name	GLUCOSE, SERUM
Code	001032
Result	93
Unit	MG/DL
Lower limit	65
Upper limit	99
Flag	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Screening

Form: Lab-BU-LabCorp CHEMISTRY(15 JAN 2014)

Data signed: (hfarmer1) 26 Mar 2015 14:18:06

Generated On: 20 Jul 2016 12:09:14

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

01557100020

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Screening

Form: Lab-BU-LabCorp (2)

Data signed: (hfarmer1) 26 Mar 2015 14:18:06

Generated On: 20 Jul 2016 12:09:14

Experiment Type	CHEMISTRY
Date of Sample Collection YYYY/MM/DD	15 JAN 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Male <input checked="" type="radio"/>
Time of Sample Collection	10:25
Analyte Name	BUN
Code	001040
Result	12
Unit	MG/DL
Lower limit	6
Upper limit	24
Flag	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Screening

Form: Lab-BU-LabCorp (2)

Data signed: (hfarmer1) 26 Mar 2015 14:18:06

Generated On: 20 Jul 2016 12:09:14

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

01557100020

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Screening

Form: Lab-BU-LabCorp (3)

Data signed: (hfarmer1) 26 Mar 2015 14:18:06

Generated On: 20 Jul 2016 12:09:14

Experiment Type	CHEMISTRY
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Date of Sample Collection YYYY/MM/DD	15 JAN 2014
---	-------------

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

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

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

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

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

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

Result	220
--------	-----

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

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

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

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Screening

Form: Lab-BU-LabCorp (3)

Data signed: (hfarmer1) 26 Mar 2015 14:18:06

Generated On: 20 Jul 2016 12:09:14

Clinically Significant?

No ☒

Comment

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

01557100020

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Screening

Form: Lab-BU-LabCorp (4)

Data signed: (hfarmer1) 26 Mar 2015 14:18:06

Generated On: 20 Jul 2016 12:09:14

Experiment Type

CHEMISTRY

Date of Sample Collection
YYYY/MM/DD

15 JAN 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male ☒

Time of Sample Collection

10:25

Analyte Name

PROTEIN, TOTAL, SERUM

Code

001073

Result

6.6

Unit

G/DL

Lower limit

6.0

Upper limit

8.5

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Screening

Form: Lab-BU-LabCorp (4)

Data signed: (hfarmer1) 26 Mar 2015 14:18:06

Generated On: 20 Jul 2016 12:09:14

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

01557100020

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Screening

Form: Lab-BU-LabCorp (5)

Data signed: (hfarmer1) 26 Mar 2015 14:18:06

Generated On: 20 Jul 2016 12:09:14

Experiment Type

CHEMISTRY

Date of Sample Collection
YYYY/MM/DD

15 JAN 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male ☒

Time of Sample Collection

10:25

Analyte Name

ALBUMIN, SERUM

Code

001081

Result

4.2

Unit

G/DL

Lower limit

3.5

Upper limit

5.5

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Screening

Form: Lab-BU-LabCorp (5)

Data signed: (hfarmer1) 26 Mar 2015 14:18:06

Generated On: 20 Jul 2016 12:09:14

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

01557100020

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Screening

Form: Lab-BU-LabCorp (6)

Data signed: (hfarmer1) 26 Mar 2015 14:18:06

Generated On: 20 Jul 2016 12:09:14

Experiment Type

CHEMISTRY

Date of Sample Collection
YYYY/MM/DD

15 JAN 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male ☒

Time of Sample Collection

10:25

Analyte Name

BILIRUBIN, TOTAL

Code

001099

Result

0.4

Unit

MG/DL

Lower limit

0.0

Upper limit

1.2

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Screening

Form: Lab-BU-LabCorp (6)

Data signed: (hfarmer1) 26 Mar 2015 14:18:06

Generated On: 20 Jul 2016 12:09:14

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

01557100020

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Screening

Form: Lab-BU-LabCorp (7)

Data signed: (hfarmer1) 26 Mar 2015 14:18:06

Generated On: 20 Jul 2016 12:09:14

Experiment Type

CHEMISTRY

Date of Sample Collection
YYYY/MM/DD

15 JAN 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male ☒

Time of Sample Collection

10:25

Analyte Name

ALKALINE PHOSPHATASE, S

Code

001107

Result

85

Unit

IU/L

Lower limit

39

Upper limit

117

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Screening

Form: Lab-BU-LabCorp (7)

Data signed: (hfarmer1) 26 Mar 2015 14:18:06

Generated On: 20 Jul 2016 12:09:14

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

01557100020

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Screening

Form: Lab-BU-LabCorp (8)

Data signed: (hfarmer1) 26 Mar 2015 14:18:06

Generated On: 20 Jul 2016 12:09:14

Experiment Type

CHEMISTRY

Date of Sample Collection
YYYY/MM/DD

15 JAN 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male ☒

Time of Sample Collection

10:25

Analyte Name

LDH

Code

001115

Result

109

Unit

IU/L

Lower limit

0

Upper limit

225

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Screening

Form: Lab-BU-LabCorp (8)

Data signed: (hfarmer1) 26 Mar 2015 14:18:06

Generated On: 20 Jul 2016 12:09:14

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

01557100020

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Screening

Form: Lab-BU-LabCorp (9)

Data signed: (hfarmer1) 26 Mar 2015 14:18:06

Generated On: 20 Jul 2016 12:09:14

Experiment Type

CHEMISTRY

Date of Sample Collection
YYYY/MM/DD

15 JAN 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male ☒

Time of Sample Collection

10:25

Analyte Name

AST (SGOT)

Code

001123

Result

12

Unit

IU/L

Lower limit

0

Upper limit

40

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Screening

Form: Lab-BU-LabCorp (9)

Data signed: (hfarmer1) 26 Mar 2015 14:18:06

Generated On: 20 Jul 2016 12:09:14

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

01557100020

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Screening

Form: Lab-BU-LabCorp (10)

Data signed: (hfarmer1) 26 Mar 2015 14:18:06

Generated On: 20 Jul 2016 12:09:14

Experiment Type

CHEMISTRY

Date of Sample Collection
YYYY/MM/DD

15 JAN 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male ☒

Time of Sample Collection

10:25

Analyte Name

TRIGLYCERIDES

Code

001172

Result

95

Unit

MG/DL

Lower limit

0

Upper limit

149

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Screening

Form: Lab-BU-LabCorp (10)

Data signed: (hfarmer1) 26 Mar 2015 14:18:06

Generated On: 20 Jul 2016 12:09:14

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

01557100020

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Screening

Form: Lab-BU-LabCorp (11)

Data signed: (hfarmer1) 26 Mar 2015 14:18:06

Generated On: 20 Jul 2016 12:09:14

Experiment Type

CHEMISTRY

Date of Sample Collection
YYYY/MM/DD

15 JAN 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male ☒

Time of Sample Collection

10:25

Analyte Name

POTASSIUM, SERUM

Code

001180

Result

5.1

Unit

MMOL/L

Lower limit

3.5

Upper limit

5.2

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Screening

Form: Lab-BU-LabCorp (11)

Data signed: (hfarmer1) 26 Mar 2015 14:18:06

Generated On: 20 Jul 2016 12:09:14

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

01557100020

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Screening

Form: Lab-BU-LabCorp (12)

Data signed: (hfarmer1) 26 Mar 2015 14:18:06

Generated On: 20 Jul 2016 12:09:14

Experiment Type

CHEMISTRY

Date of Sample Collection
YYYY/MM/DD

15 JAN 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male ☒

Time of Sample Collection

10:25

Analyte Name

SODIUM, SERUM

Code

001198

Result

140

Unit

MMOL/L

Lower limit

134

Upper limit

144

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Screening

Form: Lab-BU-LabCorp (12)

Data signed: (hfarmer1) 26 Mar 2015 14:18:06

Generated On: 20 Jul 2016 12:09:14

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

01557100020

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Screening

Form: Lab-BU-LabCorp (13)

Data signed: (hfarmer1) 26 Mar 2015 14:18:06

Generated On: 20 Jul 2016 12:09:14

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

Date of Sample Collection YYYY/MM/DD	15 JAN 2014
---	-------------

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

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

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

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

Analyte Name	BILIRUBIN, DIRECT
--------------	-------------------

Code	001222
------	--------

Result	0.10
--------	------

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

Lower limit	0.00
-------------	------

Upper limit	0.40
-------------	------

Flag	
------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Screening

Form: Lab-BU-LabCorp (13)

Data signed: (hfarmer1) 26 Mar 2015 14:18:06

Generated On: 20 Jul 2016 12:09:14

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

01557100020

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Screening

Form: Lab-BU-LabCorp (14)

Data signed: (hfarmer1) 26 Mar 2015 14:18:06

Generated On: 20 Jul 2016 12:09:14

Experiment Type	CHEMISTRY
Date of Sample Collection YYYY/MM/DD	15 JAN 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Male <input checked="" type="radio"/>
Time of Sample Collection	10:25
Analyte Name	CREATININE, SERUM
Code	001370
Result	0.95
Unit	MG/DL
Lower limit	0.76
Upper limit	1.27
Flag	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Screening

Form: Lab-BU-LabCorp (14)

Data signed: (hfarmer1) 26 Mar 2015 14:18:06

Generated On: 20 Jul 2016 12:09:14

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

01557100020

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Screening

Form: Lab-BU-LabCorp (15)

Data signed: (hfarmer1) 26 Mar 2015 14:18:06

Generated On: 20 Jul 2016 12:09:14

Experiment Type

CHEMISTRY

Date of Sample Collection
YYYY/MM/DD

15 JAN 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male ☒

Time of Sample Collection

10:25

Analyte Name

ALT (SGPT)

Code

001545

Result

15

Unit

IU/L

Lower limit

0

Upper limit

44

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Screening

Form: Lab-BU-LabCorp (15)

Data signed: (hfarmer1) 26 Mar 2015 14:18:06

Generated On: 20 Jul 2016 12:09:14

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

01557100020

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Screening

Form: Lab-BU-LabCorp (16)

Data signed: (hfarmer1) 26 Mar 2015 14:18:06

Generated On: 20 Jul 2016 12:09:14

Experiment Type	CHEMISTRY
Date of Sample Collection YYYY/MM/DD	15 JAN 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Male <input checked="" type="radio"/>
Time of Sample Collection	10:25
Analyte Name	GGT
Code	001958
Result	14
Unit	IU/L
Lower limit	0
Upper limit	65
Flag	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Screening

Form: Lab-BU-LabCorp (16)

Data signed: (hfarmer1) 26 Mar 2015 14:18:06

Generated On: 20 Jul 2016 12:09:14

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

01557100020

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Screening

Form: Lab-BU-LabCorp (17)

Data signed: (hfarmer1) 26 Mar 2015 14:18:06

Generated On: 20 Jul 2016 12:09:14

Experiment Type

CHEMISTRY

Date of Sample Collection
YYYY/MM/DD

15 JAN 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male ☒

Time of Sample Collection

10:25

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: 1062**

Folder: Screening

Form: Lab-BU-LabCorp (17)

Data signed: (hfarmer1) 26 Mar 2015 14:18:06

Generated On: 20 Jul 2016 12:09:14

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

01557100020

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Screening

Form: Lab-BU-LabCorp SEROLOGY(15 JAN 2014)

Data signed: (hfarmer1) 26 Mar 2015 14:18:08

Generated On: 20 Jul 2016 12:09:14

Experiment Type

SEROLOGY

Date of Sample Collection
YYYY/MM/DD

15 JAN 2014

Please document clinically relevant abnormalities in the AE form

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Screening

Form: Lab-BU-LabCorp SEROLOGY(15 JAN 2014)

Data signed: (hfarmer1) 26 Mar 2015 14:18:08

Generated On: 20 Jul 2016 12:09:14

Experiment Type

SEROLOGY

Date of Sample Collection
YYYY/MM/DD

15 JAN 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male ☒

Time of Sample Collection

10:25

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: 1062**

Folder: Screening

Form: Lab-BU-LabCorp SEROLOGY(15 JAN 2014)

Data signed: (hfarmer1) 26 Mar 2015 14:18:08

Generated On: 20 Jul 2016 12:09:14

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

01557100020

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Screening

Form: Lab-BU-LabCorp (2)

Data signed: (hfarmer1) 26 Mar 2015 14:18:08

Generated On: 20 Jul 2016 12:09:14

Experiment Type

SEROLOGY

Date of Sample Collection
YYYY/MM/DD

15 JAN 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male ☒

Time of Sample Collection

10:25

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: 1062**

Folder: Screening

Form: Lab-BU-LabCorp (2)

Data signed: (hfarmer1) 26 Mar 2015 14:18:08

Generated On: 20 Jul 2016 12:09:14

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

01557100020

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Screening

Form: Lab-BU-LabCorp (3)

Data signed: (hfarmer1) 26 Mar 2015 14:18:08

Generated On: 20 Jul 2016 12:09:14

Experiment Type

SEROLOGY

Date of Sample Collection
YYYY/MM/DD

15 JAN 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male ☒

Time of Sample Collection

10:25

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: 1062**

Folder: Screening

Form: Lab-BU-LabCorp (3)

Data signed: (hfarmer1) 26 Mar 2015 14:18:08

Generated On: 20 Jul 2016 12:09:14

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

01557100020

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Screening

Form: Lab-BU-LabCorp HEMATOLOGY(15 JAN 2014)

Data signed: (hfarmer1) 26 Mar 2015 14:18:09

Generated On: 20 Jul 2016 12:09:14

Experiment Type

HEMATOLOGY

Date of Sample Collection
YYYY/MM/DD

15 JAN 2014

Please document clinically relevant abnormalities in the AE form

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Screening

Form: Lab-BU-LabCorp HEMATOLOGY(15 JAN 2014)

Data signed: (hfarmer1) 26 Mar 2015 14:18:09

Generated On: 20 Jul 2016 12:09:14

Experiment Type	HEMATOLOGY
Date of Sample Collection YYYY/MM/DD	15 JAN 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Male <input checked="" type="radio"/>
Time of Sample Collection	10:25
Analyte Name	WBC
Code	005025
Result	8.2
Unit	X10E3/UL
Lower limit	3.4
Upper limit	10.8
Flag	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Screening

Form: Lab-BU-LabCorp HEMATOLOGY(15 JAN 2014)

Data signed: (hfarmer1) 26 Mar 2015 14:18:09

Generated On: 20 Jul 2016 12:09:14

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

01557100020

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Screening

Form: Lab-BU-LabCorp (2)

Data signed: (hfarmer1) 26 Mar 2015 14:18:09

Generated On: 20 Jul 2016 12:09:14

Experiment Type

HEMATOLOGY

Date of Sample Collection
YYYY/MM/DD

15 JAN 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male ☒

Time of Sample Collection

10:25

Analyte Name

RBC

Code

005033

Result

5.14

Unit

X10E6/UL

Lower limit

4.14

Upper limit

5.80

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Screening

Form: Lab-BU-LabCorp (2)

Data signed: (hfarmer1) 26 Mar 2015 14:18:09

Generated On: 20 Jul 2016 12:09:14

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

01557100020

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Screening

Form: Lab-BU-LabCorp (3)

Data signed: (hfarmer1) 26 Mar 2015 14:18:09

Generated On: 20 Jul 2016 12:09:14

Experiment Type

HEMATOLOGY

Date of Sample Collection
YYYY/MM/DD

15 JAN 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male ☒

Time of Sample Collection

10:25

Analyte Name

HEMOGLOBIN

Code

005041

Result

16.2

Unit

G/DL

Lower limit

12.6

Upper limit

17.7

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Screening

Form: Lab-BU-LabCorp (3)

Data signed: (hfarmer1) 26 Mar 2015 14:18:09

Generated On: 20 Jul 2016 12:09:14

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

01557100020

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Screening

Form: Lab-BU-LabCorp (4)

Data signed: (hfarmer1) 26 Mar 2015 14:18:09

Generated On: 20 Jul 2016 12:09:14

Experiment Type	HEMATOLOGY
Date of Sample Collection YYYY/MM/DD	15 JAN 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Male <input checked="" type="radio"/>
Time of Sample Collection	10:25
Analyte Name	HEMATOCRIT
Code	005058
Result	46.8
Unit	%
Lower limit	37.5
Upper limit	51.0
Flag	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Screening

Form: Lab-BU-LabCorp (4)

Data signed: (hfarmer1) 26 Mar 2015 14:18:09

Generated On: 20 Jul 2016 12:09:14

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

01557100020

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Screening

Form: Lab-BU-LabCorp (5)

Data signed: (hfarmer1) 26 Mar 2015 14:18:09

Generated On: 20 Jul 2016 12:09:14

Experiment Type	HEMATOLOGY
Date of Sample Collection YYYY/MM/DD	15 JAN 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Male <input checked="" type="radio"/>
Time of Sample Collection	10:25
Analyte Name	MCV
Code	015065
Result	91
Unit	FL
Lower limit	79
Upper limit	97
Flag	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Screening

Form: Lab-BU-LabCorp (5)

Data signed: (hfarmer1) 26 Mar 2015 14:18:09

Generated On: 20 Jul 2016 12:09:14

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

01557100020

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Screening

Form: Lab-BU-LabCorp (6)

Data signed: (hfarmer1) 26 Mar 2015 14:18:09

Generated On: 20 Jul 2016 12:09:14

Experiment Type	HEMATOLOGY
Date of Sample Collection YYYY/MM/DD	15 JAN 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Male <input checked="" type="radio"/>
Time of Sample Collection	10:25
Analyte Name	MCH
Code	015073
Result	31.5
Unit	PG
Lower limit	26.6
Upper limit	33.0
Flag	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Screening

Form: Lab-BU-LabCorp (6)

Data signed: (hfarmer1) 26 Mar 2015 14:18:09

Generated On: 20 Jul 2016 12:09:14

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

01557100020

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Screening

Form: Lab-BU-LabCorp (7)

Data signed: (hfarmer1) 26 Mar 2015 14:18:09

Generated On: 20 Jul 2016 12:09:14

Experiment Type	HEMATOLOGY
Date of Sample Collection YYYY/MM/DD	15 JAN 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Male <input checked="" type="radio"/>
Time of Sample Collection	10:25
Analyte Name	MCHC
Code	015081
Result	34.6
Unit	G/DL
Lower limit	31.5
Upper limit	35.7
Flag	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Screening

Form: Lab-BU-LabCorp (7)

Data signed: (hfarmer1) 26 Mar 2015 14:18:09

Generated On: 20 Jul 2016 12:09:14

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

01557100020

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Screening

Form: Lab-BU-LabCorp (8)

Data signed: (hfarmer1) 26 Mar 2015 14:18:09

Generated On: 20 Jul 2016 12:09:14

Experiment Type	HEMATOLOGY
Date of Sample Collection YYYY/MM/DD	15 JAN 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Male <input checked="" type="radio"/>
Time of Sample Collection	10:25
Analyte Name	NEUTROPHILS
Code	015107
Result	70
Unit	%
Lower limit	40
Upper limit	74
Flag	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Screening

Form: Lab-BU-LabCorp (8)

Data signed: (hfarmer1) 26 Mar 2015 14:18:09

Generated On: 20 Jul 2016 12:09:14

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

01557100020

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Screening

Form: Lab-BU-LabCorp (9)

Data signed: (hfarmer1) 26 Mar 2015 14:18:09

Generated On: 20 Jul 2016 12:09:14

Experiment Type

HEMATOLOGY

Date of Sample Collection
YYYY/MM/DD

15 JAN 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male ☒

Time of Sample Collection

10:25

Analyte Name

LYMPHS

Code

015123

Result

24

Unit

%

Lower limit

14

Upper limit

46

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Screening

Form: Lab-BU-LabCorp (9)

Data signed: (hfarmer1) 26 Mar 2015 14:18:09

Generated On: 20 Jul 2016 12:09:14

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

01557100020

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Screening

Form: Lab-BU-LabCorp (10)

Data signed: (hfarmer1) 26 Mar 2015 14:18:09

Generated On: 20 Jul 2016 12:09:14

Experiment Type

HEMATOLOGY

Date of Sample Collection
YYYY/MM/DD

15 JAN 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male ☒

Time of Sample Collection

10:25

Analyte Name

MONOCYTES

Code

015131

Result

4

Unit

%

Lower limit

4

Upper limit

12

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Screening

Form: Lab-BU-LabCorp (10)

Data signed: (hfarmer1) 26 Mar 2015 14:18:09

Generated On: 20 Jul 2016 12:09:14

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

01557100020

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Screening

Form: Lab-BU-LabCorp (11)

Data signed: (hfarmer1) 26 Mar 2015 14:18:09

Generated On: 20 Jul 2016 12:09:14

Experiment Type	HEMATOLOGY
Date of Sample Collection YYYY/MM/DD	15 JAN 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Male <input checked="" type="radio"/>
Time of Sample Collection	10:25
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: 1062**

Folder: Screening

Form: Lab-BU-LabCorp (11)

Data signed: (hfarmer1) 26 Mar 2015 14:18:09

Generated On: 20 Jul 2016 12:09:14

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

01557100020

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Screening

Form: Lab-BU-LabCorp (12)

Data signed: (hfarmer1) 26 Mar 2015 14:18:09

Generated On: 20 Jul 2016 12:09:14

Experiment Type	HEMATOLOGY
Date of Sample Collection YYYY/MM/DD	15 JAN 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Male <input checked="" type="radio"/>
Time of Sample Collection	10:25
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: 1062**

Folder: Screening

Form: Lab-BU-LabCorp (12)

Data signed: (hfarmer1) 26 Mar 2015 14:18:09

Generated On: 20 Jul 2016 12:09:14

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

01557100020

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Screening

Form: Lab-BU-LabCorp (13)

Data signed: (hfarmer1) 26 Mar 2015 14:18:09

Generated On: 20 Jul 2016 12:09:14

Experiment Type

HEMATOLOGY

Date of Sample Collection
YYYY/MM/DD

15 JAN 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male ☒

Time of Sample Collection

10:25

Analyte Name

PLATELETS

Code

015172

Result

260

Unit

X10E3/UL

Lower limit

155

Upper limit

379

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Screening

Form: Lab-BU-LabCorp (13)

Data signed: (hfarmer1) 26 Mar 2015 14:18:09

Generated On: 20 Jul 2016 12:09:14

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

01557100020

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Screening

Form: Lab-BU-LabCorp (14)

Data signed: (hfarmer1) 26 Mar 2015 14:18:09

Generated On: 20 Jul 2016 12:09:14

Experiment Type

HEMATOLOGY

Date of Sample Collection
YYYY/MM/DD

15 JAN 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male ☒

Time of Sample Collection

10:25

Analyte Name

NEUTROPHILS (ABSOLUTE)

Code

015909

Result

5.8

Unit

X10E3/UL

Lower limit

1.4

Upper limit

7.0

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Screening

Form: Lab-BU-LabCorp (14)

Data signed: (hfarmer1) 26 Mar 2015 14:18:09

Generated On: 20 Jul 2016 12:09:14

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

01557100020

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Screening

Form: Lab-BU-LabCorp (15)

Data signed: (hfarmer1) 26 Mar 2015 14:18:09

Generated On: 20 Jul 2016 12:09:14

Experiment Type	HEMATOLOGY
Date of Sample Collection YYYY/MM/DD	15 JAN 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Male <input checked="" type="radio"/>
Time of Sample Collection	10:25
Analyte Name	LYMPHS (ABSOLUTE)
Code	015917
Result	1.9
Unit	X10E3/UL
Lower limit	0.7
Upper limit	3.1
Flag	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Screening

Form: Lab-BU-LabCorp (15)

Data signed: (hfarmer1) 26 Mar 2015 14:18:09

Generated On: 20 Jul 2016 12:09:14

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

01557100020

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Screening

Form: Lab-BU-LabCorp (16)

Data signed: (hfarmer1) 26 Mar 2015 14:18:09

Generated On: 20 Jul 2016 12:09:14

Experiment Type	HEMATOLOGY
Date of Sample Collection YYYY/MM/DD	15 JAN 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Male <input checked="" type="radio"/>
Time of Sample Collection	10:25
Analyte Name	MONOCYTES(ABSOLUTE)
Code	015925
Result	0.3
Unit	X10E3/UL
Lower limit	0.1
Upper limit	0.9
Flag	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Screening

Form: Lab-BU-LabCorp (16)

Data signed: (hfarmer1) 26 Mar 2015 14:18:09

Generated On: 20 Jul 2016 12:09:14

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

01557100020

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Screening

Form: Lab-BU-LabCorp (17)

Data signed: (hfarmer1) 26 Mar 2015 14:18:09

Generated On: 20 Jul 2016 12:09:14

Experiment Type	HEMATOLOGY
Date of Sample Collection YYYY/MM/DD	15 JAN 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Male <input checked="" type="radio"/>
Time of Sample Collection	10:25
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: 1062**

Folder: Screening

Form: Lab-BU-LabCorp (17)

Data signed: (hfarmer1) 26 Mar 2015 14:18:09

Generated On: 20 Jul 2016 12:09:14

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

01557100020

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Screening

Form: Lab-BU-LabCorp (18)

Data signed: (hfarmer1) 26 Mar 2015 14:18:09

Generated On: 20 Jul 2016 12:09:14

Experiment Type

HEMATOLOGY

Date of Sample Collection
YYYY/MM/DD

15 JAN 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male ☒

Time of Sample Collection

10:25

Analyte Name

BASO (ABSOLUTE)

Code

015941

Result

0.1

Unit

X10E3/UL

Lower limit

0.0

Upper limit

0.2

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Screening

Form: Lab-BU-LabCorp (18)

Data signed: (hfarmer1) 26 Mar 2015 14:18:09

Generated On: 20 Jul 2016 12:09:14

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

01557100020

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Screening

Form: Lab-BU-LabCorp URINALYSIS(15 JAN 2014)

Data signed: (hfarmer1) 26 Mar 2015 14:18:11

Generated On: 20 Jul 2016 12:09:14

Experiment Type

URINALYSIS

Date of Sample Collection
YYYY/MM/DD

15 JAN 2014

Please document clinically relevant abnormalities in the AE form

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Screening

Form: Lab-BU-LabCorp URINALYSIS(15 JAN 2014)

Data signed: (hfarmer1) 26 Mar 2015 14:18:11

Generated On: 20 Jul 2016 12:09:14

Experiment Type

URINALYSIS

Date of Sample Collection
YYYY/MM/DD

15 JAN 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male ☒

Time of Sample Collection

09:41

Analyte Name

SPECIFIC GRAVITY

Code

13060

Result

1.01

Unit

Lower limit

1.001

Upper limit

1.035

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Screening

Form: Lab-BU-LabCorp URINALYSIS(15 JAN 2014)

Data signed: (hfarmer1) 26 Mar 2015 14:18:11

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Screening

Form: Lab-BU-LabCorp (2)

Data signed: (hfarmer1) 26 Mar 2015 14:18:11

Generated On: 20 Jul 2016 12:09:14

Experiment Type	URINALYSIS
Date of Sample Collection YYYY/MM/DD	15 JAN 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Male <input checked="" type="radio"/>
Time of Sample Collection	09:41
Analyte Name	PH
Code	13078
Result	6
Unit	
Lower limit	5
Upper limit	8
Flag	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Screening

Form: Lab-BU-LabCorp (2)

Data signed: (hfarmer1) 26 Mar 2015 14:18:11

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Screening

Form: Lab-BU-LabCorp (3)

Data signed: (hfarmer1) 26 Mar 2015 14:18:11

Generated On: 20 Jul 2016 12:09:14

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

Date of Sample Collection YYYY/MM/DD	15 JAN 2014
---	-------------

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

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

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

Time of Sample Collection	09:41
---------------------------	-------

Analyte Name	GLUCOSE
--------------	---------

Code	13086
------	-------

Result	NORMAL
--------	--------

Unit	
------	--

Lower limit	NORMAL
-------------	--------

Upper limit	
-------------	--

Flag	
------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Screening

Form: Lab-BU-LabCorp (3)

Data signed: (hfarmer1) 26 Mar 2015 14:18:11

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Screening

Form: Lab-BU-LabCorp (4)

Data signed: (hfarmer1) 26 Mar 2015 14:18:11

Generated On: 20 Jul 2016 12:09:14

Experiment Type

URINALYSIS

Date of Sample Collection
YYYY/MM/DD

15 JAN 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male

Time of Sample Collection

09:41

Analyte Name

PROTEIN

Code

13094

Result

NEGATIVE

Unit

Lower limit

NEGATIVE

Upper limit

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Screening

Form: Lab-BU-LabCorp (4)

Data signed: (hfarmer1) 26 Mar 2015 14:18:11

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Screening

Form: Lab-BU-LabCorp (5)

Data signed: (hfarmer1) 26 Mar 2015 14:18:11

Generated On: 20 Jul 2016 12:09:14

Experiment Type

URINALYSIS

Date of Sample Collection
YYYY/MM/DD

15 JAN 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male ☒

Time of Sample Collection

09:41

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: 1062**

Folder: Screening

Form: Lab-BU-LabCorp (5)

Data signed: (hfarmer1) 26 Mar 2015 14:18:11

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Screening

Form: Lab-BU-LabCorp (6)

Data signed: (hfarmer1) 26 Mar 2015 14:18:11

Generated On: 20 Jul 2016 12:09:14

Experiment Type

URINALYSIS

Date of Sample Collection
YYYY/MM/DD

15 JAN 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male ☒

Time of Sample Collection

09:41

Analyte Name

BILIRUBIN

Code

13104

Result

NEGATIVE

Unit

Lower limit

NEGATIVE

Upper limit

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Screening

Form: Lab-BU-LabCorp (6)

Data signed: (hfarmer1) 26 Mar 2015 14:18:11

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Screening

Form: Lab-BU-LabCorp (7)

Data signed: (hfarmer1) 26 Mar 2015 14:18:11

Generated On: 20 Jul 2016 12:09:14

Experiment Type

URINALYSIS

Date of Sample Collection
YYYY/MM/DD

15 JAN 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male ☒

Time of Sample Collection

09:41

Analyte Name

NITRITE, URINE

Code

13106

Result

NEGATIVE

Unit

Lower limit

NEGATIVE

Upper limit

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Screening

Form: Lab-BU-LabCorp (7)

Data signed: (hfarmer1) 26 Mar 2015 14:18:11

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Screening

Form: FTND Questionnaire

Generated On: 20 Jul 2016 12:09:14

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

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

Date of assessment	2014 JAN 15
DD/MMM/YYYY	DD/MMM/YYYY

Time of assessment	11:48
	hour:min 24-hour clock

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

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

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

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

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

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

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Screening

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

Data signed: (hfarmer1) 26 Mar 2015 14:18:05

Generated On: 20 Jul 2016 12:09:14

Was paper questionnaire used? Yes ☒

Reason not done

Type PROCHASKA STAGE OF
CHANGE QUESTIONNAIRE:
INTENTION TO QUIT
SMOKING

Date of assessment 15 JAN 2014
DD/MMM/YYYY

Time of assessment 08:51
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? 3

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Admission (Day -2)

Form: Date of Visit

Data signed: (hfarmer1) 26 Mar 2015 14:18:14

Generated On: 20 Jul 2016 12:09:14

Date of Visit

17 JAN 2014
DD/MMM/YYYY

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Admission (Day -2)

Form: Inclusion Criteria

Data signed: (hfarmer1) 26 Mar 2015 14:18:12

Generated On: 20 Jul 2016 12:09:14

*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: 1062

Folder: Admission (Day -2)

Form: Inclusion Criteria (1)

Data signed: (hfarmer1) 26 Mar 2015 14:18:12

Generated On: 20 Jul 2016 12:09:14

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: 1062

Folder: Admission (Day -2)

Form: Inclusion Criteria (2)

Data signed: (hfarmer1) 26 Mar 2015 14:18:12

Generated On: 20 Jul 2016 12:09:14

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: 1062

Folder: Admission (Day -2)

Form: Inclusion Criteria (3)

Data signed: (hfarmer1) 26 Mar 2015 14:18:12

Generated On: 20 Jul 2016 12:09:14

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: 1062

Folder: Admission (Day -2)

Form: Inclusion Criteria (4)

Data signed: (hfarmer1) 26 Mar 2015 14:18:12

Generated On: 20 Jul 2016 12:09:14

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

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

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

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Admission (Day -2)

Form: Exclusion Criteria

Data signed: (hfarmer1) 26 Mar 2015 14:18:11

Generated On: 20 Jul 2016 12:09:14

*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: 1062

Folder: Admission (Day -2)

Form: Exclusion Criteria (1)

Data signed: (hfarmer1) 26 Mar 2015 14:18:11

Generated On: 20 Jul 2016 12:09:14

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: 1062

Folder: Admission (Day -2)

Form: Exclusion Criteria (2)

Data signed: (hfarmer1) 26 Mar 2015 14:18:11

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Admission (Day -2)

Form: Exclusion Criteria (3)

Data signed: (hfarmer1) 26 Mar 2015 14:18:11

Generated On: 20 Jul 2016 12:09:14

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

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

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

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

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1062

Folder: Admission (Day -2)

Form: Exclusion Criteria (4)

Data signed: (hfarmer1) 26 Mar 2015 14:18:11

Generated On: 20 Jul 2016 12:09:14

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: 1062

Folder: Admission (Day -2)

Form: Exclusion Criteria (5)

Data signed: (hfarmer1) 26 Mar 2015 14:18:11

Generated On: 20 Jul 2016 12:09:14

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: 1062

Folder: Admission (Day -2)

Form: Exclusion Criteria (6)

Data signed: (hfarmer1) 26 Mar 2015 14:18:11

Generated On: 20 Jul 2016 12:09:14

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: 1062

Folder: Admission (Day -2)

Form: Exclusion Criteria (7)

Data signed: (hfarmer1) 26 Mar 2015 14:18:11

Generated On: 20 Jul 2016 12:09:14

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: 1062

Folder: Admission (Day -2)

Form: Exclusion Criteria (8)

Data signed: (hfarmer1) 26 Mar 2015 14:18:11

Generated On: 20 Jul 2016 12:09:14

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

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

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

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Admission (Day -2)

Form: Exclusion Criteria (9)

Data signed: (hfarmer1) 26 Mar 2015 14:18:11

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Admission (Day -2)

Form: Exclusion Criteria (10)

Data signed: (hfarmer1) 26 Mar 2015 14:18:11

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Admission (Day -2)

Form: Exclusion Criteria (11)

Data signed: (hfarmer1) 26 Mar 2015 14:18:11

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Admission (Day -2)

Form: Exclusion Criteria (12)

Data signed: (hfarmer1) 26 Mar 2015 14:18:11

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Admission (Day -2)

Form: Exclusion Criteria (13)

Data signed: (hfarmer1) 26 Mar 2015 14:18:11

Generated On: 20 Jul 2016 12:09:14

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: 1062

Folder: Admission (Day -2)

Form: Exclusion Criteria (14)

Data signed: (hfarmer1) 26 Mar 2015 14:18:11

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Admission (Day -2)

Form: Vital Signs

Data signed: (hfarmer1) 26 Mar 2015 14:18:14

Generated On: 20 Jul 2016 12:09:14

Were Vitals Signs assessed? Yes ☒

If No, please specify the reason: _____

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

Time of assessment 15:00
hour:min 24-hour clock

Pulse rate 63
beats per minute

Respiratory rate 16
breaths per minute

Blood Pressure (systolic) 118
mmHg

Blood Pressure (diastolic) 75
mmHg

Vital Signs Position of Subject Supine ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Admission (Day -2)

Form: Product preference

Data signed: (hfarmer1) 26 Mar 2015 14:18:14

Generated On: 20 Jul 2016 12:09:14

Which Product Arm would you prefer to be randomized
to:

mCC 

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Admission (Day -2)

Form: Advice on the risk of smoking and debriefing

Data signed: (hfarmer1) 26 Mar 2015 14:18:14

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Admission (Day -2)

Form: Physical Examination

Data signed: (hfarmer1) 26 Mar 2015 14:18:12

Generated On: 20 Jul 2016 12:09:14

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Admission (Day -2)

Form: Physical Examination (1)

Data signed: (hfarmer1) 26 Mar 2015 14:18:12

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Admission (Day -2)

Form: Physical Examination (2)

Data signed: (hfarmer1) 26 Mar 2015 14:18:12

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Admission (Day -2)

Form: Physical Examination (3)

Data signed: (hfarmer1) 26 Mar 2015 14:18:12

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Admission (Day -2)

Form: Physical Examination (4)

Data signed: (hfarmer1) 26 Mar 2015 14:18:12

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Admission (Day -2)

Form: Physical Examination (5)

Data signed: (hfarmer1) 26 Mar 2015 14:18:12

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Admission (Day -2)

Form: Physical Examination (6)

Data signed: (hfarmer1) 26 Mar 2015 14:18:12

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Admission (Day -2)

Form: Physical Examination (7)

Data signed: (hfarmer1) 26 Mar 2015 14:18:12

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Admission (Day -2)

Form: Physical Examination (8)

Data signed: (hfarmer1) 26 Mar 2015 14:18:12

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Admission (Day -2)

Form: Physical Examination (9)

Data signed: (hfarmer1) 26 Mar 2015 14:18:12

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Admission (Day -2)

Form: Physical Examination (10)

Data signed: (hfarmer1) 26 Mar 2015 14:18:12

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Admission (Day -2)

Form: Physical Examination (11)

Data signed: (hfarmer1) 26 Mar 2015 14:18:12

Generated On: 20 Jul 2016 12:09:14

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: 1062

Folder: Admission (Day -2)

Form: Physical Examination (12)

Data signed: (hfarmer1) 26 Mar 2015 14:18:12

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Admission (Day -2)

Form: Physical Examination (13)

Data signed: (hfarmer1) 26 Mar 2015 14:18:12

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Admission (Day -2)

Form: Physical Examination (14)

Data signed: (hfarmer1) 26 Mar 2015 14:18:12

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Admission (Day -2)

Form: Physical Examination (15)

Data signed: (hfarmer1) 26 Mar 2015 14:18:12

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Admission (Day -2)

Form: Physical Examination (16)

Data signed: (hfarmer1) 26 Mar 2015 14:18:12

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Admission (Day -2)

Form: Physical Examination (17)

Data signed: (hfarmer1) 26 Mar 2015 14:18:12

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Admission (Day -2)

Form: Physical Examination (18)

Data signed: (hfarmer1) 26 Mar 2015 14:18:12

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Admission (Day -2)

Form: Physical Examination (19)

Data signed: (hfarmer1) 26 Mar 2015 14:18:12

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Admission (Day -2)

Form: Identification of Current Cigarette Brand

Data signed: (hcoleman1) 18 Jun 2015 19:58:06

Generated On: 20 Jul 2016 12:09:14

Brand name

NEWPORT 100'S GREEN

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1062

Folder: Admission (Day -2)

Form: THS 2.2 menthol product test

Data signed: (hfarmer1) 26 Mar 2015 14:18:14

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Admission (Day -2)

Form: Smoking History

Data signed: (hfarmer1) 26 Mar 2015 14:18:14

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Admission (Day -2)

Form: Weight

Data signed: (hfarmer1) 26 Mar 2015 14:18:15

Generated On: 20 Jul 2016 12:09:14

Measurement(s) assessed?

Yes ☒

If No, please specify the reason: _____

Time of assessment

14:51
hour:min 24-hour clock

Weight

76.5
kg

Waist circumference

92
cm

BMI

23.7

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1062

Folder: Admission (Day -2)

Form: Urine Drug Screen

Data signed: (hfarmer1) 26 Mar 2015 14:18:12

Generated On: 20 Jul 2016 12:09:14

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

If Not Done, please specify the reason: _____

Time of sample collection	14:38
	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: 1062

Folder: Admission (Day -2)

Form: Urine Drug Screen (6)

Data signed: (hfarmer1) 26 Mar 2015 14:18:12

Generated On: 20 Jul 2016 12:09:14

Drug type	Result
Opiates	Negative

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Admission (Day -2)

Form: Alcohol Test

Data signed: (hfarmer1) 26 Mar 2015 14:18:12

Generated On: 20 Jul 2016 12:09:14

Was the alcohol test performed? Yes ☒

If No, please specify the reason: _____

Method used Breath test ☒

Time of assessment 14:44
hour:min 24-hour clock

Result Negative ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Admission (Day -2)

Form: CO Breath Test

Data signed: (hfarmer1) 26 Mar 2015 14:18:11

Generated On: 20 Jul 2016 12:09:14

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

If Not Done, please specify the reason: _____

Actual Time of Assessment	14:45
	hour:min 24-hour clock

Result	27
	ppm

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1062

Folder: Admission (Day -2)

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

Data signed: (hfarmer1) 26 Mar 2015 14:18:14

Generated On: 20 Jul 2016 12:09:14

Was paper questionnaire used? Yes ☒

Reason not done _____

Type PROCHASKA STAGE OF
CHANGE QUESTIONNAIRE:
INTENTION TO QUIT
SMOKING

Date of assessment 17 JAN 2014
DD/MMM/YYYY

Time of assessment 15:10
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? 3

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day -1)

Form: Date of Visit

Data signed: (hfarmer1) 26 Mar 2015 14:18:16

Generated On: 20 Jul 2016 12:09:14

Date of Visit

18 JAN 2014
DD/MMM/YYYY

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day -1)

Form: Vital Signs

Data signed: (hfarmer1) 26 Mar 2015 14:18:17

Generated On: 20 Jul 2016 12:09:14

Were Vitals Signs assessed?

Yes ☒

If No, please specify the reason: _____

Has the subject smoked within 15 minutes prior to
assessment

No ☒

Time of assessment

09:43
hour:min 24-hour clock

Pulse rate

59
beats per minute

Respiratory rate

16
breaths per minute

Blood Pressure (systolic)

113
mmHg

Blood Pressure (diastolic)

71
mmHg

Vital Signs Position of Subject

Supine ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day -1)

Form: CoHb Blood Sample

Data signed: (hfarmer1) 26 Mar 2015 14:18:15

Generated On: 20 Jul 2016 12:09:14

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	18 JAN 2014
---------------------	-------------

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

Time hour:min 24-hour clock	21:04
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day -1)

Form: CO Breath Test (1)

Data signed: (hfarmer1) 26 Mar 2015 14:18:15

Generated On: 20 Jul 2016 12:09:14

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

If Not Done, please specify the reason: _____

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

Actual Time of Assessment hour:min 24-hour clock	07:13
---	-------

Result(ppm)	17
-------------	----

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day -1)

Form: CO Breath Test (2)

Data signed: (hfarmer1) 26 Mar 2015 14:18:15

Generated On: 20 Jul 2016 12:09:14

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)	28
-------------	----

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day -1)

Form: CO Breath Test (3)

Data signed: (hfarmer1) 26 Mar 2015 14:18:15

Generated On: 20 Jul 2016 12:09:14

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

If Not Done, please specify the reason: _____

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

Actual Time of Assessment hour:min 24-hour clock	16:17
---	-------

Result(ppm)	28
-------------	----

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day -1)

Form: CO Breath Test (4)

Data signed: (hfarmer1) 26 Mar 2015 14:18:15

Generated On: 20 Jul 2016 12:09:14

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

If Not Done, please specify the reason: _____

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

Actual Time of Assessment hour:min 24-hour clock	20:55
---	-------

Result(ppm)	24
-------------	----

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day -1)

Form: 4 hour urine collection

Data signed: (hfarmer1) 26 Mar 2015 14:18:16

Generated On: 20 Jul 2016 12:09:14

Start Time	09:55
	hour:min 24-hour clock

End Time	13:57
	hour:min 24-hour clock

Volume	430
	mL

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day -1)

Form: Sample Urine Collection (4 Hour collection)

Data signed: (hfarmer1) 26 Mar 2015 14:18:16

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Baseline (Day -1)

Form: Lab_BU_COHB (1)

Data signed: (hfarmer1) 26 Mar 2015 14:18:17

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05115150000129
----------------	----------------

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

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

Result	.
--------	---

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

Lab Status	OTHER
------------	-------

Sample comment	ANALYSIS NOT REQUIRED
----------------	-----------------------

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-JAN-18
--------------------	-------------

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day -1)

Form: Lab_BU_COHB (1)

Data signed: (hfarmer1) 26 Mar 2015 14:18:17

Generated On: 20 Jul 2016 12:09:14

Start Day (24 hour urine only)

End Day (24 hour Urine Only)

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1062

Folder: Baseline (Day -1)

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)

Data signed: (hfarmer1) 26 Mar 2015 14:18:17

Generated On: 20 Jul 2016 12:09:14

Date of Birth

(b) (6)

Date of assessment

2014 JAN 18

DD/MMM/YYYY

DD/MMM/YYYY

Time of assessment

21:02

hour:min 24-hour clock

Assessment Status

Completed

1. Was smoking satisfying?

Moderately

2. Did cigarettes taste good?

Moderately

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

Very little

4. Did smoking calm you down?

Very little

5. Did smoking make you feel more awake?

Not at all

6. Did smoking make you feel less irritable?

Very little

7. Did smoking help you concentrate?

Not at all

8. Did smoking reduce your hunger for food?

Not at all

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day -1)

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)

Data signed: (hfarmer1) 26 Mar 2015 14:18:17

Generated On: 20 Jul 2016 12:09:14

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

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

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

12. Did you enjoy smoking? Moderately ☐

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day -1)

Form: Behavioral Risk Factor Surveillance System Questionnaire

Data signed: (hfarmer1) 26 Mar 2015 14:18:15

Generated On: 20 Jul 2016 12:09:14

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

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

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

Date of assessment	18 JAN 2014 DD/MMM/YYYY
--------------------	----------------------------

Time of assessment	21:34 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?	Yes <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: 1062**

Folder: Baseline (Day -1)

Form: Behavioral Risk Factor Surveillance System Questionnaire

Data signed: (hfarmer1) 26 Mar 2015 14:18:15

Generated On: 20 Jul 2016 12:09:14

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: 1062

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ)

Data signed: (hfarmer1) 26 Mar 2015 14:18:15

Generated On: 20 Jul 2016 12:09:14

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

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

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

Date of assessment	18 JAN 2014 DD/MMM/YYYY
--------------------	----------------------------

Time of assessment	21:37 hour:min 24-hour clock
--------------------	---------------------------------

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

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

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

4. If you ever smoked cigarettes regularly: At what age did you start to smoke regularly?	18 Years
---	----------

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

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ)

Data signed: (hfarmer1) 26 Mar 2015 14:18:15

Generated On: 20 Jul 2016 12:09:14

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

0 Years

Months

Days

04 Days

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

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1062

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (1)

Data signed: (hfarmer1) 26 Mar 2015 14:18:15

Generated On: 20 Jul 2016 12:09:14

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

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

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

Date of assessment	18 JAN 2014 DD/MMM/YYYY
--------------------	----------------------------

Time of assessment	21:37 hour:min 24-hour clock
--------------------	---------------------------------

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

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

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

4. If you ever smoked cigarettes regularly: At what age did you start to smoke regularly?	18 Years
---	----------

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

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

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1062

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (1)

Data signed: (hfarmer1) 26 Mar 2015 14:18:15

Generated On: 20 Jul 2016 12:09:14

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

0 Years

Months

Days

04 Days

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

Time

Currently (last 3 months) ☒

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

Manufactured Cigarettes
per day

11

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: 1062**

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (1)

Data signed: (hfarmer1) 26 Mar 2015 14:18:15

Generated On: 20 Jul 2016 12:09:14

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: 1062

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (2)

Data signed: (hfarmer1) 26 Mar 2015 14:18:15

Generated On: 20 Jul 2016 12:09:14

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

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

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

Date of assessment	18 JAN 2014 DD/MMM/YYYY
--------------------	----------------------------

Time of assessment	21:37 hour:min 24-hour clock
--------------------	---------------------------------

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

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

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

4. If you ever smoked cigarettes regularly: At what age did you start to smoke regularly?	18 Years
---	----------

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

Years	<hr/>
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1062

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (2)

Data signed: (hfarmer1) 26 Mar 2015 14:18:15

Generated On: 20 Jul 2016 12:09:14

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

0 Years

Months

Days

04 Days

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

Time

1 year ago ☒

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

Manufactured Cigarettes
per day

11

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: 1062**

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (2)

Data signed: (hfarmer1) 26 Mar 2015 14:18:15

Generated On: 20 Jul 2016 12:09:14

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: 1062

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (3)

Data signed: (hfarmer1) 26 Mar 2015 14:18:15

Generated On: 20 Jul 2016 12:09:14

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

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

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

Date of assessment	18 JAN 2014 DD/MMM/YYYY
--------------------	----------------------------

Time of assessment	21:37 hour:min 24-hour clock
--------------------	---------------------------------

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

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

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

4. If you ever smoked cigarettes regularly: At what age did you start to smoke regularly?	18 Years
---	----------

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

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

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1062

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (3)

Data signed: (hfarmer1) 26 Mar 2015 14:18:15

Generated On: 20 Jul 2016 12:09:14

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

0 Years

Months

Days

04 Days

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

Time

5 years ago

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

Manufactured Cigarettes
per day

12

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: 1062**

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (3)

Data signed: (hfarmer1) 26 Mar 2015 14:18:15

Generated On: 20 Jul 2016 12:09:14

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: 1062

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (4)

Data signed: (hfarmer1) 26 Mar 2015 14:18:15

Generated On: 20 Jul 2016 12:09:14

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

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

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

Date of assessment	18 JAN 2014 DD/MMM/YYYY
--------------------	----------------------------

Time of assessment	21:37 hour:min 24-hour clock
--------------------	---------------------------------

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

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

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

4. If you ever smoked cigarettes regularly: At what age did you start to smoke regularly?	18 Years
---	----------

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

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

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1062

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (4)

Data signed: (hfarmer1) 26 Mar 2015 14:18:15

Generated On: 20 Jul 2016 12:09:14

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

0 Years

Months

Days

04 Days

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

Time

10 years ago

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

Manufactured Cigarettes
per day

12

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: 1062**

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (4)

Data signed: (hfarmer1) 26 Mar 2015 14:18:15

Generated On: 20 Jul 2016 12:09:14

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: 1062

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (5)

Data signed: (hfarmer1) 26 Mar 2015 14:18:15

Generated On: 20 Jul 2016 12:09:14

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

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

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

Date of assessment	18 JAN 2014 DD/MMM/YYYY
--------------------	----------------------------

Time of assessment	21:37 hour:min 24-hour clock
--------------------	---------------------------------

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

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

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

4. If you ever smoked cigarettes regularly: At what age did you start to smoke regularly?	18 Years
---	----------

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

Years	<hr/>
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (5)

Data signed: (hfarmer1) 26 Mar 2015 14:18:15

Generated On: 20 Jul 2016 12:09:14

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

0 Years

Months

Days

04 Days

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

Time

15 years ago ☒

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

Manufactured Cigarettes
per day

12

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: 1062**

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (5)

Data signed: (hfarmer1) 26 Mar 2015 14:18:15

Generated On: 20 Jul 2016 12:09:14

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: 1062

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (6)

Data signed: (hfarmer1) 26 Mar 2015 14:18:15

Generated On: 20 Jul 2016 12:09:14

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

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

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

Date of assessment	18 JAN 2014 DD/MMM/YYYY
--------------------	----------------------------

Time of assessment	21:37 hour:min 24-hour clock
--------------------	---------------------------------

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

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

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

4. If you ever smoked cigarettes regularly: At what age did you start to smoke regularly?	18 Years
---	----------

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

Years	<hr/>
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1062

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (6)

Data signed: (hfarmer1) 26 Mar 2015 14:18:15

Generated On: 20 Jul 2016 12:09:14

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

0 Years

Months

Days

04 Days

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

Time

20 years ago

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

Manufactured Cigarettes
per day

12

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: 1062**

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (6)

Data signed: (hfarmer1) 26 Mar 2015 14:18:15

Generated On: 20 Jul 2016 12:09:14

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: 1062

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (7)

Data signed: (hfarmer1) 26 Mar 2015 14:18:15

Generated On: 20 Jul 2016 12:09:14

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

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

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

Date of assessment	18 JAN 2014 DD/MMM/YYYY
--------------------	----------------------------

Time of assessment	21:37 hour:min 24-hour clock
--------------------	---------------------------------

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

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

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

4. If you ever smoked cigarettes regularly: At what age did you start to smoke regularly?	18 Years
---	----------

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

Years	<hr/>
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1062

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (7)

Data signed: (hfarmer1) 26 Mar 2015 14:18:15

Generated On: 20 Jul 2016 12:09:14

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

0 Years

Months

Days

04 Days

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

Time

More than 20 years ago ☒

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

Manufactured Cigarettes
per day

12

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: 1062**

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (7)

Data signed: (hfarmer1) 26 Mar 2015 14:18:15

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Baseline (Day -1)

Form: Supplemental Questions

Data signed: (hfarmer1) 26 Mar 2015 14:18:16

Generated On: 20 Jul 2016 12:09:14

Was paper questionnaire used?

Yes ☒

Reason not done

Date of Assessment

18 JAN 2014
DD/MMM/YYYY

Time of assessment

21:39

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

3 minutes

Comments (open-end)

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day -1)

Form: Supplemental Questions (1)

Data signed: (hfarmer1) 26 Mar 2015 14:18:16

Generated On: 20 Jul 2016 12:09:14

Was paper questionnaire used? Yes ☐

Reason not done _____

Date of Assessment 18 JAN 2014
DD/MMM/YYYY

Time of assessment 21:39

1. How long it takes for the subject to complete the SQ 3 minutes

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

Answer Yes ☐

Comments (open-end) _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day -1)

Form: Supplemental Questions (2)

Data signed: (hfarmer1) 26 Mar 2015 14:18:16

Generated On: 20 Jul 2016 12:09:14

Was paper questionnaire used? Yes ☐

Reason not done _____

Date of Assessment 18 JAN 2014
DD/MMM/YYYY

Time of assessment 21:39

1. How long it takes for the subject to complete the SQ 3 minutes

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

Answer Yes ☐

Comments (open-end) _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day -1)

Form: Supplemental Questions (3)

Data signed: (hfarmer1) 26 Mar 2015 14:18:16

Generated On: 20 Jul 2016 12:09:14

Was paper questionnaire used? Yes ☐

Reason not done _____

Date of Assessment 18 JAN 2014
DD/MMM/YYYY

Time of assessment 21:39

1. How long it takes for the subject to complete the SQ 3 minutes

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

Answer Yes ☐

Comments (open-end) _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day -1)

Form: Supplemental Questions (4)

Data signed: (hfarmer1) 26 Mar 2015 14:18:16

Generated On: 20 Jul 2016 12:09:14

Was paper questionnaire used? Yes ☐

Reason not done _____

Date of Assessment 18 JAN 2014
DD/MMM/YYYY

Time of assessment 21:39

1. How long it takes for the subject to complete the SQ 3 minutes

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

Answer Yes ☐

Comments (open-end) _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day -1)

Form: Supplemental Questions (5)

Data signed: (hfarmer1) 26 Mar 2015 14:18:16

Generated On: 20 Jul 2016 12:09:14

Was paper questionnaire used? Yes ☐

Reason not done _____

Date of Assessment 18 JAN 2014
DD/MMM/YYYY

Time of assessment 21:39

1. How long it takes for the subject to complete the SQ 3 minutes

Question 6. Was the SQ self-explaining? ☐

Answer Yes ☐

Comments (open-end) _____

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1062

Folder: Baseline (Day -1)

Form: Supplemental Questions (6)

Data signed: (hfarmer1) 26 Mar 2015 14:18:16

Generated On: 20 Jul 2016 12:09:14

Was paper questionnaire used? Yes ☐

Reason not done

Date of Assessment 18 JAN 2014
DD/MMM/YYYY

Time of assessment 21:39

1. How long it takes for the subject to complete the SQ 3 minutes

Question 7. Was the SQ easy to use? ☐

Answer Yes ☐

Comments (open-end)

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1062

Folder: Baseline (Day -1)

Form: Questionnaire on smoking urges (QSU)

Data signed: (hfarmer1) 26 Mar 2015 14:18:17

Generated On: 20 Jul 2016 12:09:14

Type	QSU
Date of Birth	(b) (6)
Date of assessment	2014 JAN 18
DD/MMM/YYYY	
Time of assessment	21:01
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	Somewhat agree <input checked="" type="radio"/>
4. I could control things better right now if I could smoke	Disagree <input checked="" type="radio"/>
5. All I want right now is a cigarette	Somewhat 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: 1062**

Folder: Baseline (Day -1)

Form: Questionnaire on smoking urges (QSU)

Data signed: (hfarmer1) 26 Mar 2015 14:18:17

Generated On: 20 Jul 2016 12:09:14

7. A cigarette would taste good now Somewhat disagree ☐

8. I would do almost anything for a cigarette now Strongly disagree ☐

9. Smoking would make me less depressed Strongly disagree ☐

10. I am going to smoke as soon as possible Somewhat disagree ☐

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day -1)

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

Data signed: (hfarmer1) 26 Mar 2015 14:18:17

Generated On: 20 Jul 2016 12:09:14

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day -1)

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

Data signed: (hfarmer1) 26 Mar 2015 14:18:17

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05112450000100
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	-1
Celerion Study Number	AA99128-03
Date of Collection	2014-JAN-18
Timepoint-minutes	
Urine Start Day	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day -1)

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

Data signed: (hfarmer1) 26 Mar 2015 14:18:17

Generated On: 20 Jul 2016 12:09:14

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (2)

Data signed: (hfarmer1) 26 Mar 2015 14:18:17

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05112450000100
----------------	----------------

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	-1
--------------	----

Celerion Study Number	AA99128-03
-----------------------	------------

Date of Collection	2014-JAN-18
--------------------	-------------

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

Urine Start Day	
-----------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (2)

Data signed: (hfarmer1) 26 Mar 2015 14:18:17

Generated On: 20 Jul 2016 12:09:14

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (3)

Data signed: (hfarmer1) 26 Mar 2015 14:18:17

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05112450000100
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	-1
Celerion Study Number	AA99128-03
Date of Collection	2014-JAN-18
Timepoint-minutes	
Urine Start Day	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (3)

Data signed: (hfarmer1) 26 Mar 2015 14:18:17

Generated On: 20 Jul 2016 12:09:14

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (NNN, NNAL)

Data signed: (hfarmer1) 26 Mar 2015 14:18:17

Generated On: 20 Jul 2016 12:09:14

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (NNN, NNAL) (1)

Data signed: (hfarmer1) 26 Mar 2015 14:18:17

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05112460000100
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-JAN-18
Timepoint-minutes	
Urine Start Day	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (NNN, NNAL) (1)

Data signed: (hfarmer1) 26 Mar 2015 14:18:17

Generated On: 20 Jul 2016 12:09:14

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (NNN, NNAL) (2)

Data signed: (hfarmer1) 26 Mar 2015 14:18:17

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05112460000100
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-JAN-18
Timepoint-minutes	
Urine Start Day	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (NNN, NNAL) (2)

Data signed: (hfarmer1) 26 Mar 2015 14:18:17

Generated On: 20 Jul 2016 12:09:14

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (HEMA)

Data signed: (hfarmer1) 26 Mar 2015 14:18:17

Generated On: 20 Jul 2016 12:09:14

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (HEMA) (1)

Data signed: (hfarmer1) 26 Mar 2015 14:18:17

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05112470000100
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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-JAN-18
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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: 1062**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (HEMA) (1)

Data signed: (hfarmer1) 26 Mar 2015 14:18:17

Generated On: 20 Jul 2016 12:09:14

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)

Data signed: (hfarmer1) 26 Mar 2015 14:18:17

Generated On: 20 Jul 2016 12:09:14

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day -1)

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(1)**

Data signed: (hfarmer1) 26 Mar 2015 14:18:17

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05112480000078
Analyte	COT
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	AA99128-06
Date of Collection	2014-JAN-18
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day -1)

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(1)**

Data signed: (hfarmer1) 26 Mar 2015 14:18:17

Generated On: 20 Jul 2016 12:09:14

Urine Start Day

Urine End Day

-1

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1062

Folder: Baseline (Day -1)

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(2)**

Data signed: (hfarmer1) 26 Mar 2015 14:18:17

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05112480000078
Analyte	COT-GLUC
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	AA99128-06
Date of Collection	2014-JAN-18
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day -1)

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(2)**

Data signed: (hfarmer1) 26 Mar 2015 14:18:17

Generated On: 20 Jul 2016 12:09:14

Urine Start Day

Urine End Day

-1

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1062

Folder: Baseline (Day -1)

Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc) (3)

Data signed: (hfarmer1) 26 Mar 2015 14:18:17

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05112480000078
Analyte	NIC
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	AA99128-06
Date of Collection	2014-JAN-18
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day -1)

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(3)**

Data signed: (hfarmer1) 26 Mar 2015 14:18:17

Generated On: 20 Jul 2016 12:09:14

Urine Start Day

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day -1)

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(4)**

Data signed: (hfarmer1) 26 Mar 2015 14:18:17

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05112480000078
Analyte	NIC-GLUC
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	AA99128-06
Date of Collection	2014-JAN-18
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day -1)

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(4)**

Data signed: (hfarmer1) 26 Mar 2015 14:18:17

Generated On: 20 Jul 2016 12:09:14

Urine Start Day

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day -1)

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(5)**

Data signed: (hfarmer1) 26 Mar 2015 14:18:17

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05112480000078
Analyte	THCOT
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	AA99128-06
Date of Collection	2014-JAN-18
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day -1)

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(5)**

Data signed: (hfarmer1) 26 Mar 2015 14:18:17

Generated On: 20 Jul 2016 12:09:14

Urine Start Day

Urine End Day

-1

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1062

Folder: Baseline (Day -1)

Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc) (6)

Data signed: (hfarmer1) 26 Mar 2015 14:18:17

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05112480000078
Analyte	THCOT-GLUC
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	AA99128-06
Date of Collection	2014-JAN-18
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day -1)

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(6)**

Data signed: (hfarmer1) 26 Mar 2015 14:18:17

Generated On: 20 Jul 2016 12:09:14

Urine Start Day

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (3-OH BaP)

Data signed: (hfarmer1) 26 Mar 2015 14:18:17

Generated On: 20 Jul 2016 12:09:14

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (3-OH BaP) (1)

Data signed: (hfarmer1) 26 Mar 2015 14:18:17

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05112490000100
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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-JAN-18
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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: 1062**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (3-OH BaP) (1)

Data signed: (hfarmer1) 26 Mar 2015 14:18:17

Generated On: 20 Jul 2016 12:09:14

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP)

Data signed: (hfarmer1) 26 Mar 2015 14:18:17

Generated On: 20 Jul 2016 12:09:14

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (1)

Data signed: (hfarmer1) 26 Mar 2015 14:18:17

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05112510000100
Analyte	1-NA
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	AA99128-09
Date of Collection	2014-JAN-18
Timepoint-minutes	
Urine Start Day	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (1)

Data signed: (hfarmer1) 26 Mar 2015 14:18:17

Generated On: 20 Jul 2016 12:09:14

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (2)

Data signed: (hfarmer1) 26 Mar 2015 14:18:17

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05112510000100
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Analyte	2-NA
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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	AA99128-09
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Date of Collection	2014-JAN-18
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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: 1062**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (2)

Data signed: (hfarmer1) 26 Mar 2015 14:18:17

Generated On: 20 Jul 2016 12:09:14

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (3)

Data signed: (hfarmer1) 26 Mar 2015 14:18:17

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05112510000100
Analyte	4-ABP
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	AA99128-09
Date of Collection	2014-JAN-18
Timepoint-minutes	
Urine Start Day	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (3)

Data signed: (hfarmer1) 26 Mar 2015 14:18:17

Generated On: 20 Jul 2016 12:09:14

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (4)

Data signed: (hfarmer1) 26 Mar 2015 14:18:17

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05112510000100
Analyte	O-TOL
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	AA99128-09
Date of Collection	2014-JAN-18
Timepoint-minutes	
Urine Start Day	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (4)

Data signed: (hfarmer1) 26 Mar 2015 14:18:17

Generated On: 20 Jul 2016 12:09:14

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (11-dTXb2)

Data signed: (hfarmer1) 26 Mar 2015 14:18:17

Generated On: 20 Jul 2016 12:09:14

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (11-dTXb2) (1)

Data signed: (hfarmer1) 26 Mar 2015 14:18:17

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05112530000064
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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-JAN-18
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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: 1062**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (11-dTXb2) (1)

Data signed: (hfarmer1) 26 Mar 2015 14:18:17

Generated On: 20 Jul 2016 12:09:14

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (iPF2a-III)

Data signed: (hfarmer1) 26 Mar 2015 14:18:17

Generated On: 20 Jul 2016 12:09:14

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (iPF2a-III) (1)

Data signed: (hfarmer1) 26 Mar 2015 14:18:17

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05112540000064
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Analyte	IPF2A-III
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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
----------------	-----------------------

Detection method	LC-MS/MS
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Planned time point (Hour)	0
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Day of Visit	-1
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Celerion Study Number	AA99128-12
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Date of Collection	2014-JAN-18
--------------------	-------------

Timepoint-minutes	
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Urine Start Day	
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (iPF2a-III) (1)

Data signed: (hfarmer1) 26 Mar 2015 14:18:17

Generated On: 20 Jul 2016 12:09:14

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (1-OHP)

Data signed: (hfarmer1) 26 Mar 2015 14:18:18

Generated On: 20 Jul 2016 12:09:14

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (1-OHP) (1)

Data signed: (hfarmer1) 26 Mar 2015 14:18:18

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05115190001189
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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-JAN-18
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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: 1062**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (1-OHP) (1)

Data signed: (hfarmer1) 26 Mar 2015 14:18:18

Generated On: 20 Jul 2016 12:09:14

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (SPMA, SBMA)

Data signed: (hfarmer1) 26 Mar 2015 14:18:17

Generated On: 20 Jul 2016 12:09:14

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (SPMA, SBMA) (1)

Data signed: (hfarmer1) 26 Mar 2015 14:18:17

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05115170000100
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Analyte	SBMA
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Sample type	URINE
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Result	.
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Result Unit	NG/ML
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Lab Status	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	AA99598-01
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Date of Collection	2014-JAN-18
--------------------	-------------

Timepoint-minutes	
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Urine Start Day	
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (SPMA, SBMA) (1)

Data signed: (hfarmer1) 26 Mar 2015 14:18:17

Generated On: 20 Jul 2016 12:09:14

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (SPMA, SBMA) (2)

Data signed: (hfarmer1) 26 Mar 2015 14:18:17

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05115170000100
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Analyte	SPMA
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Sample type	URINE
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Result	.
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Result Unit	NG/ML
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Lab Status	OTHER
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Sample comment	ANALYSIS NOT REQUIRED
----------------	-----------------------

Detection method	LC-MS/MS
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Planned time point (Hour)	0
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Day of Visit	-1
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Celerion Study Number	AA99598-01
-----------------------	------------

Date of Collection	2014-JAN-18
--------------------	-------------

Timepoint-minutes	
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Urine Start Day	
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (SPMA, SBMA) (2)

Data signed: (hfarmer1) 26 Mar 2015 14:18:17

Generated On: 20 Jul 2016 12:09:14

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (MHBMA)

Data signed: (hfarmer1) 26 Mar 2015 14:18:17

Generated On: 20 Jul 2016 12:09:14

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (MHBMA) (1)

Data signed: (hfarmer1) 26 Mar 2015 14:18:17

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05115180000100
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Analyte	MHBMA
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Sample type	URINE
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Result	.
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Result Unit	NG/ML
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Lab Status	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	
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Celerion Study Number	AA99598-02
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Date of Collection	2014-JAN-18
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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: 1062**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (MHBMA) (1)

Data signed: (hfarmer1) 26 Mar 2015 14:18:17

Generated On: 20 Jul 2016 12:09:14

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (Creatinine)

Data signed: (hfarmer1) 26 Mar 2015 14:18:18

Generated On: 20 Jul 2016 12:09:14

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (Creatinine) (1)

Data signed: (hfarmer1) 26 Mar 2015 14:18:18

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05115160000100
----------------	----------------

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-JAN-18
--------------------	-------------

Timepoint-minutes	_____
-------------------	-------

Urine Start Day	_____
-----------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (Creatinine) (1)

Data signed: (hfarmer1) 26 Mar 2015 14:18:18

Generated On: 20 Jul 2016 12:09:14

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day 0)

Form: Date of Visit

Data signed: (hfarmer1) 26 Mar 2015 14:18:18

Generated On: 20 Jul 2016 12:09:14

Date of Visit

19 JAN 2014
DD/MMM/YYYY

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day 0)

Form: Randomization

Data signed: (hfarmer1) 26 Mar 2015 14:18:18

Generated On: 20 Jul 2016 12:09:14

Randomization number (4 digits)	1008
---------------------------------	------

Allocation Arm	THS 2.2 menthol <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: 1062**

Folder: Baseline (Day 0)

Form: Vital Signs

Data signed: (hfarmer1) 26 Mar 2015 14:18:18

Generated On: 20 Jul 2016 12:09:14

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 10:26
hour:min 24-hour clock

Pulse rate 64
beats per minute

Respiratory rate 16
breaths per minute

Blood Pressure (systolic) 114
mmHg

Blood Pressure (diastolic) 69
mmHg

Vital Signs Position of Subject Supine ☒

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1062

Folder: Baseline (Day 0)

Form: Gas Transfer

Data signed: (hcoleman1) 18 Jun 2015 19:58:06

Generated On: 20 Jul 2016 12:09:14

Was the Gas Transfer performed?

No ☒

If No, please specify the reason:

TEST PERFORMED BUT THEY
WERE NOT RESULTED

Category

Position

SITTING

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: 1062

Folder: Baseline (Day 0)

Form: Lung Volume Measurements

Data signed: (hcoleman1) 18 Jun 2015 19:58:06

Generated On: 20 Jul 2016 12:09:14

Were the Lung Volume Measurements performed?

No ☒

If No, please specify the reason:

TEST PERFORMED BUT THEY
WERE NOT RESULTED

Category

Position

SITTING

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: 1062

Folder: Baseline (Day 0)

Form: Spirometry with a short-acting bronchodilator

Data signed: (hcoleman1) 18 Jun 2015 19:58:07

Generated On: 20 Jul 2016 12:09:14

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

Time of assessment

Name of bronchodilator

Dose

Predicted FVC value

Best measured FVC value

Percent of predicted FVC value

Best measured FEV1 value

Predicted FEV1 value

Percent of predicted FEV1 value

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day 0)

Form: Spirometry with a short-acting bronchodilator

Data signed: (hcoleman1) 18 Jun 2015 19:58:07

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Baseline (Day 0)

Form: Haematology

Data signed: (hfarmer1) 26 Mar 2015 14:18:18

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Baseline (Day 0)

Form: Clinical Chemistry

Data signed: (hfarmer1) 26 Mar 2015 14:18:18

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Baseline (Day 0)

Form: Urine analysis

Data signed: (hfarmer1) 26 Mar 2015 14:18:18

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Baseline (Day 0)

Form: Plasma Nicotine Sample

Data signed: (hfarmer1) 26 Mar 2015 14:18:18

Generated On: 20 Jul 2016 12:09:14

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	19 JAN 2014
---------------------	-------------

Time hour:min 24-hour clock	21:17
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day 0)

Form: Plasma Cotinine Sample

Data signed: (hfarmer1) 26 Mar 2015 14:18:18

Generated On: 20 Jul 2016 12:09:14

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	19 JAN 2014
---------------------	-------------

Time hour:min 24-hour clock	21:17
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day 0)

Form: CoHb Blood Sample <D0> (1)

Data signed: (hfarmer1) 26 Mar 2015 14:18:18

Generated On: 20 Jul 2016 12:09:14

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	19 JAN 2014
---------------------	-------------

Timepoint	Prior to gas transfer assessment and prior to product use <input checked="" type="radio"/>
-----------	--

Time hour:min 24-hour clock	06:25
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day 0)

Form: CoHb Blood Sample <D0> (2)

Data signed: (hfarmer1) 26 Mar 2015 14:18:18

Generated On: 20 Jul 2016 12:09:14

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	19 JAN 2014
---------------------	-------------

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

Time hour:min 24-hour clock	21:17
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day 0)

Form: Oxysterols

Data signed: (hfarmer1) 26 Mar 2015 14:18:18

Generated On: 20 Jul 2016 12:09:14

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 JAN 2014
---------------------	-------------

Time hour:min 24-hour clock	06:25
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day 0)

Form: CO Breath Test (1)

Data signed: (hfarmer1) 26 Mar 2015 14:18:18

Generated On: 20 Jul 2016 12:09:14

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

If Not Done, please specify the reason: _____

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

Actual Time of Assessment hour:min 24-hour clock	08:48
---	-------

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day 0)

Form: CO Breath Test (2)

Data signed: (hfarmer1) 26 Mar 2015 14:18:18

Generated On: 20 Jul 2016 12:09:14

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	12:42
---	-------

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day 0)

Form: CO Breath Test (3)

Data signed: (hfarmer1) 26 Mar 2015 14:18:18

Generated On: 20 Jul 2016 12:09:14

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

If Not Done, please specify the reason: _____

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

Actual Time of Assessment hour:min 24-hour clock	16:17
---	-------

Result(ppm)	30
-------------	----

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day 0)

Form: CO Breath Test (4)

Data signed: (hfarmer1) 26 Mar 2015 14:18:18

Generated On: 20 Jul 2016 12:09:14

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	20:49
---	-------

Result(ppm)	29
-------------	----

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1062

Folder: Baseline (Day 0)

Form: CYP2A6 activity Sample

Data signed: (hfarmer1) 26 Mar 2015 14:18:18

Generated On: 20 Jul 2016 12:09:14

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 JAN 2014

06:25

trans-3'-hydroxyc
otinine

19 JAN 2014

06:25

cotinine

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1062

Folder: Baseline (Day 0)

Form: CYP1A2 activity Sample

Data signed: (hfarmer1) 26 Mar 2015 14:18:18

Generated On: 20 Jul 2016 12:09:14

Time of caffeine tablet intake	10:14
	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
19 JAN 2014	16:12	Caffeine
19 JAN 2014	16:12	Paraxanthine

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day 0)

**Form: Risk Marker: hs-CRP, fibrinogen, homocysteine, LDL, HDL,
sICAM-1, HbA1c, Apo A1, Apo B**

Data signed: (hfarmer1) 26 Mar 2015 14:18:18

Generated On: 20 Jul 2016 12:09:14

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	19 JAN 2014
---------------------	-------------

Time hour:min 24-hour clock	06:25
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day 0)

Form: 24 hour urine collections

Data signed: (hfarmer1) 26 Mar 2015 14:18:18

Generated On: 20 Jul 2016 12:09:14

Start Date	19 JAN 2014 DD/MMM/YYYY
------------	----------------------------

Start Time	06:23 hour:min 24-hour clock
------------	---------------------------------

End Date	20 JAN 2014 DD/MMM/YYYY
----------	----------------------------

End Time	05:51 hour:min 24-hour clock
----------	---------------------------------

Volume	1092 mL
--------	------------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day 0)

Form: Sample Urine Collection

Data signed: (hfarmer1) 26 Mar 2015 14:18:18

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Baseline (Day 0)

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Data signed: (hfarmer1) 26 Mar 2015 14:18:19

Generated On: 20 Jul 2016 12:09:14

Date of Birth

(b) (6)

Date of assessment
DD/MMM/YYYY

2014 JAN 19
DD/MMM/YYYY

Time of assessment

06:49
hour:min 24-hour clock

Assessment Status

Completed ☒

Please indicate for each of the items below, how you have been feeling over the past 24 hours

How have you been feeling over the past 24 hours?

None ☐

1. Angry, irritable, frustrated

How have you been feeling over the past 24 hours?

None ☐

2. Anxious, nervous

How have you been feeling over the past 24 hours?

None ☐

3. Depressed Mood, sad

How have you been feeling over the past 24 hours?

Mild ☐

4. Desire or craving to smoke

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1062

Folder: Baseline (Day 0)

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Data signed: (hfarmer1) 26 Mar 2015 14:18:19

Generated On: 20 Jul 2016 12:09:14

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? Slight ☐

7. Insomnia, sleep problems, awakening at night

How have you been feeling over the past 24 hours? Slight ☐

8. Restless

How have you been feeling over the past 24 hours? 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: 1062**

Folder: Baseline (Day 0)

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Data signed: (hfarmer1) 26 Mar 2015 14:18:19

Generated On: 20 Jul 2016 12:09:14

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: 1062

Folder: Baseline (Day 0)

Form: Cough Assessment

Data signed: (hfarmer1) 26 Mar 2015 14:18:19

Generated On: 20 Jul 2016 12:09:14

Date of Birth

(b) (6)

Date of assessment
DD/MMM/YYYY

2014 JAN 19
DD/MMM/YYYY

Time of assessment

06:47
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: 1062**

Folder: Baseline (Day 0)

Form: Bio-banking (Transcriptomics)

Data signed: (hfarmer1) 26 Mar 2015 14:18:19

Generated On: 20 Jul 2016 12:09:14

Was a Bio-banking sample for transcriptomics taken?

Yes ☒

Time of Sample Collection

06:25
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: 1062**

Folder: Baseline (Day 0)

Form: Bio-banking (Biomarkers of exposure and risk markers)

Data signed: (hfarmer1) 26 Mar 2015 14:18:19

Generated On: 20 Jul 2016 12:09:14

Was a Bio-banking sample for biomarkers of exposure
and risk markers taken?

Yes ☒

Time of Sample Collection

06:25
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: 1062**

Folder: Baseline (Day 0)

Form: Bio-banking (nasal epithelial collection/buccal collection)

Data signed: (hfarmer1) 26 Mar 2015 14:18:19

Generated On: 20 Jul 2016 12:09:14

Was a Bio-banking sample for nasal epithelial
collection/buccal collection taken?

Yes ☒

Time of Buccal Collection

17:51
hour:min 24-hour clock

Time of Nasal Epithelial Collection

17:47
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: 1062**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (1)

Data signed: (hfarmer1) 26 Mar 2015 14:18:19

Generated On: 20 Jul 2016 12:09:14

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	V225564
--------------	---------

Actual Collection Date	2014 01 19
------------------------	------------

Actual Collection Time	06:25
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	RC1029
------------	--------

Battery Name	TRIGLYCERIDES
--------------	---------------

Lab Test ID	RCT19
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (1)

Data signed: (hfarmer1) 26 Mar 2015 14:18:19

Generated On: 20 Jul 2016 12:09:14

Lab Test Name	TRIGLYCERIDES (GPO)
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	128
Reported Numeric Result	128
Reference Range low	55
Reference Range high	327
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: 1062**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (1)

Data signed: (hfarmer1) 26 Mar 2015 14:18:19

Generated On: 20 Jul 2016 12:09:14

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (2)

Data signed: (hfarmer1) 26 Mar 2015 14:18:19

Generated On: 20 Jul 2016 12:09:14

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	V225564
--------------	---------

Actual Collection Date	2014 01 19
------------------------	------------

Actual Collection Time	06:25
------------------------	-------

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: 1062**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (2)

Data signed: (hfarmer1) 26 Mar 2015 14:18:19

Generated On: 20 Jul 2016 12:09:14

Lab Test Name	FASTING GLUCOSE
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	97
Reported Numeric Result	97
Reference Range low	70
Reference Range high	100
Range Units	MG/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (2)

Data signed: (hfarmer1) 26 Mar 2015 14:18:19

Generated On: 20 Jul 2016 12:09:14

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (3)

Data signed: (hfarmer1) 26 Mar 2015 14:18:19

Generated On: 20 Jul 2016 12:09:14

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	
----------------------	--

Subject Sex	M
-------------	---

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

Visit Name	
------------	--

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	V225564
--------------	---------

Actual Collection Date	2014 01 19
------------------------	------------

Actual Collection Time	06:25
------------------------	-------

Specimen Condition	
--------------------	--

Battery ID	RC272
------------	-------

Battery Name	TOTAL CHOLESTEROL
--------------	-------------------

Lab Test ID	RCT20
-------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (3)

Data signed: (hfarmer1) 26 Mar 2015 14:18:19


Generated On: 20 Jul 2016 12:09:14

Lab Test Name

CHOLESTEROL (HIGH
PERFORMANCE)

Test ID

Test Status

Done 

Reported Text Result

215

Reported Numeric Result

215

Reference Range low

162

Reference Range high

280

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: 1062**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (3)

Data signed: (hfarmer1) 26 Mar 2015 14:18:19

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (4)

Data signed: (hfarmer1) 26 Mar 2015 14:18:19

Generated On: 20 Jul 2016 12:09:14

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	V225564
--------------	---------

Actual Collection Date	2014 01 19
------------------------	------------

Actual Collection Time	06:25
------------------------	-------

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: 1062**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (4)

Data signed: (hfarmer1) 26 Mar 2015 14:18:19

Generated On: 20 Jul 2016 12:09:14

Lab Test Name	TOTAL BILIRUBIN
Test ID	
Test Status	Done <input type="checkbox"/>
Reported Text Result	0.4
Reported Numeric Result	0.4
Reference Range low	0.2
Reference Range high	1.2
Range Units	MG/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (4)

Data signed: (hfarmer1) 26 Mar 2015 14:18:19

Generated On: 20 Jul 2016 12:09:14

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (5)

Data signed: (hfarmer1) 26 Mar 2015 14:18:19

Generated On: 20 Jul 2016 12:09:14

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	V225564
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Actual Collection Date	2014 01 19
------------------------	------------

Actual Collection Time	06:25
------------------------	-------

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: 1062**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (5)

Data signed: (hfarmer1) 26 Mar 2015 14:18:19

Generated On: 20 Jul 2016 12:09:14

Lab Test Name	TOTAL PROTEIN
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	6.3
Reported Numeric Result	6.3
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: 1062**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (5)

Data signed: (hfarmer1) 26 Mar 2015 14:18:19

Generated On: 20 Jul 2016 12:09:14

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (6)

Data signed: (hfarmer1) 26 Mar 2015 14:18:19

Generated On: 20 Jul 2016 12:09:14

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	V225564
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Actual Collection Date	2014 01 19
------------------------	------------

Actual Collection Time	06:25
------------------------	-------

Specimen Condition	<hr/>
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Battery ID	RC9255
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Battery Name	CHEMISTRY PANEL
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Lab Test ID	RCT13
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1062

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (6)

Data signed: (hfarmer1) 26 Mar 2015 14:18:19

Generated On: 20 Jul 2016 12:09:14

Lab Test Name	ALBUMIN
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	3.8
Reported Numeric Result	3.8
Reference Range low	3.3
Reference Range high	4.9
Range Units	G/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (6)

Data signed: (hfarmer1) 26 Mar 2015 14:18:19

Generated On: 20 Jul 2016 12:09:14

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (7)

Data signed: (hfarmer1) 26 Mar 2015 14:18:19

Generated On: 20 Jul 2016 12:09:14

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	V225564
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Actual Collection Date	2014 01 19
------------------------	------------

Actual Collection Time	06:25
------------------------	-------

Specimen Condition	<hr/>
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Battery ID	RC9255
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Battery Name	CHEMISTRY PANEL
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Lab Test ID	RCT1407
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1062

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (7)

Data signed: (hfarmer1) 26 Mar 2015 14:18:19

Generated On: 20 Jul 2016 12:09:14

Lab Test Name	ALKALINE PHOSPHATASE
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	81
Reported Numeric Result	81
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: 1062**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (7)

Data signed: (hfarmer1) 26 Mar 2015 14:18:19

Generated On: 20 Jul 2016 12:09:14

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (8)

Data signed: (hfarmer1) 26 Mar 2015 14:18:19

Generated On: 20 Jul 2016 12:09:14

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	V225564
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Actual Collection Date	2014 01 19
------------------------	------------

Actual Collection Time	06:25
------------------------	-------

Specimen Condition	<hr/>
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Battery ID	RC9255
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Battery Name	CHEMISTRY PANEL
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Lab Test ID	RCT1408
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (8)

Data signed: (hfarmer1) 26 Mar 2015 14:18:19

Generated On: 20 Jul 2016 12:09:14

Lab Test Name	LDH
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	87
Reported Numeric Result	87
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: 1062**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (8)

Data signed: (hfarmer1) 26 Mar 2015 14:18:19

Generated On: 20 Jul 2016 12:09:14

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (9)

Data signed: (hfarmer1) 26 Mar 2015 14:18:19

Generated On: 20 Jul 2016 12:09:14

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	V225564
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Actual Collection Date	2014 01 19
------------------------	------------

Actual Collection Time	06:25
------------------------	-------

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: 1062

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (9)

Data signed: (hfarmer1) 26 Mar 2015 14:18:19

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (9)

Data signed: (hfarmer1) 26 Mar 2015 14:18:19

Generated On: 20 Jul 2016 12:09:14

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (10)

Data signed: (hfarmer1) 26 Mar 2015 14:18:19

Generated On: 20 Jul 2016 12:09:14

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	V225564
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Actual Collection Date	2014 01 19
------------------------	------------

Actual Collection Time	06:25
------------------------	-------

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: 1062

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (10)

Data signed: (hfarmer1) 26 Mar 2015 14:18:19

Generated On: 20 Jul 2016 12:09:14

Lab Test Name	SERUM POTASSIUM
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	5.0
Reported Numeric Result	5.0
Reference Range low	3.4
Reference Range high	5.4
Range Units	MEQ/L
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (10)

Data signed: (hfarmer1) 26 Mar 2015 14:18:19

Generated On: 20 Jul 2016 12:09:14

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (11)

Data signed: (hfarmer1) 26 Mar 2015 14:18:19

Generated On: 20 Jul 2016 12:09:14

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	V225564
--------------	---------

Actual Collection Date	2014 01 19
------------------------	------------

Actual Collection Time	06:25
------------------------	-------

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: 1062

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (11)

Data signed: (hfarmer1) 26 Mar 2015 14:18:19

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (11)

Data signed: (hfarmer1) 26 Mar 2015 14:18:19

Generated On: 20 Jul 2016 12:09:14

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (12)

Data signed: (hfarmer1) 26 Mar 2015 14:18:19

Generated On: 20 Jul 2016 12:09:14

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	V225564
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Actual Collection Date	2014 01 19
------------------------	------------

Actual Collection Time	06:25
------------------------	-------

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: 1062

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (12)

Data signed: (hfarmer1) 26 Mar 2015 14:18:19

Generated On: 20 Jul 2016 12:09:14

Lab Test Name	GGT
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	11
Reported Numeric Result	11
Reference Range low	10
Reference Range high	61
Range Units	U/L
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (12)

Data signed: (hfarmer1) 26 Mar 2015 14:18:19

Generated On: 20 Jul 2016 12:09:14

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (13)

Data signed: (hfarmer1) 26 Mar 2015 14:18:19

Generated On: 20 Jul 2016 12:09:14

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	<hr/>
----------------------	-------

Subject Sex	M
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Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	V225564
--------------	---------

Actual Collection Date	2014 01 19
------------------------	------------

Actual Collection Time	06:25
------------------------	-------

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: 1062**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (13)

Data signed: (hfarmer1) 26 Mar 2015 14:18:19

Generated On: 20 Jul 2016 12:09:14

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	1.3
----------------------	-----

Reported Numeric Result	1.3
-------------------------	-----

Reference Range low	0.5
---------------------	-----

Reference Range high	1.2
----------------------	-----

Range Units	MG/DL
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Conventional Text Result	<hr/>
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Conventional Numeric Result	<hr/>
-----------------------------	-------

Conventional Reference Range Low	<hr/>
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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: 1062**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (13)

Data signed: (hfarmer1) 26 Mar 2015 14:18:19

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (14)

Data signed: (hfarmer1) 26 Mar 2015 14:18:19

Generated On: 20 Jul 2016 12:09:14

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	V225564
--------------	---------

Actual Collection Date	2014 01 19
------------------------	------------

Actual Collection Time	06:25
------------------------	-------

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: 1062**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (14)

Data signed: (hfarmer1) 26 Mar 2015 14:18:19

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (14)

Data signed: (hfarmer1) 26 Mar 2015 14:18:19

Generated On: 20 Jul 2016 12:09:14

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (15)

Data signed: (hfarmer1) 26 Mar 2015 14:18:19

Generated On: 20 Jul 2016 12:09:14

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	V225564
--------------	---------

Actual Collection Date	2014 01 19
------------------------	------------

Actual Collection Time	06:25
------------------------	-------

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: 1062

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (15)

Data signed: (hfarmer1) 26 Mar 2015 14:18:19

Generated On: 20 Jul 2016 12:09:14

Lab Test Name	AST (SGOT)
Test ID	
Test Status	Done <input type="checkbox"/>
Reported Text Result	10
Reported Numeric Result	10
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: 1062**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (15)

Data signed: (hfarmer1) 26 Mar 2015 14:18:19

Generated On: 20 Jul 2016 12:09:14

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Low ☒

Clinically Significant?

No ☒

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (16)

Data signed: (hfarmer1) 26 Mar 2015 14:18:19

Generated On: 20 Jul 2016 12:09:14

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	V225564
--------------	---------

Actual Collection Date	2014 01 19
------------------------	------------

Actual Collection Time	06:25
------------------------	-------

Specimen Condition	<hr/>
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Battery ID	RC9255
------------	--------

Battery Name	CHEMISTRY PANEL
--------------	-----------------

Lab Test ID	RCT6
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1062

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (16)

Data signed: (hfarmer1) 26 Mar 2015 14:18:19

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (16)

Data signed: (hfarmer1) 26 Mar 2015 14:18:19

Generated On: 20 Jul 2016 12:09:14

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (17)

Data signed: (hfarmer1) 26 Mar 2015 14:18:19

Generated On: 20 Jul 2016 12:09:14

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	<hr/>
----------------------	-------

Subject Sex	M
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Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	V225564
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Actual Collection Date	2014 01 19
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Actual Collection Time	06:25
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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: 1062**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (17)

Data signed: (hfarmer1) 26 Mar 2015 14:18:19

Generated On: 20 Jul 2016 12:09:14

Lab Test Name	MONOCYTES
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	0.22
Reported Numeric Result	0.22
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: 1062**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (17)

Data signed: (hfarmer1) 26 Mar 2015 14:18:19

Generated On: 20 Jul 2016 12:09:14

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (18)

Data signed: (hfarmer1) 26 Mar 2015 14:18:19

Generated On: 20 Jul 2016 12:09:14

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	V225564
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Actual Collection Date	2014 01 19
------------------------	------------

Actual Collection Time	06:25
------------------------	-------

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: 1062**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (18)

Data signed: (hfarmer1) 26 Mar 2015 14:18:19

Generated On: 20 Jul 2016 12:09:14

Lab Test Name	MCH
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	31
Reported Numeric Result	31
Reference Range low	26
Reference Range high	34
Range Units	PG
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (18)

Data signed: (hfarmer1) 26 Mar 2015 14:18:19

Generated On: 20 Jul 2016 12:09:14

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (19)

Data signed: (hfarmer1) 26 Mar 2015 14:18:19

Generated On: 20 Jul 2016 12:09:14

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	V225564
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Actual Collection Date	2014 01 19
------------------------	------------

Actual Collection Time	06:25
------------------------	-------

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: 1062**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (19)

Data signed: (hfarmer1) 26 Mar 2015 14:18:19

Generated On: 20 Jul 2016 12:09:14

Lab Test Name	MCHC
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	34
Reported Numeric Result	34
Reference Range low	31
Reference Range high	38
Range Units	G/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (19)

Data signed: (hfarmer1) 26 Mar 2015 14:18:19

Generated On: 20 Jul 2016 12:09:14

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (20)

Data signed: (hfarmer1) 26 Mar 2015 14:18:19

Generated On: 20 Jul 2016 12:09:14

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	V225564
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Actual Collection Date	2014 01 19
------------------------	------------

Actual Collection Time	06:25
------------------------	-------

Specimen Condition	<hr/>
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Battery ID	HM1604
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Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
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Lab Test ID	HMT11
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1062

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (20)

Data signed: (hfarmer1) 26 Mar 2015 14:18:19

Generated On: 20 Jul 2016 12:09:14

Lab Test Name	EOSINOPHILS
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	0.09
Reported Numeric Result	0.09
Reference Range low	0.00
Reference Range high	0.57
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: 1062**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (20)

Data signed: (hfarmer1) 26 Mar 2015 14:18:19

Generated On: 20 Jul 2016 12:09:14

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (21)

Data signed: (hfarmer1) 26 Mar 2015 14:18:19

Generated On: 20 Jul 2016 12:09:14

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	V225564
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Actual Collection Date	2014 01 19
------------------------	------------

Actual Collection Time	06:25
------------------------	-------

Specimen Condition	<hr/>
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Battery ID	HM1604
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Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
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Lab Test ID	HMT12
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (21)

Data signed: (hfarmer1) 26 Mar 2015 14:18:19

Generated On: 20 Jul 2016 12:09:14

Lab Test Name	BASOPHILS
Test ID	
Test Status	Done <input checked="" type="checkbox"/>
Reported Text Result	0.04
Reported Numeric Result	0.04
Reference Range low	0.00
Reference Range high	0.20
Range Units	X10^3/UL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (21)

Data signed: (hfarmer1) 26 Mar 2015 14:18:19

Generated On: 20 Jul 2016 12:09:14

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (22)

Data signed: (hfarmer1) 26 Mar 2015 14:18:19

Generated On: 20 Jul 2016 12:09:14

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	V225564
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Actual Collection Date	2014 01 19
------------------------	------------

Actual Collection Time	06:25
------------------------	-------

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: 1062

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (22)

Data signed: (hfarmer1) 26 Mar 2015 14:18:19

Generated On: 20 Jul 2016 12:09:14

Lab Test Name	PLATELETS
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	231
Reported Numeric Result	231
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: 1062**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (22)

Data signed: (hfarmer1) 26 Mar 2015 14:18:19

Generated On: 20 Jul 2016 12:09:14

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (23)

Data signed: (hfarmer1) 26 Mar 2015 14:18:19

Generated On: 20 Jul 2016 12:09:14

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	V225564
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Actual Collection Date	2014 01 19
------------------------	------------

Actual Collection Time	06:25
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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: 1062

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (23)

Data signed: (hfarmer1) 26 Mar 2015 14:18:19

Generated On: 20 Jul 2016 12:09:14

Lab Test Name	NEUTROPHILS (%)
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	69.7
Reported Numeric Result	69.7
Reference Range low	40.5
Reference Range high	75.0
Range Units	%
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (23)

Data signed: (hfarmer1) 26 Mar 2015 14:18:19

Generated On: 20 Jul 2016 12:09:14

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (24)

Data signed: (hfarmer1) 26 Mar 2015 14:18:19

Generated On: 20 Jul 2016 12:09:14

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	V225564
--------------	---------

Actual Collection Date	2014 01 19
------------------------	------------

Actual Collection Time	06:25
------------------------	-------

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: 1062

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (24)

Data signed: (hfarmer1) 26 Mar 2015 14:18:19

Generated On: 20 Jul 2016 12:09:14

Lab Test Name	LYMPHOCYTES (%)
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	24.8
Reported Numeric Result	24.8
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: 1062**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (24)

Data signed: (hfarmer1) 26 Mar 2015 14:18:19

Generated On: 20 Jul 2016 12:09:14

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (25)

Data signed: (hfarmer1) 26 Mar 2015 14:18:19

Generated On: 20 Jul 2016 12:09:14

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	V225564
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Actual Collection Date	2014 01 19
------------------------	------------

Actual Collection Time	06:25
------------------------	-------

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: 1062

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (25)

Data signed: (hfarmer1) 26 Mar 2015 14:18:19

Generated On: 20 Jul 2016 12:09:14

Lab Test Name	MONOCYTES (%)
Test ID	
Test Status	Done <input checked="" type="checkbox"/>
Reported Text Result	3.4
Reported Numeric Result	3.4
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: 1062**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (25)

Data signed: (hfarmer1) 26 Mar 2015 14:18:19

Generated On: 20 Jul 2016 12:09:14

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (26)

Data signed: (hfarmer1) 26 Mar 2015 14:18:19

Generated On: 20 Jul 2016 12:09:14

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	V225564
--------------	---------

Actual Collection Date	2014 01 19
------------------------	------------

Actual Collection Time	06:25
------------------------	-------

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: 1062**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (26)

Data signed: (hfarmer1) 26 Mar 2015 14:18:19

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (26)

Data signed: (hfarmer1) 26 Mar 2015 14:18:19

Generated On: 20 Jul 2016 12:09:14

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (27)

Data signed: (hfarmer1) 26 Mar 2015 14:18:19

Generated On: 20 Jul 2016 12:09:14

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	V225564
--------------	---------

Actual Collection Date	2014 01 19
------------------------	------------

Actual Collection Time	06:25
------------------------	-------

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: 1062

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (27)

Data signed: (hfarmer1) 26 Mar 2015 14:18:19

Generated On: 20 Jul 2016 12:09:14

Lab Test Name	BASOPHILS (%)
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	0.7
Reported Numeric Result	0.7
Reference Range low	0.0
Reference Range high	2.0
Range Units	%
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (27)

Data signed: (hfarmer1) 26 Mar 2015 14:18:19

Generated On: 20 Jul 2016 12:09:14

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (28)

Data signed: (hfarmer1) 26 Mar 2015 14:18:19

Generated On: 20 Jul 2016 12:09:14

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	V225564
--------------	---------

Actual Collection Date	2014 01 19
------------------------	------------

Actual Collection Time	06:25
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

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: 1062

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (28)

Data signed: (hfarmer1) 26 Mar 2015 14:18:19

Generated On: 20 Jul 2016 12:09:14

Lab Test Name	HEMATOCRIT
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	47
Reported Numeric Result	47
Reference Range low	39
Reference Range high	54
Range Units	%
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (28)

Data signed: (hfarmer1) 26 Mar 2015 14:18:19

Generated On: 20 Jul 2016 12:09:14

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (29)

Data signed: (hfarmer1) 26 Mar 2015 14:18:19

Generated On: 20 Jul 2016 12:09:14

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	V225564
--------------	---------

Actual Collection Date	2014 01 19
------------------------	------------

Actual Collection Time	06:25
------------------------	-------

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: 1062**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (29)

Data signed: (hfarmer1) 26 Mar 2015 14:18:19

Generated On: 20 Jul 2016 12:09:14

Lab Test Name	RBC
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	5.2
Reported Numeric Result	5.2
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: 1062**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (29)

Data signed: (hfarmer1) 26 Mar 2015 14:18:19

Generated On: 20 Jul 2016 12:09:14

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1062

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (30)

Data signed: (hfarmer1) 26 Mar 2015 14:18:19

Generated On: 20 Jul 2016 12:09:14

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	V225564
--------------	---------

Actual Collection Date	2014 01 19
------------------------	------------

Actual Collection Time	06:25
------------------------	-------

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: 1062

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (30)

Data signed: (hfarmer1) 26 Mar 2015 14:18:19

Generated On: 20 Jul 2016 12:09:14

Lab Test Name	MCV
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	92
Reported Numeric Result	92
Reference Range low	79
Reference Range high	96
Range Units	FL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (30)

Data signed: (hfarmer1) 26 Mar 2015 14:18:19

Generated On: 20 Jul 2016 12:09:14

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (31)

Data signed: (hfarmer1) 26 Mar 2015 14:18:19

Generated On: 20 Jul 2016 12:09:14

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	<hr/>
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Subject Sex	M
-------------	---

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

Visit Name	<hr/>
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	V225564
--------------	---------

Actual Collection Date	2014 01 19
------------------------	------------

Actual Collection Time	06:25
------------------------	-------

Specimen Condition	<hr/>
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Battery ID	HM1604
------------	--------

Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
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Lab Test ID	HMT40
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (31)

Data signed: (hfarmer1) 26 Mar 2015 14:18:19

Generated On: 20 Jul 2016 12:09:14

Lab Test Name	HEMOGLOBIN
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	16.0
Reported Numeric Result	16.0
Reference Range low	12.7
Reference Range high	18.1
Range Units	G/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (31)

Data signed: (hfarmer1) 26 Mar 2015 14:18:19

Generated On: 20 Jul 2016 12:09:14

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (32)

Data signed: (hfarmer1) 26 Mar 2015 14:18:19

Generated On: 20 Jul 2016 12:09:14

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"/>
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Accession ID	V225564
--------------	---------

Actual Collection Date	2014 01 19
------------------------	------------

Actual Collection Time	06:25
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	HM1604
------------	--------

Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
--------------	-----------------------------------

Lab Test ID	HMT7
-------------	------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (32)

Data signed: (hfarmer1) 26 Mar 2015 14:18:19

Generated On: 20 Jul 2016 12:09:14

Lab Test Name	WBC
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	6.38
Reported Numeric Result	6.38
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: 1062**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (32)

Data signed: (hfarmer1) 26 Mar 2015 14:18:19

Generated On: 20 Jul 2016 12:09:14

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (33)

Data signed: (hfarmer1) 26 Mar 2015 14:18:19

Generated On: 20 Jul 2016 12:09:14

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	<hr/>
----------------------	-------

Subject Sex	M
-------------	---

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

Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	V225564
--------------	---------

Actual Collection Date	2014 01 19
------------------------	------------

Actual Collection Time	06:25
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	HM1604
------------	--------

Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
--------------	-----------------------------------

Lab Test ID	HMT71
-------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (33)

Data signed: (hfarmer1) 26 Mar 2015 14:18:19


Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (33)

Data signed: (hfarmer1) 26 Mar 2015 14:18:19

Generated On: 20 Jul 2016 12:09:14

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (34)

Data signed: (hfarmer1) 26 Mar 2015 14:18:19

Generated On: 20 Jul 2016 12:09:14

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	V225564
--------------	---------

Actual Collection Date	2014 01 19
------------------------	------------

Actual Collection Time	06:25
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	HM1604
------------	--------

Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
--------------	-----------------------------------

Lab Test ID	HMT8
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (34)

Data signed: (hfarmer1) 26 Mar 2015 14:18:19

Generated On: 20 Jul 2016 12:09:14

Lab Test Name	NEUTROPHILS
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	4.45
Reported Numeric Result	4.45
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: 1062**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (34)

Data signed: (hfarmer1) 26 Mar 2015 14:18:19

Generated On: 20 Jul 2016 12:09:14

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1062

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (35)

Data signed: (hfarmer1) 26 Mar 2015 14:18:19

Generated On: 20 Jul 2016 12:09:14

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	V225564
--------------	---------

Actual Collection Date	2014 01 19
------------------------	------------

Actual Collection Time	06:25
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	HM1604
------------	--------

Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
--------------	-----------------------------------

Lab Test ID	HMT9
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1062

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (35)

Data signed: (hfarmer1) 26 Mar 2015 14:18:19

Generated On: 20 Jul 2016 12:09:14

Lab Test Name	LYMPHOCYTES
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	1.58
Reported Numeric Result	1.58
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: 1062**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (35)

Data signed: (hfarmer1) 26 Mar 2015 14:18:19

Generated On: 20 Jul 2016 12:09:14

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (36)

Data signed: (hfarmer1) 26 Mar 2015 14:18:19

Generated On: 20 Jul 2016 12:09:14

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	<hr/>
----------------------	-------

Subject Sex	M
-------------	---

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

Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	V225564
--------------	---------

Actual Collection Date	2014 01 19
------------------------	------------

Actual Collection Time	06:25
------------------------	-------

Specimen Condition	<hr/>
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Battery ID	UA1538
------------	--------

Battery Name	URINE MACRO PANEL
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Lab Test ID	UAT10
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1062

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (36)

Data signed: (hfarmer1) 26 Mar 2015 14:18:19


Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (36)

Data signed: (hfarmer1) 26 Mar 2015 14:18:19

Generated On: 20 Jul 2016 12:09:14

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (37)

Data signed: (hfarmer1) 26 Mar 2015 14:18:19

Generated On: 20 Jul 2016 12:09:14

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	V225564
--------------	---------

Actual Collection Date	2014 01 19
------------------------	------------

Actual Collection Time	06:25
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	UA1538
------------	--------

Battery Name	URINE MACRO PANEL
--------------	-------------------

Lab Test ID	UAT2
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1062

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (37)

Data signed: (hfarmer1) 26 Mar 2015 14:18:19

Generated On: 20 Jul 2016 12:09:14

Lab Test Name	UR SPECIFIC GRAVITY
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	1.014
Reported Numeric Result	1.014
Reference Range low	1.003
Reference Range high	1.035
Range Units	
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (37)

Data signed: (hfarmer1) 26 Mar 2015 14:18:19

Generated On: 20 Jul 2016 12:09:14

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (38)

Data signed: (hfarmer1) 26 Mar 2015 14:18:19

Generated On: 20 Jul 2016 12:09:14

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	V225564
--------------	---------

Actual Collection Date	2014 01 19
------------------------	------------

Actual Collection Time	06:25
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	UA1538
------------	--------

Battery Name	URINE MACRO PANEL
--------------	-------------------

Lab Test ID	UAT3
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1062

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (38)

Data signed: (hfarmer1) 26 Mar 2015 14:18:19

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (38)

Data signed: (hfarmer1) 26 Mar 2015 14:18:19

Generated On: 20 Jul 2016 12:09:14

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (39)

Data signed: (hfarmer1) 26 Mar 2015 14:18:19

Generated On: 20 Jul 2016 12:09:14

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	<hr/>
----------------------	-------

Subject Sex	M
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Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	V225564
--------------	---------

Actual Collection Date	2014 01 19
------------------------	------------

Actual Collection Time	06:25
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	UA1538
------------	--------

Battery Name	URINE MACRO PANEL
--------------	-------------------

Lab Test ID	UAT43
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (39)

Data signed: (hfarmer1) 26 Mar 2015 14:18:19


Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (39)

Data signed: (hfarmer1) 26 Mar 2015 14:18:19

Generated On: 20 Jul 2016 12:09:14

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (40)

Data signed: (hfarmer1) 26 Mar 2015 14:18:19

Generated On: 20 Jul 2016 12:09:14

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	V225564
--------------	---------

Actual Collection Date	2014 01 19
------------------------	------------

Actual Collection Time	06:25
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	UA1538
------------	--------

Battery Name	URINE MACRO PANEL
--------------	-------------------

Lab Test ID	UAT49
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (40)

Data signed: (hfarmer1) 26 Mar 2015 14:18:19


Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (40)

Data signed: (hfarmer1) 26 Mar 2015 14:18:19

Generated On: 20 Jul 2016 12:09:14

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (41)

Data signed: (hfarmer1) 26 Mar 2015 14:18:19

Generated On: 20 Jul 2016 12:09:14

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	V225564
--------------	---------

Actual Collection Date	2014 01 19
------------------------	------------

Actual Collection Time	06:25
------------------------	-------

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: 1062**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (41)

Data signed: (hfarmer1) 26 Mar 2015 14:18:19


Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (41)

Data signed: (hfarmer1) 26 Mar 2015 14:18:19

Generated On: 20 Jul 2016 12:09:14

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (42)

Data signed: (hfarmer1) 26 Mar 2015 14:18:19

Generated On: 20 Jul 2016 12:09:14

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	V225564
--------------	---------

Actual Collection Date	2014 01 19
------------------------	------------

Actual Collection Time	06:25
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	UA1538
------------	--------

Battery Name	URINE MACRO PANEL
--------------	-------------------

Lab Test ID	UAT7
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1062

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (42)

Data signed: (hfarmer1) 26 Mar 2015 14:18:19


Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (42)

Data signed: (hfarmer1) 26 Mar 2015 14:18:19

Generated On: 20 Jul 2016 12:09:14

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day 0)

Form: Lab_BU_COHB (1)

Data signed: (hfarmer1) 26 Mar 2015 14:18:36

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05115150000130
----------------	----------------

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

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

Result	.
--------	---

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

Lab Status	OTHER
------------	-------

Sample comment	ANALYSIS NOT REQUIRED
----------------	-----------------------

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

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

Planned time point (Hour)	6
---------------------------	---

Day of Visit	0
--------------	---

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

Date of Collection	2014-JAN-19
--------------------	-------------

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day 0)

Form: Lab_BU_COHB (1)

Data signed: (hfarmer1) 26 Mar 2015 14:18:36

Generated On: 20 Jul 2016 12:09:14

Start Day (24 hour urine only) _____

End Day (24 hour Urine Only) _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day 0)

Form: Lab_BU_COHB (2)

Data signed: (hfarmer1) 26 Mar 2015 14:18:36

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05115150000131
----------------	----------------

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

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

Result	.
--------	---

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

Lab Status	OTHER
------------	-------

Sample comment	ANALYSIS NOT REQUIRED
----------------	-----------------------

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

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

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

Day of Visit	0
--------------	---

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

Date of Collection	2014-JAN-19
--------------------	-------------

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day 0)

Form: Lab_BU_COHB (2)

Data signed: (hfarmer1) 26 Mar 2015 14:18:36

Generated On: 20 Jul 2016 12:09:14

Start Day (24 hour urine only)

End Day (24 hour Urine Only)

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1062

Folder: Baseline (Day 0)

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)

Data signed: (hfarmer1) 26 Mar 2015 14:18:19

Generated On: 20 Jul 2016 12:09:14

Date of Birth

(b) (6)

Date of assessment

2014 JAN 19
DD/MMM/YYYY

DD/MMM/YYYY

Time of assessment

20:06
hour:min 24-hour clock

Assessment Status

Completed ☒

1. Was smoking satisfying?

Moderately ☒

2. Did cigarettes taste good?

Little ☒

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

Very little ☒

4. Did smoking calm you down?

Very little ☒

5. Did smoking make you feel more awake?

Not at all ☒

6. Did smoking make you feel less irritable?

Not at all ☒

7. Did smoking help you concentrate?

Not at all ☒

8. Did smoking reduce your hunger for food?

Not at all ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day 0)

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)

Data signed: (hfarmer1) 26 Mar 2015 14:18:19

Generated On: 20 Jul 2016 12:09:14

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

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

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

12. Did you enjoy smoking? Moderately ☐

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1062

Folder: Baseline (Day 0)

Form: Human Smoking Topography Questionnaire

Data signed: (hfarmer1) 26 Mar 2015 14:18:18

Generated On: 20 Jul 2016 12:09:14

Type	HUMAN SMOKING TOPOGRAPHY QUESTIONNAIRE
------	--

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

Reason not done	
-----------------	--

Date of assessment	19 JAN 2014 DD/MMM/YYYY
--------------------	----------------------------

Time of assessment	21:09 hour:min 24-hour clock
--------------------	---------------------------------

How do you agree with the following sentences/affirmations :

1. The smoking of the conventional cigarettes/products is different with the device.	Agree <input type="radio"/>
--	-----------------------------

If you agree or strongly agree, please describe :	NO TASTE. LESS FULFILLING
---	---------------------------

2. You enjoy smoking with the device as much as without it.	Strongly disagree <input type="radio"/>
---	---

If you disagree or strongly disagree, please describe :	NOT SATISFYING
---	----------------

3. The taste of the conventional cigarettes/products is different with the device.	Neither agree nor disagree <input type="radio"/>
--	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day 0)

Form: Human Smoking Topography Questionnaire

Data signed: (hfarmer1) 26 Mar 2015 14:18:18

Generated On: 20 Jul 2016 12:09:14

If you agree or strongly agree, please describe : _____

4. The device is easy to use.

Neither agree nor disagree ☒

If you disagree or strongly disagree, please describe : _____

5. Your smoking is disturbed by the device.

Neither agree nor disagree ☒

If you agree or strongly agree, please describe : _____

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1062

Folder: Baseline (Day 0)

Form: Questionnaire on smoking urges (QSU)

Data signed: (hfarmer1) 26 Mar 2015 14:18:19

Generated On: 20 Jul 2016 12:09:14

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

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

Date of assessment	2014 JAN 19
--------------------	-------------

DD/MMM/YYYY

Time of assessment	20:05
--------------------	-------

hour:min 24-hour clock

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

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

6. I have an urge for a cigarette	Do not agree or disagree <input checked="" type="radio"/>
-----------------------------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day 0)

Form: Questionnaire on smoking urges (QSU)

Data signed: (hfarmer1) 26 Mar 2015 14:18:19

Generated On: 20 Jul 2016 12:09:14

7. A cigarette would taste good now Do not agree or disagree ☐

8. I would do almost anything for a cigarette now Strongly disagree ☐

9. Smoking would make me less depressed Strongly disagree ☐

10. I am going to smoke as soon as possible Do not agree or disagree ☐

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1062

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (1)

Data signed: (hfarmer1) 26 Mar 2015 14:18:30

Generated On: 20 Jul 2016 12:09:14

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	1062
----------------------	------

Subject Sex	M
-------------	---

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

Visit Name	DAY0
------------	------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	V225564
--------------	---------

Actual Collection Date	2014 01 19
------------------------	------------

Actual Collection Time	06:25
------------------------	-------

Specimen Condition	
--------------------	--

Battery ID	HM1054
------------	--------

Battery Name	HEMOGLOBIN A1C
--------------	----------------

Lab Test ID	HMT370
-------------	--------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1062

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (1)

Data signed: (hfarmer1) 26 Mar 2015 14:18:30

Generated On: 20 Jul 2016 12:09:14

Lab Test Name

HEMOGLOBIN
A1C,VARIANT(-70)

Test ID

Test Status

Done ☒

Reported Text Result

5.4

Reported Numeric Result

5.4

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: 1062**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (1)

Data signed: (hfarmer1) 26 Mar 2015 14:18:30

Generated On: 20 Jul 2016 12:09:14

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: 1062

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (2)

Data signed: (hfarmer1) 26 Mar 2015 14:18:30

Generated On: 20 Jul 2016 12:09:14

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	1062
----------------------	------

Subject Sex	M
-------------	---

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

Visit Name	DAY0
------------	------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	V225564
--------------	---------

Actual Collection Date	2014 01 19
------------------------	------------

Actual Collection Time	06:25
------------------------	-------

Specimen Condition	
--------------------	--

Battery ID	RC6871
------------	--------

Battery Name	HDL
--------------	-----

Lab Test ID	RCT1684
-------------	---------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (2)

Data signed: (hfarmer1) 26 Mar 2015 14:18:30

Generated On: 20 Jul 2016 12:09:14

Lab Test Name	DIRECT HDL-C 3RD GENERATION
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	39
Reported Numeric Result	39
Reference Range low	30
Reference Range high	64
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: 1062**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (2)

Data signed: (hfarmer1) 26 Mar 2015 14:18:30

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (3)

Data signed: (hfarmer1) 26 Mar 2015 14:18:30

Generated On: 20 Jul 2016 12:09:14

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	1062
----------------------	------

Subject Sex	M
-------------	---

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

Visit Name	DAY0
------------	------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	V225564
--------------	---------

Actual Collection Date	2014 01 19
------------------------	------------

Actual Collection Time	06:25
------------------------	-------

Specimen Condition	
--------------------	--

Battery ID	SC3249
------------	--------

Battery Name	HS-CRP
--------------	--------

Lab Test ID	SCT1528
-------------	---------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1062

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (3)

Data signed: (hfarmer1) 26 Mar 2015 14:18:30

Generated On: 20 Jul 2016 12:09:14

Lab Test Name	C-REACTIVE PROTEIN (NHS)-QT
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	0.063
Reported Numeric Result	0.063
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: 1062**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (3)

Data signed: (hfarmer1) 26 Mar 2015 14:18:30

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (4)

Data signed: (hfarmer1) 26 Mar 2015 14:18:30

Generated On: 20 Jul 2016 12:09:14

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	1062
----------------------	------

Subject Sex	M
-------------	---

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

Visit Name	DAY0
------------	------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	V225564
--------------	---------

Actual Collection Date	2014 01 19
------------------------	------------

Actual Collection Time	06:25
------------------------	-------

Specimen Condition	
--------------------	--

Battery ID	SC3582
------------	--------

Battery Name	APOLIPOPROTEIN
--------------	----------------

Lab Test ID	SCT3639
-------------	---------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (4)

Data signed: (hfarmer1) 26 Mar 2015 14:18:30

Generated On: 20 Jul 2016 12:09:14

Lab Test Name	APOLIPOPROTEIN A1, RAND
---------------	-------------------------

Test ID	<hr/>
---------	-------

Test Status	Done <input checked="" type="radio"/>
-------------	---------------------------------------

Reported Text Result	121
----------------------	-----

Reported Numeric Result	121
-------------------------	-----

Reference Range low	110
---------------------	-----

Reference Range high	205
----------------------	-----

Range Units	MG/DL
-------------	-------

Conventional Text Result	<hr/>
--------------------------	-------

Conventional Numeric Result	<hr/>
-----------------------------	-------

Conventional Reference Range Low	<hr/>
----------------------------------	-------

Conventional Reference Range High	<hr/>
-----------------------------------	-------

Conventional Units	<hr/>
--------------------	-------

SI Text Result	<hr/>
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (4)

Data signed: (hfarmer1) 26 Mar 2015 14:18:30

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (5)

Data signed: (hfarmer1) 26 Mar 2015 14:18:30

Generated On: 20 Jul 2016 12:09:14

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	1062
----------------------	------

Subject Sex	M
-------------	---

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

Visit Name	DAY0
------------	------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	V225564
--------------	---------

Actual Collection Date	2014 01 19
------------------------	------------

Actual Collection Time	06:25
------------------------	-------

Specimen Condition	
--------------------	--

Battery ID	SC3582
------------	--------

Battery Name	APOLIPOPROTEIN
--------------	----------------

Lab Test ID	SCT3643
-------------	---------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (5)

Data signed: (hfarmer1) 26 Mar 2015 14:18:30

Generated On: 20 Jul 2016 12:09:14

Lab Test Name	APOLIPOPROTEIN B, RAND
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	120
Reported Numeric Result	120
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: 1062**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (5)

Data signed: (hfarmer1) 26 Mar 2015 14:18:30

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (6)

Data signed: (hfarmer1) 26 Mar 2015 14:18:30

Generated On: 20 Jul 2016 12:09:14

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	1062
----------------------	------

Subject Sex	M
-------------	---

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

Visit Name	DAY0
------------	------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	V225564
--------------	---------

Actual Collection Date	2014 01 19
------------------------	------------

Actual Collection Time	06:25
------------------------	-------

Specimen Condition	
--------------------	--

Battery ID	CG267
------------	-------

Battery Name	FIBRINOGEN
--------------	------------

Lab Test ID	CGT285
-------------	--------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (6)

Data signed: (hfarmer1) 26 Mar 2015 14:18:30

Generated On: 20 Jul 2016 12:09:14

Lab Test Name	FIBRINOGEN
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	297
Reported Numeric Result	297
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: 1062**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (6)

Data signed: (hfarmer1) 26 Mar 2015 14:18:30

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (7)

Data signed: (hfarmer1) 26 Mar 2015 14:18:30

Generated On: 20 Jul 2016 12:09:14

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	1062
----------------------	------

Subject Sex	M
-------------	---

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

Visit Name	DAY0
------------	------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	V225564
--------------	---------

Actual Collection Date	2014 01 19
------------------------	------------

Actual Collection Time	06:25
------------------------	-------

Specimen Condition	
--------------------	--

Battery ID	CN236
------------	-------

Battery Name	HOMOCYSTEINE
--------------	--------------

Lab Test ID	CNT145
-------------	--------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (7)

Data signed: (hfarmer1) 26 Mar 2015 14:18:30

Generated On: 20 Jul 2016 12:09:14

Lab Test Name	HOMOCYSTEINE, EDTAPL
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	13.51
Reported Numeric Result	13.51
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: 1062**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (7)

Data signed: (hfarmer1) 26 Mar 2015 14:18:30

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (8)

Data signed: (hfarmer1) 26 Mar 2015 14:18:30

Generated On: 20 Jul 2016 12:09:14

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	1062
----------------------	------

Subject Sex	M
-------------	---

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

Visit Name	DAY0
------------	------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	V225564
--------------	---------

Actual Collection Date	2014 01 19
------------------------	------------

Actual Collection Time	06:25
------------------------	-------

Specimen Condition	
--------------------	--

Battery ID	IM2293
------------	--------

Battery Name	SICAM-1
--------------	---------

Lab Test ID	IMT1768
-------------	---------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (8)

Data signed: (hfarmer1) 26 Mar 2015 14:18:30

Generated On: 20 Jul 2016 12:09:14

Lab Test Name	SICAM-1-RUO
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	128.2
Reported Numeric Result	128.2
Reference Range low	98.8
Reference Range high	320.0
Range Units	NG/ML
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (8)

Data signed: (hfarmer1) 26 Mar 2015 14:18:30

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (9)

Data signed: (hfarmer1) 26 Mar 2015 14:18:30

Generated On: 20 Jul 2016 12:09:14

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	1062
----------------------	------

Subject Sex	M
-------------	---

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

Visit Name	DAY0
------------	------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	V225564
--------------	---------

Actual Collection Date	2014 01 19
------------------------	------------

Actual Collection Time	06:25
------------------------	-------

Specimen Condition	
--------------------	--

Battery ID	RC9267
------------	--------

Battery Name	LDL
--------------	-----

Lab Test ID	RCT2394
-------------	---------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (9)

Data signed: (hfarmer1) 26 Mar 2015 14:18:30

Generated On: 20 Jul 2016 12:09:14

Lab Test Name	DIRECT LDL-C 2ND GEN (-70)
---------------	----------------------------

Test ID	<hr/>
---------	-------

Test Status	Done 
-------------	--

Reported Text Result	157
----------------------	-----

Reported Numeric Result	157
-------------------------	-----

Reference Range low	88
---------------------	----

Reference Range high	203
----------------------	-----

Range Units	MG/DL
-------------	-------

Conventional Text Result	<hr/>
--------------------------	-------

Conventional Numeric Result	<hr/>
-----------------------------	-------

Conventional Reference Range Low	<hr/>
----------------------------------	-------

Conventional Reference Range High	<hr/>
-----------------------------------	-------

Conventional Units	<hr/>
--------------------	-------

SI Text Result	<hr/>
----------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (9)

Data signed: (hfarmer1) 26 Mar 2015 14:18:30

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Baseline (Day 0)

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

Data signed: (hfarmer1) 26 Mar 2015 14:18:37

Generated On: 20 Jul 2016 12:09:14

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day 0)

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

Data signed: (hfarmer1) 26 Mar 2015 14:18:37

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05112450000102
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	0
Celerion Study Number	AA99128-03
Date of Collection	2014-JAN-19
Timepoint-minutes	
Urine Start Day	0

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day 0)

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

Data signed: (hfarmer1) 26 Mar 2015 14:18:37

Generated On: 20 Jul 2016 12:09:14

Urine End Day

1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (2)

Data signed: (hfarmer1) 26 Mar 2015 14:18:37

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05112450000102
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	0
Celerion Study Number	AA99128-03
Date of Collection	2014-JAN-19
Timepoint-minutes	
Urine Start Day	0

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (2)

Data signed: (hfarmer1) 26 Mar 2015 14:18:37

Generated On: 20 Jul 2016 12:09:14

Urine End Day	1
---------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (CEMA, HPMa, HBMA) (3)

Data signed: (hfarmer1) 26 Mar 2015 14:18:37

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05112450000102
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	0
Celerion Study Number	AA99128-03
Date of Collection	2014-JAN-19
Timepoint-minutes	
Urine Start Day	0

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (3)

Data signed: (hfarmer1) 26 Mar 2015 14:18:37

Generated On: 20 Jul 2016 12:09:14

Urine End Day	1
---------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (NNN, NNAL)

Data signed: (hfarmer1) 26 Mar 2015 14:18:35

Generated On: 20 Jul 2016 12:09:14

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (NNN, NNAL) (1)

Data signed: (hfarmer1) 26 Mar 2015 14:18:35

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05112460000102
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-JAN-19
Timepoint-minutes	
Urine Start Day	0

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (NNN, NNAL) (1)

Data signed: (hfarmer1) 26 Mar 2015 14:18:35

Generated On: 20 Jul 2016 12:09:14

Urine End Day

1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (NNN, NNAL) (2)

Data signed: (hfarmer1) 26 Mar 2015 14:18:35

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05112460000102
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-JAN-19
Timepoint-minutes	
Urine Start Day	0

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (NNN, NNAL) (2)

Data signed: (hfarmer1) 26 Mar 2015 14:18:35

Generated On: 20 Jul 2016 12:09:14

Urine End Day

1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (HEMA)

Data signed: (hfarmer1) 26 Mar 2015 14:18:36

Generated On: 20 Jul 2016 12:09:14

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (HEMA) (1)

Data signed: (hfarmer1) 26 Mar 2015 14:18:36

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05112470000102
Analyte	HEMA
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	AA99128-05
Date of Collection	2014-JAN-19
Timepoint-minutes	
Urine Start Day	0

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (HEMA) (1)

Data signed: (hfarmer1) 26 Mar 2015 14:18:36

Generated On: 20 Jul 2016 12:09:14

Urine End Day	1
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)

Data signed: (hfarmer1) 26 Mar 2015 14:18:37

Generated On: 20 Jul 2016 12:09:14

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day 0)

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(1)**

Data signed: (hfarmer1) 26 Mar 2015 14:18:37

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05112480000080
Analyte	COT
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	AA99128-06
Date of Collection	2014-JAN-20
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day 0)

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(1)**

Data signed: (hfarmer1) 26 Mar 2015 14:18:37

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Baseline (Day 0)

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(2)**

Data signed: (hfarmer1) 26 Mar 2015 14:18:37

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05112480000080
Analyte	COT-GLUC
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	AA99128-06
Date of Collection	2014-JAN-20
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day 0)

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(2)**

Data signed: (hfarmer1) 26 Mar 2015 14:18:37

Generated On: 20 Jul 2016 12:09:14

Urine Start Day	0
<hr/>	
Urine End Day	1
<hr/>	

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1062

Folder: Baseline (Day 0)

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(3)**

Data signed: (hfarmer1) 26 Mar 2015 14:18:37

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05112480000080
Analyte	NIC
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	AA99128-06
Date of Collection	2014-JAN-20
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day 0)

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(3)**

Data signed: (hfarmer1) 26 Mar 2015 14:18:37

Generated On: 20 Jul 2016 12:09:14

Urine Start Day	0
<hr/>	
Urine End Day	1
<hr/>	

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1062

Folder: Baseline (Day 0)

Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc) (4)

Data signed: (hfarmer1) 26 Mar 2015 14:18:37

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05112480000080
Analyte	NIC-GLUC
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	AA99128-06
Date of Collection	2014-JAN-20
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day 0)

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(4)**

Data signed: (hfarmer1) 26 Mar 2015 14:18:37

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Baseline (Day 0)

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(5)**

Data signed: (hfarmer1) 26 Mar 2015 14:18:37

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05112480000080
Analyte	THCOT
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	AA99128-06
Date of Collection	2014-JAN-20
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day 0)

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(5)**

Data signed: (hfarmer1) 26 Mar 2015 14:18:37

Generated On: 20 Jul 2016 12:09:14

Urine Start Day	0
<hr/>	
Urine End Day	1
<hr/>	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day 0)

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(6)**

Data signed: (hfarmer1) 26 Mar 2015 14:18:37

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05112480000080
Analyte	THCOT-GLUC
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	AA99128-06
Date of Collection	2014-JAN-20
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day 0)

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(6)**

Data signed: (hfarmer1) 26 Mar 2015 14:18:37

Generated On: 20 Jul 2016 12:09:14

Urine Start Day	0
<hr/>	
Urine End Day	1
<hr/>	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (3-OH BaP)

Data signed: (hfarmer1) 26 Mar 2015 14:18:37

Generated On: 20 Jul 2016 12:09:14

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (3-OH BaP) (1)

Data signed: (hfarmer1) 26 Mar 2015 14:18:37

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05112490000102
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-JAN-19
Timepoint-minutes	
Urine Start Day	0

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (3-OH BaP) (1)

Data signed: (hfarmer1) 26 Mar 2015 14:18:37

Generated On: 20 Jul 2016 12:09:14

Urine End Day

1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day 0)

Form: Biomarker-Plasma (Caffeine, Paraxanthine)

Generated On: 20 Jul 2016 12:09:14

Sample type

PLASMA

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day 0)

Form: Biomarker-Plasma (Caffeine, Paraxanthine) (1)

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05112500000028
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Analyte	CAFFEINE
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Sample type	PLASMA
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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)	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-JAN-16
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Timepoint-minutes	0
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Urine Start Day	
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day 0)

Form: Biomarker-Plasma (Caffeine, Paraxanthine) (1)

Generated On: 20 Jul 2016 12:09:14

Urine End Day	0
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day 0)

Form: Biomarker-Plasma (Caffeine, Paraxanthine) (2)

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05112500000028
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Analyte	PARAXANTHINE
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Sample type	PLASMA
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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)	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-JAN-16
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Timepoint-minutes	0
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Urine Start Day	
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day 0)

Form: Biomarker-Plasma (Caffeine, Paraxanthine) (2)

Generated On: 20 Jul 2016 12:09:14

Urine End Day	0
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP)

Data signed: (hfarmer1) 26 Mar 2015 14:18:37

Generated On: 20 Jul 2016 12:09:14

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (1)

Data signed: (hfarmer1) 26 Mar 2015 14:18:37

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05112510000102
Analyte	1-NA
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	AA99128-09
Date of Collection	2014-JAN-19
Timepoint-minutes	
Urine Start Day	0

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (1)

Data signed: (hfarmer1) 26 Mar 2015 14:18:37

Generated On: 20 Jul 2016 12:09:14

Urine End Day

1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (2)

Data signed: (hfarmer1) 26 Mar 2015 14:18:37

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05112510000102
Analyte	2-NA
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	AA99128-09
Date of Collection	2014-JAN-19
Timepoint-minutes	
Urine Start Day	0

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (2)

Data signed: (hfarmer1) 26 Mar 2015 14:18:37

Generated On: 20 Jul 2016 12:09:14

Urine End Day	1
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (3)

Data signed: (hfarmer1) 26 Mar 2015 14:18:37

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05112510000102
Analyte	4-ABP
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	AA99128-09
Date of Collection	2014-JAN-19
Timepoint-minutes	
Urine Start Day	0

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (3)

Data signed: (hfarmer1) 26 Mar 2015 14:18:37

Generated On: 20 Jul 2016 12:09:14

Urine End Day

1

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1062

Folder: Baseline (Day 0)

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (4)

Data signed: (hfarmer1) 26 Mar 2015 14:18:37

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05112510000102
Analyte	O-TOL
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	AA99128-09
Date of Collection	2014-JAN-19
Timepoint-minutes	
Urine Start Day	0

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (4)

Data signed: (hfarmer1) 26 Mar 2015 14:18:37

Generated On: 20 Jul 2016 12:09:14

Urine End Day	1
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (11-dTXb2)

Data signed: (hfarmer1) 26 Mar 2015 14:18:36

Generated On: 20 Jul 2016 12:09:14

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (11-dTXb2) (1)

Data signed: (hfarmer1) 26 Mar 2015 14:18:36

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05112530000066
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-JAN-19
Timepoint-minutes	
Urine Start Day	0

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (11-dTXb2) (1)

Data signed: (hfarmer1) 26 Mar 2015 14:18:36

Generated On: 20 Jul 2016 12:09:14

Urine End Day	1
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (iPF2a-III)

Data signed: (hfarmer1) 26 Mar 2015 14:18:36

Generated On: 20 Jul 2016 12:09:14

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (iPF2a-III) (1)

Data signed: (hfarmer1) 26 Mar 2015 14:18:36

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05112540000066
Analyte	IPF2A-III
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	AA99128-12
Date of Collection	2014-JAN-19
Timepoint-minutes	
Urine Start Day	0

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (iPF2a-III) (1)

Data signed: (hfarmer1) 26 Mar 2015 14:18:36

Generated On: 20 Jul 2016 12:09:14

Urine End Day

1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (Ames)

Data signed: (hfarmer1) 26 Mar 2015 14:18:37

Generated On: 20 Jul 2016 12:09:14

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (Ames) (1)

Data signed: (hfarmer1) 26 Mar 2015 14:18:37

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05113320000025
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	0
Celerion Study Number	AA99128-15
Date of Collection	2014-JAN-19
Timepoint-minutes	
Urine Start Day	0

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (Ames) (1)

Data signed: (hfarmer1) 26 Mar 2015 14:18:37

Generated On: 20 Jul 2016 12:09:14

Urine End Day	1
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (1-OHP)

Data signed: (hfarmer1) 26 Mar 2015 14:18:37

Generated On: 20 Jul 2016 12:09:14

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (1-OHP) (1)

Data signed: (hfarmer1) 26 Mar 2015 14:18:37

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05115190001191
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-JAN-19
Timepoint-minutes	
Urine Start Day	0

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (1-OHP) (1)

Data signed: (hfarmer1) 26 Mar 2015 14:18:37

Generated On: 20 Jul 2016 12:09:14

Urine End Day	1
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (SPMA, SBMA)

Data signed: (hfarmer1) 26 Mar 2015 14:18:36

Generated On: 20 Jul 2016 12:09:14

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (SPMA, SBMA) (1)

Data signed: (hfarmer1) 26 Mar 2015 14:18:36

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05115170000102
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-JAN-19
Timepoint-minutes	
Urine Start Day	0

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (SPMA, SBMA) (1)

Data signed: (hfarmer1) 26 Mar 2015 14:18:36

Generated On: 20 Jul 2016 12:09:14

Urine End Day

1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (SPMA, SBMA) (2)

Data signed: (hfarmer1) 26 Mar 2015 14:18:36

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05115170000102
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-JAN-19
Timepoint-minutes	
Urine Start Day	0

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (SPMA, SBMA) (2)

Data signed: (hfarmer1) 26 Mar 2015 14:18:36

Generated On: 20 Jul 2016 12:09:14

Urine End Day	1
---------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (MHBMA)

Data signed: (hfarmer1) 26 Mar 2015 14:18:36

Generated On: 20 Jul 2016 12:09:14

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (MHBMA) (1)

Data signed: (hfarmer1) 26 Mar 2015 14:18:36

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05115180000102
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-JAN-19
Timepoint-minutes	
Urine Start Day	0

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (MHBMA) (1)

Data signed: (hfarmer1) 26 Mar 2015 14:18:36

Generated On: 20 Jul 2016 12:09:14

Urine End Day	1
---------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (Creatinine)

Data signed: (hfarmer1) 26 Mar 2015 14:18:37

Generated On: 20 Jul 2016 12:09:14

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (Creatinine) (1)

Data signed: (hfarmer1) 26 Mar 2015 14:18:37

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05115160000102
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-JAN-19
Timepoint-minutes	
Urine Start Day	0

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (Creatinine) (1)

Data signed: (hfarmer1) 26 Mar 2015 14:18:37

Generated On: 20 Jul 2016 12:09:14

Urine End Day	1
---------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day 0)

Form: Biomarker-Plasma (Nic, Cot, tHCot)

Generated On: 20 Jul 2016 12:09:14

Sample type

PLASMA

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day 0)

Form: Biomarker-Plasma (Nic, Cot, tHCot) (1)

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05112430000134
----------------	----------------

Analyte	COT
---------	-----

Sample type	PLASMA
-------------	--------

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	AA99128-01
-----------------------	------------

Date of Collection	2014-JAN-19
--------------------	-------------

Timepoint-minutes	0
-------------------	---

Urine Start Day	
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day 0)

Form: Biomarker-Plasma (Nic, Cot, tHCot) (1)

Generated On: 20 Jul 2016 12:09:14

Urine End Day	0
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day 0)

Form: Biomarker-Plasma (Nic, Cot, tHCot) (2)

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05112430000134
----------------	----------------

Analyte	NIC
---------	-----

Sample type	PLASMA
-------------	--------

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	AA99128-01
-----------------------	------------

Date of Collection	2014-JAN-19
--------------------	-------------

Timepoint-minutes	0
-------------------	---

Urine Start Day	
-----------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day 0)

Form: Biomarker-Plasma (Nic, Cot, tHCot) (2)

Generated On: 20 Jul 2016 12:09:14

Urine End Day	0
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day 0)

Form: Biomarker-Plasma (Nic, Cot, tHCot) (3)

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05112520000028
----------------	----------------

Analyte	COT
---------	-----

Sample type	PLASMA
-------------	--------

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	AA99128-10
-----------------------	------------

Date of Collection	2014-JAN-16
--------------------	-------------

Timepoint-minutes	0
-------------------	---

Urine Start Day	
-----------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day 0)

Form: Biomarker-Plasma (Nic, Cot, tHCot) (3)

Generated On: 20 Jul 2016 12:09:14

Urine End Day	0
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day 0)

Form: Biomarker-Plasma (Nic, Cot, tHCot) (4)

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05112520000028
----------------	----------------

Analyte	THCOT
---------	-------

Sample type	PLASMA
-------------	--------

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	AA99128-10
-----------------------	------------

Date of Collection	2014-JAN-16
--------------------	-------------

Timepoint-minutes	0
-------------------	---

Urine Start Day	
-----------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Baseline (Day 0)

Form: Biomarker-Plasma (Nic, Cot, tHCot) (4)

Generated On: 20 Jul 2016 12:09:14

Urine End Day	0
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 1

Form: Date of Visit

Data signed: (hfarmer1) 26 Mar 2015 14:18:37

Generated On: 20 Jul 2016 12:09:14

Date of Visit

20 JAN 2014
DD/MMM/YYYY

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 1

Form: Vital Signs

Data signed: (hfarmer1) 26 Mar 2015 14:18:37

Generated On: 20 Jul 2016 12:09:14

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

10:33
hour:min 24-hour clock

Pulse rate

56
beats per minute

Respiratory rate

16
breaths per minute

Blood Pressure (systolic)

107
mmHg

Blood Pressure (diastolic)

64
mmHg

Vital Signs Position of Subject

Supine ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 1

Form: Plasma Nicotine Sample

Data signed: (hfarmer1) 26 Mar 2015 14:18:37

Generated On: 20 Jul 2016 12:09:14

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	20 JAN 2014
---------------------	-------------

Time hour:min 24-hour clock	20:59
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 1

Form: Plasma Cotinine Sample

Data signed: (hfarmer1) 26 Mar 2015 14:18:37

Generated On: 20 Jul 2016 12:09:14

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	20 JAN 2014
---------------------	-------------

Time hour:min 24-hour clock	20:59
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 1

Form: CoHb Blood Sample

Data signed: (hfarmer1) 26 Mar 2015 14:18:37

Generated On: 20 Jul 2016 12:09:14

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	20 JAN 2014
---------------------	-------------

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

Time hour:min 24-hour clock	20:59
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 1

Form: CO Breath Test (1)

Data signed: (hfarmer1) 26 Mar 2015 14:18:37

Generated On: 20 Jul 2016 12:09:14

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	07:06
---	-------

Result(ppm)	17
-------------	----

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 1

Form: CO Breath Test (2)

Data signed: (hfarmer1) 26 Mar 2015 14:18:37

Generated On: 20 Jul 2016 12:09:14

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

If Not Done, please specify the reason: _____

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

Actual Time of Assessment hour:min 24-hour clock	12:19
---	-------

Result(ppm)	11
-------------	----

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 1

Form: CO Breath Test (3)

Data signed: (hfarmer1) 26 Mar 2015 14:18:37

Generated On: 20 Jul 2016 12:09:14

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	16:27
---	-------

Result(ppm)	6
-------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 1

Form: CO Breath Test (4)

Data signed: (hfarmer1) 26 Mar 2015 14:18:37

Generated On: 20 Jul 2016 12:09:14

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	21:23
---	-------

Result(ppm)	5
-------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 1

Form: 24 hour urine collections

Data signed: (hfarmer1) 26 Mar 2015 14:18:37

Generated On: 20 Jul 2016 12:09:14

Start Time	05:51
	hour:min 24-hour clock

End Date	21 JAN 2014
	DD/MMM/YYYY

End Time	06:25
	hour:min 24-hour clock

Volume	2538
	mL

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 1

Form: Sample Urine Collection

Data signed: (hfarmer1) 26 Mar 2015 14:18:37

Generated On: 20 Jul 2016 12:09:14

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: 1062

Folder: Day 1

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Data signed: (hfarmer1) 26 Mar 2015 14:18:38

Generated On: 20 Jul 2016 12:09:14

Date of Birth

(b) (6)

Date of assessment
DD/MMM/YYYY

2014 JAN 20
DD/MMM/YYYY

Time of assessment

06:36
hour:min 24-hour clock

Assessment Status

Completed ☒

Please indicate for each of the items below, how you have been feeling over the past 24 hours

How have you been feeling over the past 24 hours?

Slight ☒

1. Angry, irritable, frustrated

How have you been feeling over the past 24 hours?

None ☒

2. Anxious, nervous

How have you been feeling over the past 24 hours?

None ☒

3. Depressed Mood, sad

How have you been feeling over the past 24 hours?

Mild ☒

4. Desire or craving to smoke

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1062

Folder: Day 1

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Data signed: (hfarmer1) 26 Mar 2015 14:18:38

Generated On: 20 Jul 2016 12:09:14

How have you been feeling over the past 24 hours? None ☐

5. Difficulty concentrating

How have you been feeling over the past 24 hours? Mild ☐

6. Increased appetite, hungry, weight gain

How have you been feeling over the past 24 hours? None ☐

7. Insomnia, sleep problems, awakening at night

How have you been feeling over the past 24 hours? Slight ☐

8. Restless

How have you been feeling over the past 24 hours? Slight ☐

9. Impatient

How have you been feeling over the past 24 hours? None ☐

10. Constipation

How have you been feeling over the past 24 hours? None ☐

11. Dizziness

How have you been feeling over the past 24 hours? None ☐

12. Coughing

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 1

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Data signed: (hfarmer1) 26 Mar 2015 14:18:38

Generated On: 20 Jul 2016 12:09:14

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: 1062

Folder: Day 1

Form: Cough Assessment

Data signed: (hfarmer1) 26 Mar 2015 14:18:38

Generated On: 20 Jul 2016 12:09:14

Date of Birth

(b) (6)

Date of assessment
DD/MMM/YYYY

2014 JAN 20
DD/MMM/YYYY

Time of assessment

06:35
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: 1062**

Folder: Day 1

Form: Lab_BU_COHB (1)

Data signed: (hfarmer1) 26 Mar 2015 14:18:40

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05115150000132
Analyte	CARBOXYHEMOGLOBIN
Sample type	BLOOD
Result	.
Result Unit	%
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
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-JAN-20
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 1

Form: Lab_BU_COHB (1)

Data signed: (hfarmer1) 26 Mar 2015 14:18:40

Generated On: 20 Jul 2016 12:09:14

Start Day (24 hour urine only)

End Day (24 hour Urine Only)

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 1

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)

Data signed: (hfarmer1) 26 Mar 2015 14:18:38

Generated On: 20 Jul 2016 12:09:14

Date of Birth

(b) (6)

Date of assessment

2014 JAN 20
DD/MMM/YYYY

DD/MMM/YYYY

Time of assessment

20:03
hour:min 24-hour clock

Assessment Status

Completed ☐

1. Was smoking satisfying?

Very little ☐

2. Did cigarettes taste good?

Very little ☐

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

Very little ☐

4. Did smoking calm you down?

Very little ☐

5. Did smoking make you feel more awake?

Not at all ☐

6. Did smoking make you feel less irritable?

Very little ☐

7. Did smoking help you concentrate?

Not at all ☐

8. Did smoking reduce your hunger for food?

Not at all ☐

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 1

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)

Data signed: (hfarmer1) 26 Mar 2015 14:18:38

Generated On: 20 Jul 2016 12:09:14

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

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

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

12. Did you enjoy smoking? Very little ☐

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 1

Form: Questionnaire on smoking urges (QSU)

Data signed: (hfarmer1) 26 Mar 2015 14:18:38

Generated On: 20 Jul 2016 12:09:14

Type	QSU
Date of Birth	(b) (6)
Date of assessment DD/MMM/YYYY	2014 JAN 20
Time of assessment hour:min 24-hour clock	20:02
Assessment Status	Completed <input checked="" type="radio"/>
1. I have a desire for a cigarette right now	Agree <input checked="" type="radio"/>
2. Nothing would be better than smoking a cigarette right now	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	Disagree <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: 1062**

Folder: Day 1

Form: Questionnaire on smoking urges (QSU)

Data signed: (hfarmer1) 26 Mar 2015 14:18:38

Generated On: 20 Jul 2016 12:09:14

7. A cigarette would taste good now Agree ☐

8. I would do almost anything for a cigarette now Disagree ☐

9. Smoking would make me less depressed Disagree ☐

10. I am going to smoke as soon as possible Agree ☐

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 1

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

Data signed: (hfarmer1) 26 Mar 2015 14:18:40

Generated On: 20 Jul 2016 12:09:14

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 1

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

Data signed: (hfarmer1) 26 Mar 2015 14:18:40

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05112450000103
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	1
Celerion Study Number	AA99128-03
Date of Collection	2014-JAN-20
Timepoint-minutes	
Urine Start Day	1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 1

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

Data signed: (hfarmer1) 26 Mar 2015 14:18:40

Generated On: 20 Jul 2016 12:09:14

Urine End Day

2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 1

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (2)

Data signed: (hfarmer1) 26 Mar 2015 14:18:40

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05112450000103
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	1
Celerion Study Number	AA99128-03
Date of Collection	2014-JAN-20
Timepoint-minutes	
Urine Start Day	1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 1

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (2)

Data signed: (hfarmer1) 26 Mar 2015 14:18:40

Generated On: 20 Jul 2016 12:09:14

Urine End Day

2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 1

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (3)

Data signed: (hfarmer1) 26 Mar 2015 14:18:40

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05112450000103
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	1
Celerion Study Number	AA99128-03
Date of Collection	2014-JAN-20
Timepoint-minutes	
Urine Start Day	1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 1

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (3)

Data signed: (hfarmer1) 26 Mar 2015 14:18:40

Generated On: 20 Jul 2016 12:09:14

Urine End Day

2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 1

Form: Biomarker-Urine (NNN, NNAL)

Data signed: (hfarmer1) 26 Mar 2015 14:18:38

Generated On: 20 Jul 2016 12:09:14

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 1

Form: Biomarker-Urine (NNN, NNAL) (1)

Data signed: (hfarmer1) 26 Mar 2015 14:18:38

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05112460000103
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-JAN-20
Timepoint-minutes	
Urine Start Day	1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 1

Form: Biomarker-Urine (NNN, NNAL) (1)

Data signed: (hfarmer1) 26 Mar 2015 14:18:38

Generated On: 20 Jul 2016 12:09:14

Urine End Day

2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 1

Form: Biomarker-Urine (NNN, NNAL) (2)

Data signed: (hfarmer1) 26 Mar 2015 14:18:38

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05112460000103
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-JAN-20
Timepoint-minutes	
Urine Start Day	1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 1

Form: Biomarker-Urine (NNN, NNAL) (2)

Data signed: (hfarmer1) 26 Mar 2015 14:18:38

Generated On: 20 Jul 2016 12:09:14

Urine End Day

2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 1

Form: Biomarker-Urine (HEMA)

Data signed: (hfarmer1) 26 Mar 2015 14:18:38

Generated On: 20 Jul 2016 12:09:14

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 1

Form: Biomarker-Urine (HEMA) (1)

Data signed: (hfarmer1) 26 Mar 2015 14:18:38

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05112470000103
Analyte	HEMA
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	AA99128-05
Date of Collection	2014-JAN-20
Timepoint-minutes	
Urine Start Day	1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 1

Form: Biomarker-Urine (HEMA) (1)

Data signed: (hfarmer1) 26 Mar 2015 14:18:38

Generated On: 20 Jul 2016 12:09:14

Urine End Day

2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 1

Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)

Data signed: (hfarmer1) 26 Mar 2015 14:18:40

Generated On: 20 Jul 2016 12:09:14

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 1

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(1)**

Data signed: (hfarmer1) 26 Mar 2015 14:18:40

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05112480000081
Analyte	COT
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	AA99128-06
Date of Collection	2014-JAN-21
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 1

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(1)**

Data signed: (hfarmer1) 26 Mar 2015 14:18:40

Generated On: 20 Jul 2016 12:09:14

Urine Start Day	1
-----------------	---

Urine End Day	2
---------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 1

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(2)**

Data signed: (hfarmer1) 26 Mar 2015 14:18:40

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05112480000081
Analyte	COT-GLUC
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	AA99128-06
Date of Collection	2014-JAN-21
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 1

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(2)**

Data signed: (hfarmer1) 26 Mar 2015 14:18:40

Generated On: 20 Jul 2016 12:09:14

Urine Start Day	1
-----------------	---

Urine End Day	2
---------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 1

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(3)**

Data signed: (hfarmer1) 26 Mar 2015 14:18:40

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05112480000081
Analyte	NIC
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	AA99128-06
Date of Collection	2014-JAN-21
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 1

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(3)**

Data signed: (hfarmer1) 26 Mar 2015 14:18:40

Generated On: 20 Jul 2016 12:09:14

Urine Start Day	1
-----------------	---

Urine End Day	2
---------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 1

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(4)**

Data signed: (hfarmer1) 26 Mar 2015 14:18:40

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05112480000081
Analyte	NIC-GLUC
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	AA99128-06
Date of Collection	2014-JAN-21
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 1

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(4)**

Data signed: (hfarmer1) 26 Mar 2015 14:18:40

Generated On: 20 Jul 2016 12:09:14

Urine Start Day	1
-----------------	---

Urine End Day	2
---------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 1

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(5)**

Data signed: (hfarmer1) 26 Mar 2015 14:18:40

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05112480000081
Analyte	THCOT
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	AA99128-06
Date of Collection	2014-JAN-21
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 1

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(5)**

Data signed: (hfarmer1) 26 Mar 2015 14:18:40

Generated On: 20 Jul 2016 12:09:14

Urine Start Day	1
-----------------	---

Urine End Day	2
---------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 1

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(6)**

Data signed: (hfarmer1) 26 Mar 2015 14:18:40

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05112480000081
Analyte	THCOT-GLUC
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	AA99128-06
Date of Collection	2014-JAN-21
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 1

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(6)**

Data signed: (hfarmer1) 26 Mar 2015 14:18:40

Generated On: 20 Jul 2016 12:09:14

Urine Start Day	1
-----------------	---

Urine End Day	2
---------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 1

Form: Biomarker-Urine (3-OH BaP)

Data signed: (hfarmer1) 26 Mar 2015 14:18:41

Generated On: 20 Jul 2016 12:09:14

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 1

Form: Biomarker-Urine (3-OH BaP) (1)

Data signed: (hfarmer1) 26 Mar 2015 14:18:41

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05112490000103
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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-JAN-20
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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: 1062**

Folder: Day 1

Form: Biomarker-Urine (3-OH BaP) (1)

Data signed: (hfarmer1) 26 Mar 2015 14:18:41

Generated On: 20 Jul 2016 12:09:14

Urine End Day

2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 1

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP)

Data signed: (hfarmer1) 26 Mar 2015 14:18:41

Generated On: 20 Jul 2016 12:09:14

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 1

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (1)

Data signed: (hfarmer1) 26 Mar 2015 14:18:41

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05112510000103
Analyte	1-NA
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	AA99128-09
Date of Collection	2014-JAN-20
Timepoint-minutes	
Urine Start Day	1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 1

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (1)

Data signed: (hfarmer1) 26 Mar 2015 14:18:41

Generated On: 20 Jul 2016 12:09:14

Urine End Day

2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 1

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (2)

Data signed: (hfarmer1) 26 Mar 2015 14:18:41

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05112510000103
Analyte	2-NA
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	AA99128-09
Date of Collection	2014-JAN-20
Timepoint-minutes	
Urine Start Day	1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 1

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (2)

Data signed: (hfarmer1) 26 Mar 2015 14:18:41

Generated On: 20 Jul 2016 12:09:14

Urine End Day

2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 1

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (3)

Data signed: (hfarmer1) 26 Mar 2015 14:18:41

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05112510000103
Analyte	4-ABP
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	AA99128-09
Date of Collection	2014-JAN-20
Timepoint-minutes	
Urine Start Day	1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 1

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (3)

Data signed: (hfarmer1) 26 Mar 2015 14:18:41

Generated On: 20 Jul 2016 12:09:14

Urine End Day

2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 1

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (4)

Data signed: (hfarmer1) 26 Mar 2015 14:18:41

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05112510000103
Analyte	O-TOL
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	AA99128-09
Date of Collection	2014-JAN-20
Timepoint-minutes	
Urine Start Day	1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 1

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (4)

Data signed: (hfarmer1) 26 Mar 2015 14:18:41

Generated On: 20 Jul 2016 12:09:14

Urine End Day

2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 1

Form: Biomarker-Urine (1-OHP)

Data signed: (hfarmer1) 26 Mar 2015 14:18:41

Generated On: 20 Jul 2016 12:09:14

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 1

Form: Biomarker-Urine (1-OHP) (1)

Data signed: (hfarmer1) 26 Mar 2015 14:18:41

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05115190001192
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-JAN-20
Timepoint-minutes	
Urine Start Day	1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 1

Form: Biomarker-Urine (1-OHP) (1)

Data signed: (hfarmer1) 26 Mar 2015 14:18:41

Generated On: 20 Jul 2016 12:09:14

Urine End Day

2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 1

Form: Biomarker-Urine (SPMA, SBMA)

Data signed: (hfarmer1) 26 Mar 2015 14:18:38

Generated On: 20 Jul 2016 12:09:14

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 1

Form: Biomarker-Urine (SPMA, SBMA) (1)

Data signed: (hfarmer1) 26 Mar 2015 14:18:38

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05115170000103
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-JAN-20
Timepoint-minutes	
Urine Start Day	1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 1

Form: Biomarker-Urine (SPMA, SBMA) (1)

Data signed: (hfarmer1) 26 Mar 2015 14:18:38

Generated On: 20 Jul 2016 12:09:14

Urine End Day

2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 1

Form: Biomarker-Urine (SPMA, SBMA) (2)

Data signed: (hfarmer1) 26 Mar 2015 14:18:38

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05115170000103
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-JAN-20
Timepoint-minutes	
Urine Start Day	1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 1

Form: Biomarker-Urine (SPMA, SBMA) (2)

Data signed: (hfarmer1) 26 Mar 2015 14:18:38

Generated On: 20 Jul 2016 12:09:14

Urine End Day

2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 1

Form: Biomarker-Urine (MHBMA)

Data signed: (hfarmer1) 26 Mar 2015 14:18:39

Generated On: 20 Jul 2016 12:09:14

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 1

Form: Biomarker-Urine (MHBMA) (1)

Data signed: (hfarmer1) 26 Mar 2015 14:18:39

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05115180000103
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-JAN-20
Timepoint-minutes	
Urine Start Day	1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 1

Form: Biomarker-Urine (MHBMA) (1)

Data signed: (hfarmer1) 26 Mar 2015 14:18:39

Generated On: 20 Jul 2016 12:09:14

Urine End Day

2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 1

Form: Biomarker-Urine (Creatinine)

Data signed: (hfarmer1) 26 Mar 2015 14:18:41

Generated On: 20 Jul 2016 12:09:14

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 1

Form: Biomarker-Urine (Creatinine) (1)

Data signed: (hfarmer1) 26 Mar 2015 14:18:41

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05115160000103
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-JAN-20
Timepoint-minutes	
Urine Start Day	1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 1

Form: Biomarker-Urine (Creatinine) (1)

Data signed: (hfarmer1) 26 Mar 2015 14:18:41

Generated On: 20 Jul 2016 12:09:14

Urine End Day

2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 1

Form: Biomarker-Plasma (Nic, Cot, tHCot)

Data signed: (hfarmer1) 26 Mar 2015 14:18:40

Generated On: 20 Jul 2016 12:09:14

Sample type

PLASMA

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 1

Form: Biomarker-Plasma (Nic, Cot, tHCot) (1)

Data signed: (hfarmer1) 26 Mar 2015 14:18:40

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05112430000135
Analyte	COT
Sample type	PLASMA
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	AA99128-01
Date of Collection	2014-JAN-20
Timepoint-minutes	0
Urine Start Day	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 1

Form: Biomarker-Plasma (Nic, Cot, tHCot) (1)

Data signed: (hfarmer1) 26 Mar 2015 14:18:40

Generated On: 20 Jul 2016 12:09:14

Urine End Day

1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 1

Form: Biomarker-Plasma (Nic, Cot, tHCot) (2)

Data signed: (hfarmer1) 26 Mar 2015 14:18:40

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05112430000135
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Analyte	NIC
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Sample type	PLASMA
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Result	.
--------	---

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	AA99128-01
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Date of Collection	2014-JAN-20
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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: 1062**

Folder: Day 1

Form: Biomarker-Plasma (Nic, Cot, tHCot) (2)

Data signed: (hfarmer1) 26 Mar 2015 14:18:40

Generated On: 20 Jul 2016 12:09:14

Urine End Day

1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 2

Form: Date of Visit

Data signed: (hfarmer1) 26 Mar 2015 14:18:42

Generated On: 20 Jul 2016 12:09:14

Date of Visit

21 JAN 2014
DD/MMM/YYYY

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 2

Form: Vital Signs

Data signed: (hfarmer1) 26 Mar 2015 14:18:42

Generated On: 20 Jul 2016 12:09:14

Were Vitals Signs assessed? Yes ☒

If No, please specify the reason: _____

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

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

Pulse rate 53
beats per minute

Respiratory rate _____

Blood Pressure (systolic) 106
mmHg

Blood Pressure (diastolic) 61
mmHg

Vital Signs Position of Subject Supine ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 2

Form: Plasma Nicotine Sample

Data signed: (hfarmer1) 26 Mar 2015 14:18:41

Generated On: 20 Jul 2016 12:09:14

Not Done	False
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If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	21 JAN 2014
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Time hour:min 24-hour clock	21:14
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 2

Form: Plasma Cotinine Sample

Data signed: (hfarmer1) 26 Mar 2015 14:18:41

Generated On: 20 Jul 2016 12:09:14

Not Done	False
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If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	21 JAN 2014
---------------------	-------------

Time hour:min 24-hour clock	21:14
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 2

Form: CoHb Blood Sample

Data signed: (hfarmer1) 26 Mar 2015 14:18:41

Generated On: 20 Jul 2016 12:09:14

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	21 JAN 2014
---------------------	-------------

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

Time hour:min 24-hour clock	21:14
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 2

Form: CO Breath Test (1)

Data signed: (hfarmer1) 26 Mar 2015 14:18:42

Generated On: 20 Jul 2016 12:09:14

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	07:11
---	-------

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 2

Form: CO Breath Test (2)

Data signed: (hfarmer1) 26 Mar 2015 14:18:42

Generated On: 20 Jul 2016 12:09:14

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

If Not Done, please specify the reason: _____

Scheduled Time	12:00 - 13:30	<input checked="" type="radio"/>
----------------	---------------	----------------------------------

Actual Time of Assessment hour:min 24-hour clock	12:15
---	-------

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 2

Form: CO Breath Test (3)

Data signed: (hfarmer1) 26 Mar 2015 14:18:42

Generated On: 20 Jul 2016 12:09:14

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

If Not Done, please specify the reason: _____

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

Actual Time of Assessment hour:min 24-hour clock	16:47
---	-------

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 2

Form: CO Breath Test (4)

Data signed: (hfarmer1) 26 Mar 2015 14:18:42

Generated On: 20 Jul 2016 12:09:14

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	20:55
---	-------

Result(ppm)	2
-------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 2

Form: 24 hour urine collections

Data signed: (hfarmer1) 26 Mar 2015 14:18:42

Generated On: 20 Jul 2016 12:09:14

Start Time	06:25
	hour:min 24-hour clock

End Date	22 JAN 2014
	DD/MMM/YYYY

End Time	06:27
	hour:min 24-hour clock

Volume	2652
	mL

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 2

Form: Sample Urine Collection

Data signed: (hfarmer1) 26 Mar 2015 14:18:41

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Day 2

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Data signed: (hfarmer1) 26 Mar 2015 14:18:42

Generated On: 20 Jul 2016 12:09:14

Date of Birth

(b) (6)

Date of assessment
DD/MMM/YYYY

2014 JAN 21
DD/MMM/YYYY

Time of assessment

06:04
hour:min 24-hour clock

Assessment Status

Completed ☒

Please indicate for each of the items below, how you have been feeling over the past 24 hours

How have you been feeling over the past 24 hours?

Slight ☒

1. Angry, irritable, frustrated

How have you been feeling over the past 24 hours?

None ☒

2. Anxious, nervous

How have you been feeling over the past 24 hours?

None ☒

3. Depressed Mood, sad

How have you been feeling over the past 24 hours?

Mild ☒

4. Desire or craving to smoke

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1062

Folder: Day 2

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Data signed: (hfarmer1) 26 Mar 2015 14:18:42

Generated On: 20 Jul 2016 12:09:14

How have you been feeling over the past 24 hours? None ☐

5. Difficulty concentrating

How have you been feeling over the past 24 hours? Mild ☐

6. Increased appetite, hungry, weight gain

How have you been feeling over the past 24 hours? Slight ☐

7. Insomnia, sleep problems, awakening at night

How have you been feeling over the past 24 hours? Slight ☐

8. Restless

How have you been feeling over the past 24 hours? Slight ☐

9. Impatient

How have you been feeling over the past 24 hours? None ☐

10. Constipation

How have you been feeling over the past 24 hours? None ☐

11. Dizziness

How have you been feeling over the past 24 hours? None ☐

12. Coughing

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 2

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Data signed: (hfarmer1) 26 Mar 2015 14:18:42

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Day 2

Form: Cough Assessment

Data signed: (hfarmer1) 26 Mar 2015 14:18:42

Generated On: 20 Jul 2016 12:09:14

Date of Birth

(b) (6)

Date of assessment
DD/MMM/YYYY

2014 JAN 21
DD/MMM/YYYY

Time of assessment

06:01
hour:min 24-hour clock

Assessment Status

Completed ☒

Have you experienced a regular need to cough e.g.
coughing several times in the last 24 hrs?

No ☒

If YES, please answer the following questions:

First Question: Cough Impact Scale
How much is your cough bothering you?

-9

Second Question: Cough Intensity Scale:
How intense is your cough?

Not Applicable ☒

Third Question: Cough Frequency Scale:
How frequently do you normally have to cough each
day?

Not Applicable ☒

Fourth Question: Sputum Production
To what extent do you produce sputum when coughing?

Not Applicable ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 2

Form: Lab_BU_COHB (1)

Data signed: (hfarmer1) 26 Mar 2015 14:18:43

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05115150000133
Analyte	CARBOXYHEMOGLOBIN
Sample type	BLOOD
Result	.
Result Unit	%
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	SPECTROPHOTOMETRIC
Lower limit of quantification	0.500
Planned time point (Hour)	20
Day of Visit	2
Celerion Study Number	AA99128-16
Date of Collection	2014-JAN-21
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 2

Form: Lab_BU_COHB (1)

Data signed: (hfarmer1) 26 Mar 2015 14:18:43

Generated On: 20 Jul 2016 12:09:14

Start Day (24 hour urine only) _____

End Day (24 hour Urine Only) _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 2

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)

Data signed: (hfarmer1) 26 Mar 2015 14:18:42

Generated On: 20 Jul 2016 12:09:14

Date of Birth

(b) (6)

Date of assessment

2014 JAN 21
DD/MMM/YYYY

DD/MMM/YYYY

Time of assessment

20:13
hour:min 24-hour clock

Assessment Status

Completed ☒

1. Was smoking satisfying?

Very little ☐

2. Did cigarettes taste good?

Very little ☐

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

Very little ☐

4. Did smoking calm you down?

Not at all ☐

5. Did smoking make you feel more awake?

Not at all ☐

6. Did smoking make you feel less irritable?

Not at all ☐

7. Did smoking help you concentrate?

Not at all ☐

8. Did smoking reduce your hunger for food?

Not at all ☐

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 2

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)

Data signed: (hfarmer1) 26 Mar 2015 14:18:42

Generated On: 20 Jul 2016 12:09:14

9. Did smoking make you dizzy? Very little ☐

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

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

12. Did you enjoy smoking? Very little ☐

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 2

Form: Questionnaire on smoking urges (QSU)

Data signed: (hfarmer1) 26 Mar 2015 14:18:42

Generated On: 20 Jul 2016 12:09:14

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

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

Date of assessment	2014 JAN 21
--------------------	-------------

DD/MMM/YYYY

Time of assessment	20:12
--------------------	-------

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	Somewhat agree <input checked="" type="radio"/>
---	---

4. I could control things better right now if I could smoke	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: 1062**

Folder: Day 2

Form: Questionnaire on smoking urges (QSU)

Data signed: (hfarmer1) 26 Mar 2015 14:18:42

Generated On: 20 Jul 2016 12:09:14

7. A cigarette would taste good now Somewhat agree ☐

8. I would do almost anything for a cigarette now Disagree ☐

9. Smoking would make me less depressed Disagree ☐

10. I am going to smoke as soon as possible Somewhat agree ☐

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 2

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

Data signed: (hfarmer1) 26 Mar 2015 14:18:43

Generated On: 20 Jul 2016 12:09:14

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 2

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

Data signed: (hfarmer1) 26 Mar 2015 14:18:43

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05112450000104
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	2
Celerion Study Number	AA99128-03
Date of Collection	2014-JAN-21
Timepoint-minutes	
Urine Start Day	2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 2

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

Data signed: (hfarmer1) 26 Mar 2015 14:18:43

Generated On: 20 Jul 2016 12:09:14

Urine End Day

3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 2

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (2)

Data signed: (hfarmer1) 26 Mar 2015 14:18:43

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05112450000104
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	2
Celerion Study Number	AA99128-03
Date of Collection	2014-JAN-21
Timepoint-minutes	
Urine Start Day	2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 2

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (2)

Data signed: (hfarmer1) 26 Mar 2015 14:18:43

Generated On: 20 Jul 2016 12:09:14

Urine End Day

3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 2

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (3)

Data signed: (hfarmer1) 26 Mar 2015 14:18:43

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05112450000104
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	2
Celerion Study Number	AA99128-03
Date of Collection	2014-JAN-21
Timepoint-minutes	
Urine Start Day	2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 2

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (3)

Data signed: (hfarmer1) 26 Mar 2015 14:18:43

Generated On: 20 Jul 2016 12:09:14

Urine End Day

3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 2

Form: Biomarker-Urine (NNN, NNAL)

Data signed: (hfarmer1) 26 Mar 2015 14:18:42

Generated On: 20 Jul 2016 12:09:14

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 2

Form: Biomarker-Urine (NNN, NNAL) (1)

Data signed: (hfarmer1) 26 Mar 2015 14:18:42

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05112460000104
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-JAN-21
Timepoint-minutes	
Urine Start Day	2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 2

Form: Biomarker-Urine (NNN, NNAL) (1)

Data signed: (hfarmer1) 26 Mar 2015 14:18:42

Generated On: 20 Jul 2016 12:09:14

Urine End Day

3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 2

Form: Biomarker-Urine (NNN, NNAL) (2)

Data signed: (hfarmer1) 26 Mar 2015 14:18:42

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05112460000104
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-JAN-21
Timepoint-minutes	
Urine Start Day	2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 2

Form: Biomarker-Urine (NNN, NNAL) (2)

Data signed: (hfarmer1) 26 Mar 2015 14:18:42

Generated On: 20 Jul 2016 12:09:14

Urine End Day

3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 2

Form: Biomarker-Urine (HEMA)

Data signed: (hfarmer1) 26 Mar 2015 14:18:42

Generated On: 20 Jul 2016 12:09:14

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 2

Form: Biomarker-Urine (HEMA) (1)

Data signed: (hfarmer1) 26 Mar 2015 14:18:42

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05112470000104
Analyte	HEMA
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	AA99128-05
Date of Collection	2014-JAN-21
Timepoint-minutes	
Urine Start Day	2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 2

Form: Biomarker-Urine (HEMA) (1)

Data signed: (hfarmer1) 26 Mar 2015 14:18:42

Generated On: 20 Jul 2016 12:09:14

Urine End Day

3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 2

Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)

Data signed: (hfarmer1) 26 Mar 2015 14:18:43

Generated On: 20 Jul 2016 12:09:14

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 2

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(1)**

Data signed: (hfarmer1) 26 Mar 2015 14:18:43

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05112480000082
Analyte	COT
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	AA99128-06
Date of Collection	2014-JAN-22
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 2

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(1)**

Data signed: (hfarmer1) 26 Mar 2015 14:18:43

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Day 2

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(2)**

Data signed: (hfarmer1) 26 Mar 2015 14:18:43

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05112480000082
Analyte	COT-GLUC
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	AA99128-06
Date of Collection	2014-JAN-22
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 2

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(2)**

Data signed: (hfarmer1) 26 Mar 2015 14:18:43

Generated On: 20 Jul 2016 12:09:14

Urine Start Day	2
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Urine End Day	3
---------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 2

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(3)**

Data signed: (hfarmer1) 26 Mar 2015 14:18:43

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05112480000082
Analyte	NIC
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	AA99128-06
Date of Collection	2014-JAN-22
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 2

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(3)**

Data signed: (hfarmer1) 26 Mar 2015 14:18:43

Generated On: 20 Jul 2016 12:09:14

Urine Start Day	2
-----------------	---

Urine End Day	3
---------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 2

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(4)**

Data signed: (hfarmer1) 26 Mar 2015 14:18:43

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05112480000082
Analyte	NIC-GLUC
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	AA99128-06
Date of Collection	2014-JAN-22
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 2

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(4)**

Data signed: (hfarmer1) 26 Mar 2015 14:18:43

Generated On: 20 Jul 2016 12:09:14

Urine Start Day	2
-----------------	---

Urine End Day	3
---------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 2

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(5)**

Data signed: (hfarmer1) 26 Mar 2015 14:18:43

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05112480000082
Analyte	THCOT
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	AA99128-06
Date of Collection	2014-JAN-22
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 2

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(5)**

Data signed: (hfarmer1) 26 Mar 2015 14:18:43

Generated On: 20 Jul 2016 12:09:14

Urine Start Day	2
-----------------	---

Urine End Day	3
---------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 2

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(6)**

Data signed: (hfarmer1) 26 Mar 2015 14:18:43

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05112480000082
Analyte	THCOT-GLUC
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	AA99128-06
Date of Collection	2014-JAN-22
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 2

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(6)**

Data signed: (hfarmer1) 26 Mar 2015 14:18:43

Generated On: 20 Jul 2016 12:09:14

Urine Start Day	2
-----------------	---

Urine End Day	3
---------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 2

Form: Biomarker-Urine (3-OH BaP)

Data signed: (hfarmer1) 26 Mar 2015 14:18:44

Generated On: 20 Jul 2016 12:09:14

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 2

Form: Biomarker-Urine (3-OH BaP) (1)

Data signed: (hfarmer1) 26 Mar 2015 14:18:44

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05112490000104
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Analyte	3-OH BAP
---------	----------

Sample type	URINE
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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-JAN-21
--------------------	-------------

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

Urine Start Day	2
-----------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 2

Form: Biomarker-Urine (3-OH BaP) (1)

Data signed: (hfarmer1) 26 Mar 2015 14:18:44

Generated On: 20 Jul 2016 12:09:14

Urine End Day

3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 2

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP)

Data signed: (hfarmer1) 26 Mar 2015 14:18:44

Generated On: 20 Jul 2016 12:09:14

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 2

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (1)

Data signed: (hfarmer1) 26 Mar 2015 14:18:44

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05112510000104
Analyte	1-NA
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	AA99128-09
Date of Collection	2014-JAN-21
Timepoint-minutes	
Urine Start Day	2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 2

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (1)

Data signed: (hfarmer1) 26 Mar 2015 14:18:44

Generated On: 20 Jul 2016 12:09:14

Urine End Day

3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 2

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (2)

Data signed: (hfarmer1) 26 Mar 2015 14:18:44

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05112510000104
Analyte	2-NA
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	AA99128-09
Date of Collection	2014-JAN-21
Timepoint-minutes	
Urine Start Day	2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 2

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (2)

Data signed: (hfarmer1) 26 Mar 2015 14:18:44

Generated On: 20 Jul 2016 12:09:14

Urine End Day

3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 2

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (3)

Data signed: (hfarmer1) 26 Mar 2015 14:18:44

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05112510000104
Analyte	4-ABP
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	AA99128-09
Date of Collection	2014-JAN-21
Timepoint-minutes	
Urine Start Day	2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 2

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (3)

Data signed: (hfarmer1) 26 Mar 2015 14:18:44

Generated On: 20 Jul 2016 12:09:14

Urine End Day

3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 2

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (4)

Data signed: (hfarmer1) 26 Mar 2015 14:18:44

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05112510000104
Analyte	O-TOL
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	AA99128-09
Date of Collection	2014-JAN-21
Timepoint-minutes	
Urine Start Day	2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 2

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (4)

Data signed: (hfarmer1) 26 Mar 2015 14:18:44

Generated On: 20 Jul 2016 12:09:14

Urine End Day

3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 2

Form: Biomarker-Urine (1-OHP)

Data signed: (hfarmer1) 26 Mar 2015 14:18:44

Generated On: 20 Jul 2016 12:09:14

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 2

Form: Biomarker-Urine (1-OHP) (1)

Data signed: (hfarmer1) 26 Mar 2015 14:18:44

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05115190001193
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-JAN-21
Timepoint-minutes	
Urine Start Day	2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 2

Form: Biomarker-Urine (1-OHP) (1)

Data signed: (hfarmer1) 26 Mar 2015 14:18:44

Generated On: 20 Jul 2016 12:09:14

Urine End Day

3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 2

Form: Biomarker-Urine (SPMA, SBMA)

Data signed: (hfarmer1) 26 Mar 2015 14:18:43

Generated On: 20 Jul 2016 12:09:14

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 2

Form: Biomarker-Urine (SPMA, SBMA) (1)

Data signed: (hfarmer1) 26 Mar 2015 14:18:43

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05115170000104
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-JAN-21
Timepoint-minutes	
Urine Start Day	2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 2

Form: Biomarker-Urine (SPMA, SBMA) (1)

Data signed: (hfarmer1) 26 Mar 2015 14:18:43

Generated On: 20 Jul 2016 12:09:14

Urine End Day

3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 2

Form: Biomarker-Urine (SPMA, SBMA) (2)

Data signed: (hfarmer1) 26 Mar 2015 14:18:43

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05115170000104
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-JAN-21
Timepoint-minutes	
Urine Start Day	2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 2

Form: Biomarker-Urine (SPMA, SBMA) (2)

Data signed: (hfarmer1) 26 Mar 2015 14:18:43

Generated On: 20 Jul 2016 12:09:14

Urine End Day

3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 2

Form: Biomarker-Urine (MHBMA)

Data signed: (hfarmer1) 26 Mar 2015 14:18:43

Generated On: 20 Jul 2016 12:09:14

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 2

Form: Biomarker-Urine (MHBMA) (1)

Data signed: (hfarmer1) 26 Mar 2015 14:18:43

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05115180000104
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-JAN-21
Timepoint-minutes	
Urine Start Day	2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 2

Form: Biomarker-Urine (MHBMA) (1)

Data signed: (hfarmer1) 26 Mar 2015 14:18:43

Generated On: 20 Jul 2016 12:09:14

Urine End Day

3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 2

Form: Biomarker-Urine (Creatinine)

Data signed: (hfarmer1) 26 Mar 2015 14:18:44

Generated On: 20 Jul 2016 12:09:14

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 2

Form: Biomarker-Urine (Creatinine) (1)

Data signed: (hfarmer1) 26 Mar 2015 14:18:44

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05115160000104
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-JAN-21
Timepoint-minutes	
Urine Start Day	2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 2

Form: Biomarker-Urine (Creatinine) (1)

Data signed: (hfarmer1) 26 Mar 2015 14:18:44

Generated On: 20 Jul 2016 12:09:14

Urine End Day

3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 2

Form: Biomarker-Plasma (Nic, Cot, tHCot)

Data signed: (hfarmer1) 26 Mar 2015 14:18:43

Generated On: 20 Jul 2016 12:09:14

Sample type

PLASMA

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 2

Form: Biomarker-Plasma (Nic, Cot, tHCot) (1)

Data signed: (hfarmer1) 26 Mar 2015 14:18:43

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05112430000136
Analyte	COT
Sample type	PLASMA
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	AA99128-01
Date of Collection	2014-JAN-21
Timepoint-minutes	0
Urine Start Day	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 2

Form: Biomarker-Plasma (Nic, Cot, tHCot) (1)

Data signed: (hfarmer1) 26 Mar 2015 14:18:43

Generated On: 20 Jul 2016 12:09:14

Urine End Day

2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 2

Form: Biomarker-Plasma (Nic, Cot, tHCot) (2)

Data signed: (hfarmer1) 26 Mar 2015 14:18:43

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05112430000136
Analyte	NIC
Sample type	PLASMA
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	AA99128-01
Date of Collection	2014-JAN-21
Timepoint-minutes	0
Urine Start Day	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 2

Form: Biomarker-Plasma (Nic, Cot, tHCot) (2)

Data signed: (hfarmer1) 26 Mar 2015 14:18:43

Generated On: 20 Jul 2016 12:09:14

Urine End Day

2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 3

Form: Date of Visit

Data signed: (hfarmer1) 26 Mar 2015 14:18:45

Generated On: 20 Jul 2016 12:09:14

Date of Visit

22 JAN 2014
DD/MMM/YYYY

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 3

Form: Vital Signs

Data signed: (hfarmer1) 26 Mar 2015 14:18:45

Generated On: 20 Jul 2016 12:09:14

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

09:29
hour:min 24-hour clock

Pulse rate

53
beats per minute

Respiratory rate

16
breaths per minute

Blood Pressure (systolic)

110
mmHg

Blood Pressure (diastolic)

68
mmHg

Vital Signs Position of Subject

Supine ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 3

Form: Plasma Nicotine Sample

Data signed: (hfarmer1) 26 Mar 2015 14:18:44

Generated On: 20 Jul 2016 12:09:14

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	22 JAN 2014
---------------------	-------------

Time hour:min 24-hour clock	20:42
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 3

Form: Plasma Cotinine Sample

Data signed: (hfarmer1) 26 Mar 2015 14:18:44

Generated On: 20 Jul 2016 12:09:14

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	22 JAN 2014
---------------------	-------------

Time hour:min 24-hour clock	20:42
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 3

Form: CoHb Blood Sample

Data signed: (hfarmer1) 26 Mar 2015 14:18:44

Generated On: 20 Jul 2016 12:09:14

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	22 JAN 2014
---------------------	-------------

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

Time hour:min 24-hour clock	20:42
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 3

Form: CO Breath Test (1)

Data signed: (hfarmer1) 26 Mar 2015 14:18:45

Generated On: 20 Jul 2016 12:09:14

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

If Not Done, please specify the reason: _____

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

Actual Time of Assessment hour:min 24-hour clock	06:49
---	-------

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 3

Form: CO Breath Test (2)

Data signed: (hfarmer1) 26 Mar 2015 14:18:45

Generated On: 20 Jul 2016 12:09:14

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	12:06
---	-------

Result(ppm)	2
-------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 3

Form: CO Breath Test (3)

Data signed: (hfarmer1) 26 Mar 2015 14:18:45

Generated On: 20 Jul 2016 12:09:14

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	17:01
---	-------

Result(ppm)	2
-------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 3

Form: CO Breath Test (4)

Data signed: (hfarmer1) 26 Mar 2015 14:18:45

Generated On: 20 Jul 2016 12:09:14

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	20:13
---	-------

Result(ppm)	5
-------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 3

Form: 24 hour urine collections

Data signed: (hfarmer1) 26 Mar 2015 14:18:45

Generated On: 20 Jul 2016 12:09:14

Start Time	06:27
	hour:min 24-hour clock

End Date	23 JAN 2014
	DD/MMM/YYYY

End Time	06:13
	hour:min 24-hour clock

Volume	1833
	mL

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 3

Form: Sample Urine Collection

Data signed: (hfarmer1) 26 Mar 2015 14:18:45

Generated On: 20 Jul 2016 12:09:14

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: 1062

Folder: Day 3

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Data signed: (hfarmer1) 26 Mar 2015 14:18:45

Generated On: 20 Jul 2016 12:09:14

Date of Birth

(b) (6)

Date of assessment
DD/MMM/YYYY

2014 JAN 22
DD/MMM/YYYY

Time of assessment

07:02
hour:min 24-hour clock

Assessment Status

Completed ☒

Please indicate for each of the items below, how you have been feeling over the past 24 hours

How have you been feeling over the past 24 hours?

Slight ☒

1. Angry, irritable, frustrated

How have you been feeling over the past 24 hours?

Slight ☒

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: 1062

Folder: Day 3

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Data signed: (hfarmer1) 26 Mar 2015 14:18:45

Generated On: 20 Jul 2016 12:09:14

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? Slight ☐

8. Restless

How have you been feeling over the past 24 hours? Slight ☐

9. Impatient

How have you been feeling over the past 24 hours? None ☐

10. Constipation

How have you been feeling over the past 24 hours? Slight ☐

11. Dizziness

How have you been feeling over the past 24 hours? None ☐

12. Coughing

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 3

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Data signed: (hfarmer1) 26 Mar 2015 14:18:45

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Day 3

Form: Cough Assessment

Data signed: (hfarmer1) 26 Mar 2015 14:18:45

Generated On: 20 Jul 2016 12:09:14

Date of Birth

(b) (6)

Date of assessment
DD/MMM/YYYY

2014 JAN 22
DD/MMM/YYYY

Time of assessment

07:01
hour:min 24-hour clock

Assessment Status

Completed ☒

Have you experienced a regular need to cough e.g.
coughing several times in the last 24 hrs?

No ☒

If YES, please answer the following questions:

First Question: Cough Impact Scale
How much is your cough bothering you?

-9

Second Question: Cough Intensity Scale:
How intense is your cough?

Not Applicable ☒

Third Question: Cough Frequency Scale:
How frequently do you normally have to cough each
day?

Not Applicable ☒

Fourth Question: Sputum Production
To what extent do you produce sputum when coughing?

Not Applicable ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 3

Form: Lab_BU_COHB (1)

Data signed: (hfarmer1) 26 Mar 2015 14:18:46

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05115150000134
Analyte	CARBOXYHEMOGLOBIN
Sample type	BLOOD
Result	.
Result Unit	%
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	SPECTROPHOTOMETRIC
Lower limit of quantification	0.500
Planned time point (Hour)	20
Day of Visit	3
Celerion Study Number	AA99128-16
Date of Collection	2014-JAN-22
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 3

Form: Lab_BU_COHB (1)

Data signed: (hfarmer1) 26 Mar 2015 14:18:46

Generated On: 20 Jul 2016 12:09:14

Start Day (24 hour urine only) _____

End Day (24 hour Urine Only) _____

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1062

Folder: Day 3

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)

Data signed: (hfarmer1) 26 Mar 2015 14:18:45

Generated On: 20 Jul 2016 12:09:14

Date of Birth

(b) (6)

Date of assessment

2014 JAN 22

DD/MMM/YYYY

DD/MMM/YYYY

Time of assessment

20:11

hour:min 24-hour clock

Assessment Status

Completed ☒

1. Was smoking satisfying?

Moderately ☒

2. Did cigarettes taste good?

Very little ☒

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

Very little ☒

4. Did smoking calm you down?

Very little ☒

5. Did smoking make you feel more awake?

Very little ☒

6. Did smoking make you feel less irritable?

Very little ☒

7. Did smoking help you concentrate?

Not at all ☒

8. Did smoking reduce your hunger for food?

Not at all ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 3

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)

Data signed: (hfarmer1) 26 Mar 2015 14:18:45

Generated On: 20 Jul 2016 12:09:14

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

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

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

12. Did you enjoy smoking? Little ☐

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 3

Form: Questionnaire on smoking urges (QSU)

Data signed: (hfarmer1) 26 Mar 2015 14:18:45

Generated On: 20 Jul 2016 12:09:14

Type	QSU
Date of Birth	(b) (6)
Date of assessment	2014 JAN 22
DD/MMM/YYYY	
Time of assessment	20:10
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	Somewhat agree <input checked="" type="radio"/>
4. I could control things better right now if I could smoke	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: 1062**

Folder: Day 3

Form: Questionnaire on smoking urges (QSU)

Data signed: (hfarmer1) 26 Mar 2015 14:18:45

Generated On: 20 Jul 2016 12:09:14

7. A cigarette would taste good now Somewhat agree ☐

8. I would do almost anything for a cigarette now Disagree ☐

9. Smoking would make me less depressed Disagree ☐

10. I am going to smoke as soon as possible Somewhat agree ☐

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 3

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

Data signed: (hfarmer1) 26 Mar 2015 14:18:46

Generated On: 20 Jul 2016 12:09:14

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 3

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

Data signed: (hfarmer1) 26 Mar 2015 14:18:46

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05112450000105
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	3
Celerion Study Number	AA99128-03
Date of Collection	2014-JAN-22
Timepoint-minutes	
Urine Start Day	3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 3

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

Data signed: (hfarmer1) 26 Mar 2015 14:18:46

Generated On: 20 Jul 2016 12:09:14

Urine End Day

4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 3

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (2)

Data signed: (hfarmer1) 26 Mar 2015 14:18:46

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05112450000105
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	3
Celerion Study Number	AA99128-03
Date of Collection	2014-JAN-22
Timepoint-minutes	
Urine Start Day	3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 3

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (2)

Data signed: (hfarmer1) 26 Mar 2015 14:18:46

Generated On: 20 Jul 2016 12:09:14

Urine End Day

4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 3

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (3)

Data signed: (hfarmer1) 26 Mar 2015 14:18:46

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05112450000105
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	3
Celerion Study Number	AA99128-03
Date of Collection	2014-JAN-22
Timepoint-minutes	
Urine Start Day	3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 3

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (3)

Data signed: (hfarmer1) 26 Mar 2015 14:18:46

Generated On: 20 Jul 2016 12:09:14

Urine End Day

4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 3

Form: Biomarker-Urine (NNN, NNAL)

Data signed: (hfarmer1) 26 Mar 2015 14:18:46

Generated On: 20 Jul 2016 12:09:14

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 3

Form: Biomarker-Urine (NNN, NNAL) (1)

Data signed: (hfarmer1) 26 Mar 2015 14:18:46

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05112460000105
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-JAN-22
Timepoint-minutes	
Urine Start Day	3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 3

Form: Biomarker-Urine (NNN, NNAL) (1)

Data signed: (hfarmer1) 26 Mar 2015 14:18:46

Generated On: 20 Jul 2016 12:09:14

Urine End Day

4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 3

Form: Biomarker-Urine (NNN, NNAL) (2)

Data signed: (hfarmer1) 26 Mar 2015 14:18:46

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05112460000105
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-JAN-22
Timepoint-minutes	
Urine Start Day	3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 3

Form: Biomarker-Urine (NNN, NNAL) (2)

Data signed: (hfarmer1) 26 Mar 2015 14:18:46

Generated On: 20 Jul 2016 12:09:14

Urine End Day

4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 3

Form: Biomarker-Urine (HEMA)

Data signed: (hfarmer1) 26 Mar 2015 14:18:46

Generated On: 20 Jul 2016 12:09:14

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 3

Form: Biomarker-Urine (HEMA) (1)

Data signed: (hfarmer1) 26 Mar 2015 14:18:46

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05112470000105
Analyte	HEMA
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	AA99128-05
Date of Collection	2014-JAN-22
Timepoint-minutes	
Urine Start Day	3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 3

Form: Biomarker-Urine (HEMA) (1)

Data signed: (hfarmer1) 26 Mar 2015 14:18:46

Generated On: 20 Jul 2016 12:09:14

Urine End Day

4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 3

Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)

Data signed: (hfarmer1) 26 Mar 2015 14:18:46

Generated On: 20 Jul 2016 12:09:14

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 3

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(1)**

Data signed: (hfarmer1) 26 Mar 2015 14:18:46

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05112480000083
Analyte	COT
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	AA99128-06
Date of Collection	2014-JAN-23
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 3

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(1)**

Data signed: (hfarmer1) 26 Mar 2015 14:18:46

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Day 3

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(2)**

Data signed: (hfarmer1) 26 Mar 2015 14:18:46

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05112480000083
Analyte	COT-GLUC
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	AA99128-06
Date of Collection	2014-JAN-23
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 3

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(2)**

Data signed: (hfarmer1) 26 Mar 2015 14:18:46

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Day 3

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(3)**

Data signed: (hfarmer1) 26 Mar 2015 14:18:46

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05112480000083
Analyte	NIC
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	AA99128-06
Date of Collection	2014-JAN-23
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 3

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(3)**

Data signed: (hfarmer1) 26 Mar 2015 14:18:46

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Day 3

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(4)**

Data signed: (hfarmer1) 26 Mar 2015 14:18:46

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05112480000083
Analyte	NIC-GLUC
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	AA99128-06
Date of Collection	2014-JAN-23
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 3

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(4)**

Data signed: (hfarmer1) 26 Mar 2015 14:18:46

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Day 3

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(5)**

Data signed: (hfarmer1) 26 Mar 2015 14:18:46

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05112480000083
Analyte	THCOT
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	AA99128-06
Date of Collection	2014-JAN-23
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 3

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(5)**

Data signed: (hfarmer1) 26 Mar 2015 14:18:46

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Day 3

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(6)**

Data signed: (hfarmer1) 26 Mar 2015 14:18:46

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05112480000083
Analyte	THCOT-GLUC
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	AA99128-06
Date of Collection	2014-JAN-23
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 3

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(6)**

Data signed: (hfarmer1) 26 Mar 2015 14:18:46

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Day 3

Form: Biomarker-Urine (3-OH BaP)

Data signed: (hfarmer1) 26 Mar 2015 14:18:47

Generated On: 20 Jul 2016 12:09:14

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 3

Form: Biomarker-Urine (3-OH BaP) (1)

Data signed: (hfarmer1) 26 Mar 2015 14:18:47

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05112490000105
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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	3
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Celerion Study Number	AA99128-07
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Date of Collection	2014-JAN-22
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Timepoint-minutes	
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Urine Start Day	3
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 3

Form: Biomarker-Urine (3-OH BaP) (1)

Data signed: (hfarmer1) 26 Mar 2015 14:18:47

Generated On: 20 Jul 2016 12:09:14

Urine End Day

4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 3

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP)

Data signed: (hfarmer1) 26 Mar 2015 14:18:47

Generated On: 20 Jul 2016 12:09:14

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 3

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (1)

Data signed: (hfarmer1) 26 Mar 2015 14:18:47

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05112510000105
Analyte	1-NA
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	AA99128-09
Date of Collection	2014-JAN-22
Timepoint-minutes	
Urine Start Day	3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 3

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (1)

Data signed: (hfarmer1) 26 Mar 2015 14:18:47

Generated On: 20 Jul 2016 12:09:14

Urine End Day

4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 3

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (2)

Data signed: (hfarmer1) 26 Mar 2015 14:18:47

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05112510000105
Analyte	2-NA
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	AA99128-09
Date of Collection	2014-JAN-22
Timepoint-minutes	
Urine Start Day	3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 3

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (2)

Data signed: (hfarmer1) 26 Mar 2015 14:18:47

Generated On: 20 Jul 2016 12:09:14

Urine End Day

4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 3

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (3)

Data signed: (hfarmer1) 26 Mar 2015 14:18:47

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05112510000105
Analyte	4-ABP
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	AA99128-09
Date of Collection	2014-JAN-22
Timepoint-minutes	
Urine Start Day	3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 3

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (3)

Data signed: (hfarmer1) 26 Mar 2015 14:18:47

Generated On: 20 Jul 2016 12:09:14

Urine End Day

4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 3

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (4)

Data signed: (hfarmer1) 26 Mar 2015 14:18:47

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05112510000105
Analyte	O-TOL
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	AA99128-09
Date of Collection	2014-JAN-22
Timepoint-minutes	
Urine Start Day	3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 3

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (4)

Data signed: (hfarmer1) 26 Mar 2015 14:18:47

Generated On: 20 Jul 2016 12:09:14

Urine End Day

4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 3

Form: Biomarker-Urine (1-OHP)

Data signed: (hfarmer1) 26 Mar 2015 14:18:47

Generated On: 20 Jul 2016 12:09:14

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 3

Form: Biomarker-Urine (1-OHP) (1)

Data signed: (hfarmer1) 26 Mar 2015 14:18:47

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05115190001194
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	3
Celerion Study Number	AA99598-03
Date of Collection	2014-JAN-22
Timepoint-minutes	
Urine Start Day	3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 3

Form: Biomarker-Urine (1-OHP) (1)

Data signed: (hfarmer1) 26 Mar 2015 14:18:47

Generated On: 20 Jul 2016 12:09:14

Urine End Day

4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 3

Form: Biomarker-Urine (SPMA, SBMA)

Data signed: (hfarmer1) 26 Mar 2015 14:18:46

Generated On: 20 Jul 2016 12:09:14

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 3

Form: Biomarker-Urine (SPMA, SBMA) (1)

Data signed: (hfarmer1) 26 Mar 2015 14:18:46

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05115170000105
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-JAN-22
Timepoint-minutes	
Urine Start Day	3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 3

Form: Biomarker-Urine (SPMA, SBMA) (1)

Data signed: (hfarmer1) 26 Mar 2015 14:18:46

Generated On: 20 Jul 2016 12:09:14

Urine End Day

4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 3

Form: Biomarker-Urine (SPMA, SBMA) (2)

Data signed: (hfarmer1) 26 Mar 2015 14:18:46

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05115170000105
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-JAN-22
Timepoint-minutes	
Urine Start Day	3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 3

Form: Biomarker-Urine (SPMA, SBMA) (2)

Data signed: (hfarmer1) 26 Mar 2015 14:18:46

Generated On: 20 Jul 2016 12:09:14

Urine End Day

4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 3

Form: Biomarker-Urine (MHBMA)

Data signed: (hfarmer1) 26 Mar 2015 14:18:46

Generated On: 20 Jul 2016 12:09:14

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 3

Form: Biomarker-Urine (MHBMA) (1)

Data signed: (hfarmer1) 26 Mar 2015 14:18:46

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05115180000105
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-JAN-22
Timepoint-minutes	
Urine Start Day	3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 3

Form: Biomarker-Urine (MHBMA) (1)

Data signed: (hfarmer1) 26 Mar 2015 14:18:46

Generated On: 20 Jul 2016 12:09:14

Urine End Day

4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 3

Form: Biomarker-Urine (Creatinine)

Data signed: (hfarmer1) 26 Mar 2015 14:18:47

Generated On: 20 Jul 2016 12:09:14

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 3

Form: Biomarker-Urine (Creatinine) (1)

Data signed: (hfarmer1) 26 Mar 2015 14:18:47

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05115160000105
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-JAN-22
Timepoint-minutes	
Urine Start Day	3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 3

Form: Biomarker-Urine (Creatinine) (1)

Data signed: (hfarmer1) 26 Mar 2015 14:18:47

Generated On: 20 Jul 2016 12:09:14

Urine End Day

4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 3

Form: Biomarker-Plasma (Nic, Cot, tHCot)

Data signed: (hfarmer1) 26 Mar 2015 14:18:46

Generated On: 20 Jul 2016 12:09:14

Sample type

PLASMA

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 3

Form: Biomarker-Plasma (Nic, Cot, tHCot) (1)

Data signed: (hfarmer1) 26 Mar 2015 14:18:46

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05112430000137
Analyte	COT
Sample type	PLASMA
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	AA99128-01
Date of Collection	2014-JAN-22
Timepoint-minutes	0
Urine Start Day	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 3

Form: Biomarker-Plasma (Nic, Cot, tHCot) (1)

Data signed: (hfarmer1) 26 Mar 2015 14:18:46

Generated On: 20 Jul 2016 12:09:14

Urine End Day

3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 3

Form: Biomarker-Plasma (Nic, Cot, tHCot) (2)

Data signed: (hfarmer1) 26 Mar 2015 14:18:46

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05112430000137
----------------	----------------

Analyte	NIC
---------	-----

Sample type	PLASMA
-------------	--------

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	AA99128-01
-----------------------	------------

Date of Collection	2014-JAN-22
--------------------	-------------

Timepoint-minutes	0
-------------------	---

Urine Start Day	
-----------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 3

Form: Biomarker-Plasma (Nic, Cot, tHCot) (2)

Data signed: (hfarmer1) 26 Mar 2015 14:18:46

Generated On: 20 Jul 2016 12:09:14

Urine End Day

3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 4

Form: Date of Visit

Data signed: (hfarmer1) 26 Mar 2015 14:18:47

Generated On: 20 Jul 2016 12:09:14

Date of Visit

23 JAN 2014
DD/MMM/YYYY

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 4

Form: Vital Signs

Data signed: (hfarmer1) 26 Mar 2015 14:18:47

Generated On: 20 Jul 2016 12:09:14

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

10:16
hour:min 24-hour clock

Pulse rate

54
beats per minute

Respiratory rate

16
breaths per minute

Blood Pressure (systolic)

109
mmHg

Blood Pressure (diastolic)

68
mmHg

Vital Signs Position of Subject

Supine ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 4

Form: Socio-Economic Status

Data signed: (hfarmer1) 26 Mar 2015 14:18:47

Generated On: 20 Jul 2016 12:09:14

Was paper questionnaire used? Yes ☒

Reason not done _____

Date 23 JAN 2014
DD/MMM/YYYY

Time 08:29
hour:min 24-hour clock

Q1. What is the highest level of education you have completed? High School Graduate ☒

Q2. What is your current occupational status? Only temporarily laid off, ☒
sick leave or maternity
leave

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: 1062**

Folder: Day 4

Form: Socio-Economic Status

Data signed: (hfarmer1) 26 Mar 2015 14:18:47

Generated On: 20 Jul 2016 12:09:14

Q7. Which of these categories best describes your total combined family income for the past 12 months? This should include income (before taxes) from all sources, wages, rent from properties, social security, disability and/or veteran's benefits, unemployment benefits, workman's compensation, help from relatives (including child payments and alimony), and so on.

No response ☐

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 4

Form: Plasma Nicotine Sample

Data signed: (hfarmer1) 26 Mar 2015 14:18:47

Generated On: 20 Jul 2016 12:09:14

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	23 JAN 2014
---------------------	-------------

Time hour:min 24-hour clock	20:42
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 4

Form: Plasma Cotinine Sample

Data signed: (hfarmer1) 26 Mar 2015 14:18:47

Generated On: 20 Jul 2016 12:09:14

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	23 JAN 2014
---------------------	-------------

Time hour:min 24-hour clock	20:42
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 4

Form: CoHb Blood Sample

Data signed: (hfarmer1) 26 Mar 2015 14:18:47

Generated On: 20 Jul 2016 12:09:14

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	23 JAN 2014
---------------------	-------------

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

Time hour:min 24-hour clock	20:42
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 4

Form: CO Breath Test (1)

Data signed: (hfarmer1) 26 Mar 2015 14:18:47

Generated On: 20 Jul 2016 12:09:14

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

If Not Done, please specify the reason: _____

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

Actual Time of Assessment hour:min 24-hour clock	06:31
---	-------

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 4

Form: CO Breath Test (2)

Data signed: (hfarmer1) 26 Mar 2015 14:18:47

Generated On: 20 Jul 2016 12:09:14

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	12:20
---	-------

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 4

Form: CO Breath Test (3)

Data signed: (hfarmer1) 26 Mar 2015 14:18:47

Generated On: 20 Jul 2016 12:09:14

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)	2
-------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 4

Form: CO Breath Test (4)

Data signed: (hfarmer1) 26 Mar 2015 14:18:47

Generated On: 20 Jul 2016 12:09:14

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	20:11
---	-------

Result(ppm)	2
-------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 4

Form: 24 hour urine collections

Data signed: (hfarmer1) 26 Mar 2015 14:18:47

Generated On: 20 Jul 2016 12:09:14

Start Time	06:13
	hour:min 24-hour clock

End Date	24 JAN 2014
	DD/MMM/YYYY

End Time	06:15
	hour:min 24-hour clock

Volume	2262
	mL

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 4

Form: Sample Urine Collection

Data signed: (hfarmer1) 26 Mar 2015 14:18:47

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Day 4

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Data signed: (hfarmer1) 26 Mar 2015 14:18:48

Generated On: 20 Jul 2016 12:09:14

Date of Birth

(b) (6)

Date of assessment
DD/MMM/YYYY

2014 JAN 23
DD/MMM/YYYY

Time of assessment

06:07
hour:min 24-hour clock

Assessment Status

Completed ☒

Please indicate for each of the items below, how you have been feeling over the past 24 hours

How have you been feeling over the past 24 hours?

None ☐

1. Angry, irritable, frustrated

How have you been feeling over the past 24 hours?

None ☐

2. Anxious, nervous

How have you been feeling over the past 24 hours?

None ☐

3. Depressed Mood, sad

How have you been feeling over the past 24 hours?

Mild ☐

4. Desire or craving to smoke

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 4

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Data signed: (hfarmer1) 26 Mar 2015 14:18:48

Generated On: 20 Jul 2016 12:09:14

How have you been feeling over the past 24 hours? None ☐

5. Difficulty concentrating

How have you been feeling over the past 24 hours? Mild ☐

6. Increased appetite, hungry, weight gain

How have you been feeling over the past 24 hours? None ☐

7. Insomnia, sleep problems, awakening at night

How have you been feeling over the past 24 hours? None ☐

8. Restless

How have you been feeling over the past 24 hours? Slight ☐

9. Impatient

How have you been feeling over the past 24 hours? None ☐

10. Constipation

How have you been feeling over the past 24 hours? None ☐

11. Dizziness

How have you been feeling over the past 24 hours? Slight ☐

12. Coughing

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 4

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Data signed: (hfarmer1) 26 Mar 2015 14:18:48

Generated On: 20 Jul 2016 12:09:14

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: 1062

Folder: Day 4

Form: Cough Assessment

Data signed: (hfarmer1) 26 Mar 2015 14:18:48

Generated On: 20 Jul 2016 12:09:14

Date of Birth

(b) (6)

Date of assessment
DD/MMM/YYYY

2014 JAN 23
DD/MMM/YYYY

Time of assessment

06:06
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: 1062**

Folder: Day 4

Form: Lab_BU_COHB (1)

Data signed: (hfarmer1) 26 Mar 2015 14:18:51

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05115150000135
----------------	----------------

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

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

Result	.
--------	---

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

Lab Status	OTHER
------------	-------

Sample comment	ANALYSIS NOT REQUIRED
----------------	-----------------------

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

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

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

Day of Visit	4
--------------	---

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

Date of Collection	2014-JAN-23
--------------------	-------------

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 4

Form: Lab_BU_COHB (1)

Data signed: (hfarmer1) 26 Mar 2015 14:18:51

Generated On: 20 Jul 2016 12:09:14

Start Day (24 hour urine only) _____

End Day (24 hour Urine Only) _____

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1062

Folder: Day 4

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)

Data signed: (hfarmer1) 26 Mar 2015 14:18:48

Generated On: 20 Jul 2016 12:09:14

Date of Birth

(b) (6)

Date of assessment

2014 JAN 23

DD/MMM/YYYY

DD/MMM/YYYY

Time of assessment

20:03

hour:min 24-hour clock

Assessment Status

Completed ☐

1. Was smoking satisfying?

Very little ☐

2. Did cigarettes taste good?

Very little ☐

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

Very little ☐

4. Did smoking calm you down?

Not at all ☐

5. Did smoking make you feel more awake?

Not at all ☐

6. Did smoking make you feel less irritable?

Very little ☐

7. Did smoking help you concentrate?

Not at all ☐

8. Did smoking reduce your hunger for food?

Not at all ☐

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 4

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)

Data signed: (hfarmer1) 26 Mar 2015 14:18:48

Generated On: 20 Jul 2016 12:09:14

9. Did smoking make you dizzy? Very little ☐

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

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

12. Did you enjoy smoking? Very little ☐

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1062

Folder: Day 4

Form: Human Smoking Topography Questionnaire

Data signed: (hfarmer1) 26 Mar 2015 14:18:47

Generated On: 20 Jul 2016 12:09:14

Type	HUMAN SMOKING TOPOGRAPHY QUESTIONNAIRE
------	--

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

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

Date of assessment	23 JAN 2014 DD/MMM/YYYY
--------------------	----------------------------

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

How do you agree with the following sentences/affirmations :

1. The smoking of the conventional cigarettes/products is different with the device.	Neither agree nor disagree <input type="radio"/>
--	--

If you agree or strongly agree, please describe :	<hr/>
---	-------

2. You enjoy smoking with the device as much as without it.	Neither agree nor disagree <input type="radio"/>
---	--

If you disagree or strongly disagree, please describe :	<hr/>
---	-------

3. The taste of the conventional cigarettes/products is different with the device.	Neither agree nor disagree <input type="radio"/>
--	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 4

Form: Human Smoking Topography Questionnaire

Data signed: (hfarmer1) 26 Mar 2015 14:18:47

Generated On: 20 Jul 2016 12:09:14

If you agree or strongly agree, please describe : _____

4. The device is easy to use.

Neither agree nor disagree ☒

If you disagree or strongly disagree, please describe : _____

5. Your smoking is disturbed by the device.

Neither agree nor disagree ☒

If you agree or strongly agree, please describe : _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 4

Form: Questionnaire on smoking urges (QSU)

Data signed: (hfarmer1) 26 Mar 2015 14:18:47

Generated On: 20 Jul 2016 12:09:14

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

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

Date of assessment	2014 JAN 23
--------------------	-------------

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	Agree <input checked="" type="radio"/>
--	--

2. Nothing would be better than smoking a cigarette right now	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	Disagree <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: 1062**

Folder: Day 4

Form: Questionnaire on smoking urges (QSU)

Data signed: (hfarmer1) 26 Mar 2015 14:18:47

Generated On: 20 Jul 2016 12:09:14

7. A cigarette would taste good now Agree ☐

8. I would do almost anything for a cigarette now Disagree ☐

9. Smoking would make me less depressed Disagree ☐

10. I am going to smoke as soon as possible Agree ☐

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 4

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

Data signed: (hfarmer1) 26 Mar 2015 14:18:52

Generated On: 20 Jul 2016 12:09:14

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 4

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

Data signed: (hfarmer1) 26 Mar 2015 14:18:52

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05112450000106
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	4
Celerion Study Number	AA99128-03
Date of Collection	2014-JAN-23
Timepoint-minutes	
Urine Start Day	4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 4

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

Data signed: (hfarmer1) 26 Mar 2015 14:18:52

Generated On: 20 Jul 2016 12:09:14

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 4

Form: Biomarker-Urine (CEMA, HPMa, HBMA) (2)

Data signed: (hfarmer1) 26 Mar 2015 14:18:52

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05112450000106
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	4
Celerion Study Number	AA99128-03
Date of Collection	2014-JAN-23
Timepoint-minutes	
Urine Start Day	4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 4

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (2)

Data signed: (hfarmer1) 26 Mar 2015 14:18:52

Generated On: 20 Jul 2016 12:09:14

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 4

Form: Biomarker-Urine (CEMA, HPMa, HBMA) (3)

Data signed: (hfarmer1) 26 Mar 2015 14:18:52

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05112450000106
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	4
Celerion Study Number	AA99128-03
Date of Collection	2014-JAN-23
Timepoint-minutes	
Urine Start Day	4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 4

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (3)

Data signed: (hfarmer1) 26 Mar 2015 14:18:52

Generated On: 20 Jul 2016 12:09:14

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 4

Form: Biomarker-Urine (NNN, NNAL)

Data signed: (hfarmer1) 26 Mar 2015 14:18:49

Generated On: 20 Jul 2016 12:09:14

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 4

Form: Biomarker-Urine (NNN, NNAL) (1)

Data signed: (hfarmer1) 26 Mar 2015 14:18:49

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05112460000106
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-JAN-23
Timepoint-minutes	
Urine Start Day	4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 4

Form: Biomarker-Urine (NNN, NNAL) (1)

Data signed: (hfarmer1) 26 Mar 2015 14:18:49

Generated On: 20 Jul 2016 12:09:14

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 4

Form: Biomarker-Urine (NNN, NNAL) (2)

Data signed: (hfarmer1) 26 Mar 2015 14:18:49

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05112460000106
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-JAN-23
Timepoint-minutes	
Urine Start Day	4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 4

Form: Biomarker-Urine (NNN, NNAL) (2)

Data signed: (hfarmer1) 26 Mar 2015 14:18:49

Generated On: 20 Jul 2016 12:09:14

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 4

Form: Biomarker-Urine (HEMA)

Data signed: (hfarmer1) 26 Mar 2015 14:18:50

Generated On: 20 Jul 2016 12:09:14

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 4

Form: Biomarker-Urine (HEMA) (1)

Data signed: (hfarmer1) 26 Mar 2015 14:18:50

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05112470000106
Analyte	HEMA
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	AA99128-05
Date of Collection	2014-JAN-23
Timepoint-minutes	
Urine Start Day	4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 4

Form: Biomarker-Urine (HEMA) (1)

Data signed: (hfarmer1) 26 Mar 2015 14:18:50

Generated On: 20 Jul 2016 12:09:14

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 4

Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)

Data signed: (hfarmer1) 26 Mar 2015 14:18:53

Generated On: 20 Jul 2016 12:09:14

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 4

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(1)**

Data signed: (hfarmer1) 26 Mar 2015 14:18:53

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05112480000084
Analyte	COT
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	AA99128-06
Date of Collection	2014-JAN-24
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 4

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(1)**

Data signed: (hfarmer1) 26 Mar 2015 14:18:53

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Day 4

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(2)**

Data signed: (hfarmer1) 26 Mar 2015 14:18:53

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05112480000084
Analyte	COT-GLUC
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	AA99128-06
Date of Collection	2014-JAN-24
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 4

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(2)**

Data signed: (hfarmer1) 26 Mar 2015 14:18:53

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Day 4

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(3)**

Data signed: (hfarmer1) 26 Mar 2015 14:18:53

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05112480000084
Analyte	NIC
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	AA99128-06
Date of Collection	2014-JAN-24
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 4

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(3)**

Data signed: (hfarmer1) 26 Mar 2015 14:18:53

Generated On: 20 Jul 2016 12:09:14

Urine Start Day	4
-----------------	---

Urine End Day	5
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 4

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(4)**

Data signed: (hfarmer1) 26 Mar 2015 14:18:53

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05112480000084
Analyte	NIC-GLUC
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	AA99128-06
Date of Collection	2014-JAN-24
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 4

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(4)**

Data signed: (hfarmer1) 26 Mar 2015 14:18:53

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Day 4

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(5)**

Data signed: (hfarmer1) 26 Mar 2015 14:18:53

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05112480000084
Analyte	THCOT
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	AA99128-06
Date of Collection	2014-JAN-24
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 4

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(5)**

Data signed: (hfarmer1) 26 Mar 2015 14:18:53

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Day 4

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(6)**

Data signed: (hfarmer1) 26 Mar 2015 14:18:53

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05112480000084
Analyte	THCOT-GLUC
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	AA99128-06
Date of Collection	2014-JAN-24
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 4

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(6)**

Data signed: (hfarmer1) 26 Mar 2015 14:18:53

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Day 4

Form: Biomarker-Urine (3-OH BaP)

Data signed: (hfarmer1) 26 Mar 2015 14:18:54

Generated On: 20 Jul 2016 12:09:14

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 4

Form: Biomarker-Urine (3-OH BaP) (1)

Data signed: (hfarmer1) 26 Mar 2015 14:18:54

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05112490000106
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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	4
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Celerion Study Number	AA99128-07
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Date of Collection	2014-JAN-23
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Timepoint-minutes	
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Urine Start Day	4
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 4

Form: Biomarker-Urine (3-OH BaP) (1)

Data signed: (hfarmer1) 26 Mar 2015 14:18:54

Generated On: 20 Jul 2016 12:09:14

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 4

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP)

Data signed: (hfarmer1) 26 Mar 2015 14:18:54

Generated On: 20 Jul 2016 12:09:14

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 4

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (1)

Data signed: (hfarmer1) 26 Mar 2015 14:18:54

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05112510000106
Analyte	1-NA
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	AA99128-09
Date of Collection	2014-JAN-23
Timepoint-minutes	
Urine Start Day	4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 4

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (1)

Data signed: (hfarmer1) 26 Mar 2015 14:18:54

Generated On: 20 Jul 2016 12:09:14

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 4

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (2)

Data signed: (hfarmer1) 26 Mar 2015 14:18:54

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05112510000106
Analyte	2-NA
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	AA99128-09
Date of Collection	2014-JAN-23
Timepoint-minutes	
Urine Start Day	4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 4

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (2)

Data signed: (hfarmer1) 26 Mar 2015 14:18:54

Generated On: 20 Jul 2016 12:09:14

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 4

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (3)

Data signed: (hfarmer1) 26 Mar 2015 14:18:54

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05112510000106
Analyte	4-ABP
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	AA99128-09
Date of Collection	2014-JAN-23
Timepoint-minutes	
Urine Start Day	4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 4

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (3)

Data signed: (hfarmer1) 26 Mar 2015 14:18:54

Generated On: 20 Jul 2016 12:09:14

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 4

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (4)

Data signed: (hfarmer1) 26 Mar 2015 14:18:54

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05112510000106
Analyte	O-TOL
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	AA99128-09
Date of Collection	2014-JAN-23
Timepoint-minutes	
Urine Start Day	4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 4

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (4)

Data signed: (hfarmer1) 26 Mar 2015 14:18:54

Generated On: 20 Jul 2016 12:09:14

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 4

Form: Biomarker-Urine (1-OHP)

Data signed: (hfarmer1) 26 Mar 2015 14:18:54

Generated On: 20 Jul 2016 12:09:14

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 4

Form: Biomarker-Urine (1-OHP) (1)

Data signed: (hfarmer1) 26 Mar 2015 14:18:54

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05115190001195
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-JAN-23
Timepoint-minutes	
Urine Start Day	4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 4

Form: Biomarker-Urine (1-OHP) (1)

Data signed: (hfarmer1) 26 Mar 2015 14:18:54

Generated On: 20 Jul 2016 12:09:14

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 4

Form: Biomarker-Urine (SPMA, SBMA)

Data signed: (hfarmer1) 26 Mar 2015 14:18:50

Generated On: 20 Jul 2016 12:09:14

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 4

Form: Biomarker-Urine (SPMA, SBMA) (1)

Data signed: (hfarmer1) 26 Mar 2015 14:18:50

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05115170000106
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-JAN-23
Timepoint-minutes	
Urine Start Day	4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 4

Form: Biomarker-Urine (SPMA, SBMA) (1)

Data signed: (hfarmer1) 26 Mar 2015 14:18:50

Generated On: 20 Jul 2016 12:09:14

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 4

Form: Biomarker-Urine (SPMA, SBMA) (2)

Data signed: (hfarmer1) 26 Mar 2015 14:18:50

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05115170000106
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-JAN-23
Timepoint-minutes	
Urine Start Day	4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 4

Form: Biomarker-Urine (SPMA, SBMA) (2)

Data signed: (hfarmer1) 26 Mar 2015 14:18:50

Generated On: 20 Jul 2016 12:09:14

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 4

Form: Biomarker-Urine (MHBMA)

Data signed: (hfarmer1) 26 Mar 2015 14:18:50

Generated On: 20 Jul 2016 12:09:14

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 4

Form: Biomarker-Urine (MHBMA) (1)

Data signed: (hfarmer1) 26 Mar 2015 14:18:50

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05115180000106
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-JAN-23
Timepoint-minutes	
Urine Start Day	4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 4

Form: Biomarker-Urine (MHBMA) (1)

Data signed: (hfarmer1) 26 Mar 2015 14:18:50

Generated On: 20 Jul 2016 12:09:14

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 4

Form: Biomarker-Urine (Creatinine)

Data signed: (hfarmer1) 26 Mar 2015 14:18:54

Generated On: 20 Jul 2016 12:09:14

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 4

Form: Biomarker-Urine (Creatinine) (1)

Data signed: (hfarmer1) 26 Mar 2015 14:18:54

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05115160000106
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-JAN-23
Timepoint-minutes	
Urine Start Day	4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 4

Form: Biomarker-Urine (Creatinine) (1)

Data signed: (hfarmer1) 26 Mar 2015 14:18:54

Generated On: 20 Jul 2016 12:09:14

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 4

Form: Biomarker-Plasma (Nic, Cot, tHCot)

Data signed: (hfarmer1) 26 Mar 2015 14:18:50

Generated On: 20 Jul 2016 12:09:14

Sample type

PLASMA

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 4

Form: Biomarker-Plasma (Nic, Cot, tHCot) (1)

Data signed: (hfarmer1) 26 Mar 2015 14:18:50

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05112430000138
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Analyte	COT
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Sample type	PLASMA
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Result	.
--------	---

Result Unit	NG/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
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Celerion Study Number	AA99128-01
-----------------------	------------

Date of Collection	2014-JAN-23
--------------------	-------------

Timepoint-minutes	0
-------------------	---

Urine Start Day	
-----------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 4

Form: Biomarker-Plasma (Nic, Cot, tHCot) (1)

Data signed: (hfarmer1) 26 Mar 2015 14:18:50

Generated On: 20 Jul 2016 12:09:14

Urine End Day

4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 4

Form: Biomarker-Plasma (Nic, Cot, tHCot) (2)

Data signed: (hfarmer1) 26 Mar 2015 14:18:50

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05112430000138
----------------	----------------

Analyte	NIC
---------	-----

Sample type	PLASMA
-------------	--------

Result	.
--------	---

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

Lab Status	OTHER
------------	-------

Sample comment	ANALYSIS NOT REQUIRED
----------------	-----------------------

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
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Day of Visit	4
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Celerion Study Number	AA99128-01
-----------------------	------------

Date of Collection	2014-JAN-23
--------------------	-------------

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: 1062**

Folder: Day 4

Form: Biomarker-Plasma (Nic, Cot, tHCot) (2)

Data signed: (hfarmer1) 26 Mar 2015 14:18:50

Generated On: 20 Jul 2016 12:09:14

Urine End Day

4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 5

Form: Date of Visit

Data signed: (hfarmer1) 26 Mar 2015 14:18:57

Generated On: 20 Jul 2016 12:09:14

Date of Visit

24 JAN 2014
DD/MMM/YYYY

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 5

Form: Vital Signs

Data signed: (hfarmer1) 26 Mar 2015 14:18:57

Generated On: 20 Jul 2016 12:09:14

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

10:18
hour:min 24-hour clock

Pulse rate

54
beats per minute

Respiratory rate

16
breaths per minute

Blood Pressure (systolic)

108
mmHg

Blood Pressure (diastolic)

67
mmHg

Vital Signs Position of Subject

Supine ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 5

Form: Plasma Nicotine Samples <Day 5> (1)

Data signed: (hfarmer1) 26 Mar 2015 14:18:58

Generated On: 20 Jul 2016 12:09:14

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	24 JAN 2014
---------------------	-------------

Scheduled Time	T0 -15 min <input checked="" type="radio"/>
----------------	---

Time hour:min 24-hour clock	06:30
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 5

Form: Plasma Nicotine Samples <Day 5> (2)

Data signed: (hfarmer1) 26 Mar 2015 14:18:58

Generated On: 20 Jul 2016 12:09:14

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	24 JAN 2014
---------------------	-------------

Scheduled Time	T1 <input checked="" type="radio"/>
----------------	-------------------------------------

Time hour:min 24-hour clock	08:42
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 5

Form: Plasma Nicotine Samples <Day 5> (3)

Data signed: (hfarmer1) 26 Mar 2015 14:18:58

Generated On: 20 Jul 2016 12:09:14

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	24 JAN 2014
---------------------	-------------

Scheduled Time	T2 <input checked="" type="radio"/>
----------------	-------------------------------------

Time hour:min 24-hour clock	10:42
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 5

Form: Plasma Nicotine Samples <Day 5> (4)

Data signed: (hfarmer1) 26 Mar 2015 14:18:58

Generated On: 20 Jul 2016 12:09:14

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	24 JAN 2014
---------------------	-------------

Scheduled Time	T3 <input checked="" type="radio"/>
----------------	-------------------------------------

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 5

Form: Plasma Nicotine Samples <Day 5> (5)

Data signed: (hfarmer1) 26 Mar 2015 14:18:58

Generated On: 20 Jul 2016 12:09:14

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	24 JAN 2014
---------------------	-------------

Scheduled Time	T4 <input checked="" type="radio"/>
----------------	-------------------------------------

Time hour:min 24-hour clock	14:42
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 5

Form: Plasma Nicotine Samples <Day 5> (6)

Data signed: (hfarmer1) 26 Mar 2015 14:18:58

Generated On: 20 Jul 2016 12:09:14

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	24 JAN 2014
---------------------	-------------

Scheduled Time	T5 <input checked="" type="radio"/>
----------------	-------------------------------------

Time hour:min 24-hour clock	16:42
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 5

Form: Plasma Nicotine Samples <Day 5> (7)

Data signed: (hfarmer1) 26 Mar 2015 14:18:58

Generated On: 20 Jul 2016 12:09:14

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	24 JAN 2014
---------------------	-------------

Scheduled Time	T6 <input checked="" type="radio"/>
----------------	-------------------------------------

Time hour:min 24-hour clock	18:42
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 5

Form: Plasma Nicotine Samples <Day 5> (8)

Data signed: (hfarmer1) 26 Mar 2015 14:18:58

Generated On: 20 Jul 2016 12:09:14

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	24 JAN 2014
---------------------	-------------

Scheduled Time	T7 <input checked="" type="radio"/>
----------------	-------------------------------------

Time hour:min 24-hour clock	20:42
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 5

Form: Plasma Nicotine Samples <Day 5> (9)

Data signed: (hfarmer1) 26 Mar 2015 14:18:58

Generated On: 20 Jul 2016 12:09:14

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	24 JAN 2014
---------------------	-------------

Scheduled Time	T8 <input checked="" type="radio"/>
----------------	-------------------------------------

Time hour:min 24-hour clock	22:42
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 5

Form: Plasma Cotinine Samples <Day 5> (1)

Data signed: (hfarmer1) 26 Mar 2015 14:18:58

Generated On: 20 Jul 2016 12:09:14

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	24 JAN 2014
---------------------	-------------

Scheduled Time	T0 -15 min <input checked="" type="radio"/>
----------------	---

Time hour:min 24-hour clock	06:30
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 5

Form: Plasma Cotinine Samples <Day 5> (2)

Data signed: (hfarmer1) 26 Mar 2015 14:18:58

Generated On: 20 Jul 2016 12:09:14

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	24 JAN 2014
---------------------	-------------

Scheduled Time	T1 <input checked="" type="radio"/>
----------------	-------------------------------------

Time hour:min 24-hour clock	08:42
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 5

Form: Plasma Cotinine Samples <Day 5> (3)

Data signed: (hfarmer1) 26 Mar 2015 14:18:58

Generated On: 20 Jul 2016 12:09:14

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	24 JAN 2014
---------------------	-------------

Scheduled Time	T2 <input checked="" type="radio"/>
----------------	-------------------------------------

Time hour:min 24-hour clock	10:42
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 5

Form: Plasma Cotinine Samples <Day 5> (4)

Data signed: (hfarmer1) 26 Mar 2015 14:18:58

Generated On: 20 Jul 2016 12:09:14

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	24 JAN 2014
---------------------	-------------

Scheduled Time	T3 <input checked="" type="radio"/>
----------------	-------------------------------------

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 5

Form: Plasma Cotinine Samples <Day 5> (5)

Data signed: (hfarmer1) 26 Mar 2015 14:18:58

Generated On: 20 Jul 2016 12:09:14

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	24 JAN 2014
---------------------	-------------

Scheduled Time	T4 <input checked="" type="radio"/>
----------------	-------------------------------------

Time hour:min 24-hour clock	14:42
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 5

Form: Plasma Cotinine Samples <Day 5> (6)

Data signed: (hfarmer1) 26 Mar 2015 14:18:58

Generated On: 20 Jul 2016 12:09:14

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	24 JAN 2014
---------------------	-------------

Scheduled Time	T5 <input checked="" type="radio"/>
----------------	-------------------------------------

Time hour:min 24-hour clock	16:42
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 5

Form: Plasma Cotinine Samples <Day 5> (7)

Data signed: (hfarmer1) 26 Mar 2015 14:18:58

Generated On: 20 Jul 2016 12:09:14

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	24 JAN 2014
---------------------	-------------

Scheduled Time	T6 <input checked="" type="radio"/>
----------------	-------------------------------------

Time hour:min 24-hour clock	18:42
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 5

Form: Plasma Cotinine Samples <Day 5> (8)

Data signed: (hfarmer1) 26 Mar 2015 14:18:58

Generated On: 20 Jul 2016 12:09:14

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	24 JAN 2014
---------------------	-------------

Scheduled Time	T7 <input checked="" type="radio"/>
----------------	-------------------------------------

Time hour:min 24-hour clock	20:42
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 5

Form: Plasma Cotinine Samples <Day 5> (9)

Data signed: (hfarmer1) 26 Mar 2015 14:18:58

Generated On: 20 Jul 2016 12:09:14

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	24 JAN 2014
---------------------	-------------

Scheduled Time	T8 <input checked="" type="radio"/>
----------------	-------------------------------------

Time hour:min 24-hour clock	22:42
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 5

Form: CoHb Blood Sample(CC/THS) (1)

Data signed: (hfarmer1) 26 Mar 2015 14:18:57

Generated On: 20 Jul 2016 12:09:14

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	24 JAN 2014
---------------------	-------------

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

Time hour:min 24-hour clock	06:30
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 5

Form: CoHb Blood Sample(CC/THS) (2)

Data signed: (hfarmer1) 26 Mar 2015 14:18:57

Generated On: 20 Jul 2016 12:09:14

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	24 JAN 2014
---------------------	-------------

Scheduled Time	12:00 - 13:30 <input checked="" type="radio"/>
----------------	--

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 5

Form: CoHb Blood Sample(CC/THS) (3)

Data signed: (hfarmer1) 26 Mar 2015 14:18:57

Generated On: 20 Jul 2016 12:09:14

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	24 JAN 2014
---------------------	-------------

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

Time hour:min 24-hour clock	16:12
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 5

Form: CoHb Blood Sample(CC/THS) (4)

Data signed: (hfarmer1) 26 Mar 2015 14:18:57

Generated On: 20 Jul 2016 12:09:14

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	24 JAN 2014
---------------------	-------------

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

Time hour:min 24-hour clock	20:42
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 5

Form: CO Breath Test (1)

Data signed: (hfarmer1) 26 Mar 2015 14:18:57

Generated On: 20 Jul 2016 12:09:14

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

If Not Done, please specify the reason: _____

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

Actual Time of Assessment hour:min 24-hour clock	06:29
---	-------

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 5

Form: CO Breath Test (2)

Data signed: (hfarmer1) 26 Mar 2015 14:18:57

Generated On: 20 Jul 2016 12:09:14

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	12:17
---	-------

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 5

Form: CO Breath Test (3)

Data signed: (hfarmer1) 26 Mar 2015 14:18:57

Generated On: 20 Jul 2016 12:09:14

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

If Not Done, please specify the reason: _____

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

Actual Time of Assessment hour:min 24-hour clock	16:14
---	-------

Result(ppm)	5
-------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 5

Form: CO Breath Test (4)

Data signed: (hfarmer1) 26 Mar 2015 14:18:57

Generated On: 20 Jul 2016 12:09:14

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

If Not Done, please specify the reason: _____

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

Actual Time of Assessment hour:min 24-hour clock	20:32
---	-------

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

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1062

Folder: Day 5

Form: CYP1A2 activity Sample

Data signed: (hfarmer1) 26 Mar 2015 14:18:54

Generated On: 20 Jul 2016 12:09:14

Time of caffeine tablet intake	10:12
	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
24 JAN 2014	16:12	Caffeine
24 JAN 2014	16:12	Paraxanthine

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 5

Form: 24 hour urine collections

Data signed: (hfarmer1) 26 Mar 2015 14:18:57

Generated On: 20 Jul 2016 12:09:14

Start Time	06:15
	hour:min 24-hour clock

End Date	25 JAN 2014
	DD/MMM/YYYY

End Time	06:17
	hour:min 24-hour clock

Volume	1643
	mL

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 5

Form: Sample Urine Collection

Data signed: (hfarmer1) 26 Mar 2015 14:18:57

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Day 5

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Data signed: (hfarmer1) 26 Mar 2015 14:18:59

Generated On: 20 Jul 2016 12:09:14

Date of Birth

(b) (6)

Date of assessment
DD/MMM/YYYY

2014 JAN 24
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?

Slight ☒

1. Angry, irritable, frustrated

How have you been feeling over the past 24 hours?

None ☒

2. Anxious, nervous

How have you been feeling over the past 24 hours?

None ☒

3. Depressed Mood, sad

How have you been feeling over the past 24 hours?

Mild ☒

4. Desire or craving to smoke

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 5

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Data signed: (hfarmer1) 26 Mar 2015 14:18:59

Generated On: 20 Jul 2016 12:09:14

How have you been feeling over the past 24 hours? None ☐

5. Difficulty concentrating

How have you been feeling over the past 24 hours? Mild ☐

6. Increased appetite, hungry, weight gain

How have you been feeling over the past 24 hours? None ☐

7. Insomnia, sleep problems, awakening at night

How have you been feeling over the past 24 hours? Slight ☐

8. Restless

How have you been feeling over the past 24 hours? Slight ☐

9. Impatient

How have you been feeling over the past 24 hours? None ☐

10. Constipation

How have you been feeling over the past 24 hours? None ☐

11. Dizziness

How have you been feeling over the past 24 hours? None ☐

12. Coughing

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 5

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Data signed: (hfarmer1) 26 Mar 2015 14:18:59

Generated On: 20 Jul 2016 12:09:14

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: 1062

Folder: Day 5

Form: Cough Assessment

Data signed: (hfarmer1) 26 Mar 2015 14:19:00

Generated On: 20 Jul 2016 12:09:14

Date of Birth

(b) (6)

Date of assessment
DD/MMM/YYYY

2014 JAN 24
DD/MMM/YYYY

Time of assessment

06:17
hour:min 24-hour clock

Assessment Status

Completed ☒

Have you experienced a regular need to cough e.g.
coughing several times in the last 24 hrs?

Yes ☒

If YES, please answer the following questions:

First Question: Cough Impact Scale
How much is your cough bothering you?

34

Second Question: Cough Intensity Scale:
How intense is your cough?

Very mild ☒

Third Question: Cough Frequency Scale:
How frequently do you normally have to cough each
day?

Sometimes ☒

Fourth Question: Sputum Production
To what extent do you produce sputum when coughing?

No sputum ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 5

Form: Lab_BU_COHB (1)

Data signed: (hfarmer1) 26 Mar 2015 14:19:03

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05115150000136
----------------	----------------

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

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

Result	.
--------	---

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

Lab Status	OTHER
------------	-------

Sample comment	ANALYSIS NOT REQUIRED
----------------	-----------------------

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

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

Planned time point (Hour)	6
---------------------------	---

Day of Visit	5
--------------	---

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

Date of Collection	2014-JAN-24
--------------------	-------------

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 5

Form: Lab_BU_COHB (1)

Data signed: (hfarmer1) 26 Mar 2015 14:19:03

Generated On: 20 Jul 2016 12:09:14

Start Day (24 hour urine only) _____

End Day (24 hour Urine Only) _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 5

Form: Lab_BU_COHB (2)

Data signed: (hfarmer1) 26 Mar 2015 14:19:03

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05115150000137
----------------	----------------

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

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

Result	.
--------	---

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

Lab Status	OTHER
------------	-------

Sample comment	ANALYSIS NOT REQUIRED
----------------	-----------------------

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

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

Planned time point (Hour)	12
---------------------------	----

Day of Visit	5
--------------	---

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

Date of Collection	2014-JAN-24
--------------------	-------------

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 5

Form: Lab_BU_COHB (2)

Data signed: (hfarmer1) 26 Mar 2015 14:19:03

Generated On: 20 Jul 2016 12:09:14

Start Day (24 hour urine only) _____

End Day (24 hour Urine Only) _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 5

Form: Lab_BU_COHB (3)

Data signed: (hfarmer1) 26 Mar 2015 14:19:03

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05115150000138
Analyte	CARBOXYHEMOGLOBIN
Sample type	BLOOD
Result	.
Result Unit	%
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	SPECTROPHOTOMETRIC
Lower limit of quantification	0.500
Planned time point (Hour)	16
Day of Visit	5
Celerion Study Number	AA99128-16
Date of Collection	2014-JAN-24
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 5

Form: Lab_BU_COHB (3)

Data signed: (hfarmer1) 26 Mar 2015 14:19:03

Generated On: 20 Jul 2016 12:09:14

Start Day (24 hour urine only) _____

End Day (24 hour Urine Only) _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 5

Form: Lab_BU_COHB (4)

Data signed: (hfarmer1) 26 Mar 2015 14:19:03

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05115150000139
Analyte	CARBOXYHEMOGLOBIN
Sample type	BLOOD
Result	.
Result Unit	%
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	SPECTROPHOTOMETRIC
Lower limit of quantification	0.500
Planned time point (Hour)	20
Day of Visit	5
Celerion Study Number	AA99128-16
Date of Collection	2014-JAN-24
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 5

Form: Lab_BU_COHB (4)

Data signed: (hfarmer1) 26 Mar 2015 14:19:03

Generated On: 20 Jul 2016 12:09:14

Start Day (24 hour urine only) _____

End Day (24 hour Urine Only) _____

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1062

Folder: Day 5

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)

Data signed: (hfarmer1) 26 Mar 2015 14:19:00

Generated On: 20 Jul 2016 12:09:14

Date of Birth

(b) (6)

Date of assessment

2014 JAN 24
DD/MMM/YYYY

DD/MMM/YYYY

Time of assessment

20:03
hour:min 24-hour clock

Assessment Status

Completed ☒

1. Was smoking satisfying?

Very little ☐

2. Did cigarettes taste good?

Very little ☐

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

Not at all ☐

4. Did smoking calm you down?

Very little ☐

5. Did smoking make you feel more awake?

Not at all ☐

6. Did smoking make you feel less irritable?

Very little ☐

7. Did smoking help you concentrate?

Not at all ☐

8. Did smoking reduce your hunger for food?

Not at all ☐

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 5

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)

Data signed: (hfarmer1) 26 Mar 2015 14:19:00

Generated On: 20 Jul 2016 12:09:14

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

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

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

12. Did you enjoy smoking? Very little ☐

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 5

Form: Behavioral Risk Factor Surveillance System Questionnaire

Data signed: (hfarmer1) 26 Mar 2015 14:18:54

Generated On: 20 Jul 2016 12:09:14

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

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

Reason not done	
-----------------	--

Date of assessment	24 JAN 2014 DD/MMM/YYYY
--------------------	----------------------------

Time of assessment	20:11 hour:min 24-hour clock
--------------------	---------------------------------

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

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

During the past 12 months, have you stopped smoking for one day or longer because you were trying to quit smoking?	Yes <input type="radio"/>
--	---------------------------

How long has it been since you last smoked a cigarette, even one or two puffs?	Within the past month (less than 1 month ago) <input type="radio"/>
--	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 5

Form: Behavioral Risk Factor Surveillance System Questionnaire

Data signed: (hfarmer1) 26 Mar 2015 14:18:54

Generated On: 20 Jul 2016 12:09:14

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: 1062

Folder: Day 5

Form: Smoking Questionnaire (SQ)

Data signed: (hfarmer1) 26 Mar 2015 14:18:54

Generated On: 20 Jul 2016 12:09:14

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

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

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

Date of assessment	24 JAN 2014 DD/MMM/YYYY
--------------------	----------------------------

Time of assessment	20:13 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?	16 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: 1062**

Folder: Day 5

Form: Smoking Questionnaire (SQ)

Data signed: (hfarmer1) 26 Mar 2015 14:18:54

Generated On: 20 Jul 2016 12:09:14

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 **NEWPORT 100'S**
predominantly smoke in the last 12 months of smoking?

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1062

Folder: Day 5

Form: Smoking Questionnaire (SQ) (1)

Data signed: (hfarmer1) 26 Mar 2015 14:18:54

Generated On: 20 Jul 2016 12:09:14

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

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

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

Date of assessment	24 JAN 2014 DD/MMM/YYYY
--------------------	----------------------------

Time of assessment	20:13 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?	16 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: 1062

Folder: Day 5

Form: Smoking Questionnaire (SQ) (1)

Data signed: (hfarmer1) 26 Mar 2015 14:18:54

Generated On: 20 Jul 2016 12:09:14

Months _____

Days _____

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

Years _____

Months _____

Days _____

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

Time

Currently (last 3 months) ☒

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

Manufactured Cigarettes
per day

12

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: 1062**

Folder: Day 5

Form: Smoking Questionnaire (SQ) (1)

Data signed: (hfarmer1) 26 Mar 2015 14:18:54

Generated On: 20 Jul 2016 12:09:14

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: 1062

Folder: Day 5

Form: Smoking Questionnaire (SQ) (2)

Data signed: (hfarmer1) 26 Mar 2015 14:18:54

Generated On: 20 Jul 2016 12:09:14

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

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

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

Date of assessment	24 JAN 2014 DD/MMM/YYYY
--------------------	----------------------------

Time of assessment	20:13 hour:min 24-hour clock
--------------------	---------------------------------

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

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

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

4. If you ever smoked cigarettes regularly: At what age did you start to smoke regularly?	16 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: 1062**

Folder: Day 5

Form: Smoking Questionnaire (SQ) (2)

Data signed: (hfarmer1) 26 Mar 2015 14:18:54

Generated On: 20 Jul 2016 12:09:14

Months

Days

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

Years

Months

Days

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

Time

1 year ago ☒

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

Manufactured Cigarettes
per day

12

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: 1062**

Folder: Day 5

Form: Smoking Questionnaire (SQ) (2)

Data signed: (hfarmer1) 26 Mar 2015 14:18:54

Generated On: 20 Jul 2016 12:09:14

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: 1062

Folder: Day 5

Form: Smoking Questionnaire (SQ) (3)

Data signed: (hfarmer1) 26 Mar 2015 14:18:54

Generated On: 20 Jul 2016 12:09:14

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

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

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

Date of assessment	24 JAN 2014 DD/MMM/YYYY
--------------------	----------------------------

Time of assessment	20:13 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?	16 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: 1062

Folder: Day 5

Form: Smoking Questionnaire (SQ) (3)

Data signed: (hfarmer1) 26 Mar 2015 14:18:54

Generated On: 20 Jul 2016 12:09:14

Months

Days

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

Years

Months

Days

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

Time

5 years ago ☒

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

Manufactured Cigarettes
per day

12

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: 1062**

Folder: Day 5

Form: Smoking Questionnaire (SQ) (3)

Data signed: (hfarmer1) 26 Mar 2015 14:18:54

Generated On: 20 Jul 2016 12:09:14

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: 1062

Folder: Day 5

Form: Smoking Questionnaire (SQ) (4)

Data signed: (hfarmer1) 26 Mar 2015 14:18:54

Generated On: 20 Jul 2016 12:09:14

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

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

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

Date of assessment	24 JAN 2014 DD/MMM/YYYY
--------------------	----------------------------

Time of assessment	20:13 hour:min 24-hour clock
--------------------	---------------------------------

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

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

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

4. If you ever smoked cigarettes regularly: At what age did you start to smoke regularly?	16 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: 1062

Folder: Day 5

Form: Smoking Questionnaire (SQ) (4)

Data signed: (hfarmer1) 26 Mar 2015 14:18:54

Generated On: 20 Jul 2016 12:09:14

Months

Days

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

Years

Months

Days

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

Time

10 years ago ☒

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

Manufactured Cigarettes
per day

12

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: 1062**

Folder: Day 5

Form: Smoking Questionnaire (SQ) (4)

Data signed: (hfarmer1) 26 Mar 2015 14:18:54

Generated On: 20 Jul 2016 12:09:14

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: 1062

Folder: Day 5

Form: Smoking Questionnaire (SQ) (5)

Data signed: (hfarmer1) 26 Mar 2015 14:18:54

Generated On: 20 Jul 2016 12:09:14

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

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

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

Date of assessment	24 JAN 2014 DD/MMM/YYYY
--------------------	----------------------------

Time of assessment	20:13 hour:min 24-hour clock
--------------------	---------------------------------

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

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

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

4. If you ever smoked cigarettes regularly: At what age did you start to smoke regularly?	16 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: 1062

Folder: Day 5

Form: Smoking Questionnaire (SQ) (5)

Data signed: (hfarmer1) 26 Mar 2015 14:18:54

Generated On: 20 Jul 2016 12:09:14

Months

Days

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

Years

Months

Days

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

Time

15 years ago ☒

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

Manufactured Cigarettes
per day

12

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: 1062**

Folder: Day 5

Form: Smoking Questionnaire (SQ) (5)

Data signed: (hfarmer1) 26 Mar 2015 14:18:54

Generated On: 20 Jul 2016 12:09:14

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: 1062

Folder: Day 5

Form: Smoking Questionnaire (SQ) (6)

Data signed: (hfarmer1) 26 Mar 2015 14:18:54

Generated On: 20 Jul 2016 12:09:14

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

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

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

Date of assessment	24 JAN 2014 DD/MMM/YYYY
--------------------	----------------------------

Time of assessment	20:13 hour:min 24-hour clock
--------------------	---------------------------------

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

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

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

4. If you ever smoked cigarettes regularly: At what age did you start to smoke regularly?	16 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: 1062

Folder: Day 5

Form: Smoking Questionnaire (SQ) (6)

Data signed: (hfarmer1) 26 Mar 2015 14:18:54

Generated On: 20 Jul 2016 12:09:14

Months

Days

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

Years

Months

Days

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

Time

20 years ago ☒

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

Manufactured Cigarettes
per day

12

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: 1062**

Folder: Day 5

Form: Smoking Questionnaire (SQ) (6)

Data signed: (hfarmer1) 26 Mar 2015 14:18:54

Generated On: 20 Jul 2016 12:09:14

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: 1062

Folder: Day 5

Form: Smoking Questionnaire (SQ) (7)

Data signed: (hfarmer1) 26 Mar 2015 14:18:54

Generated On: 20 Jul 2016 12:09:14

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

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

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

Date of assessment	24 JAN 2014 DD/MMM/YYYY
--------------------	----------------------------

Time of assessment	20:13 hour:min 24-hour clock
--------------------	---------------------------------

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

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

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

4. If you ever smoked cigarettes regularly: At what age did you start to smoke regularly?	16 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: 1062

Folder: Day 5

Form: Smoking Questionnaire (SQ) (7)

Data signed: (hfarmer1) 26 Mar 2015 14:18:54

Generated On: 20 Jul 2016 12:09:14

Months

Days

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

Years

Months

Days

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

Time

More than 20 years ago ☒

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

Manufactured Cigarettes
per day

12

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: 1062**

Folder: Day 5

Form: Smoking Questionnaire (SQ) (7)

Data signed: (hfarmer1) 26 Mar 2015 14:18:54

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Day 5

Form: Supplemental Questions

Data signed: (hfarmer1) 26 Mar 2015 14:18:55

Generated On: 20 Jul 2016 12:09:14

Was paper questionnaire used?

Yes ☒

Reason not done

Date of Assessment

24 JAN 2014
DD/MMM/YYYY

Time of assessment

20:14

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: 1062**

Folder: Day 5

Form: Supplemental Questions (1)

Data signed: (hfarmer1) 26 Mar 2015 14:18:55

Generated On: 20 Jul 2016 12:09:14

Was paper questionnaire used?

Yes ☒

Reason not done

Date of Assessment

24 JAN 2014
DD/MMM/YYYY

Time of assessment

20:14

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

Comments (open-end)

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 5

Form: Supplemental Questions (2)

Data signed: (hfarmer1) 26 Mar 2015 14:18:55

Generated On: 20 Jul 2016 12:09:14

Was paper questionnaire used? Yes ☐

Reason not done _____

Date of Assessment 24 JAN 2014
DD/MMM/YYYY

Time of assessment 20:14

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 _____

Comments (open-end) _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 5

Form: Supplemental Questions (3)

Data signed: (hfarmer1) 26 Mar 2015 14:18:55

Generated On: 20 Jul 2016 12:09:14

Was paper questionnaire used?

Yes ☒

Reason not done

Date of Assessment

24 JAN 2014
DD/MMM/YYYY

Time of assessment

20:14

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

Comments (open-end)

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 5

Form: Supplemental Questions (4)

Data signed: (hfarmer1) 26 Mar 2015 14:18:55

Generated On: 20 Jul 2016 12:09:14

Was paper questionnaire used? Yes ☐

Reason not done _____

Date of Assessment 24 JAN 2014
DD/MMM/YYYY

Time of assessment 20:14

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 _____

Comments (open-end) _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 5

Form: Supplemental Questions (5)

Data signed: (hfarmer1) 26 Mar 2015 14:18:55

Generated On: 20 Jul 2016 12:09:14

Was paper questionnaire used? Yes ☐

Reason not done _____

Date of Assessment 24 JAN 2014
DD/MMM/YYYY

Time of assessment 20:14

1. How long it takes for the subject to complete the SQ 02 minutes

Question 6. Was the SQ ☐
self-explaining?

Answer _____

Comments (open-end) _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 5

Form: Supplemental Questions (6)

Data signed: (hfarmer1) 26 Mar 2015 14:18:55

Generated On: 20 Jul 2016 12:09:14

Was paper questionnaire used? Yes ☐

Reason not done _____

Date of Assessment 24 JAN 2014
DD/MMM/YYYY

Time of assessment 20:14

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: 1062**

Folder: Day 5

Form: Questionnaire on smoking urges (QSU)

Data signed: (hfarmer1) 26 Mar 2015 14:18:59

Generated On: 20 Jul 2016 12:09:14

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

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

Date of assessment	2014 JAN 24
--------------------	-------------

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	Somewhat 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: 1062**

Folder: Day 5

Form: Questionnaire on smoking urges (QSU)

Data signed: (hfarmer1) 26 Mar 2015 14:18:59

Generated On: 20 Jul 2016 12:09:14

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 Disagree ☐

10. I am going to smoke as soon as possible Somewhat agree ☐

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 5

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

Data signed: (hfarmer1) 26 Mar 2015 14:19:03

Generated On: 20 Jul 2016 12:09:14

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 5

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

Data signed: (hfarmer1) 26 Mar 2015 14:19:03

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05112450000107
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	5
Celerion Study Number	AA99128-03
Date of Collection	2014-JAN-24
Timepoint-minutes	
Urine Start Day	5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 5

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

Data signed: (hfarmer1) 26 Mar 2015 14:19:03

Generated On: 20 Jul 2016 12:09:14

Urine End Day

6

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 5

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (2)

Data signed: (hfarmer1) 26 Mar 2015 14:19:03

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05112450000107
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	5
Celerion Study Number	AA99128-03
Date of Collection	2014-JAN-24
Timepoint-minutes	
Urine Start Day	5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 5

Form: Biomarker-Urine (CEMA, HPMa, HBMA) (2)

Data signed: (hfarmer1) 26 Mar 2015 14:19:03

Generated On: 20 Jul 2016 12:09:14

Urine End Day

6

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 5

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (3)

Data signed: (hfarmer1) 26 Mar 2015 14:19:03

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05112450000107
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	5
Celerion Study Number	AA99128-03
Date of Collection	2014-JAN-24
Timepoint-minutes	
Urine Start Day	5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 5

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (3)

Data signed: (hfarmer1) 26 Mar 2015 14:19:03

Generated On: 20 Jul 2016 12:09:14

Urine End Day

6

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 5

Form: Biomarker-Urine (NNN, NNAL)

Data signed: (hfarmer1) 26 Mar 2015 14:19:00

Generated On: 20 Jul 2016 12:09:14

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 5

Form: Biomarker-Urine (NNN, NNAL) (1)

Data signed: (hfarmer1) 26 Mar 2015 14:19:00

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05112460000107
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-JAN-24
Timepoint-minutes	
Urine Start Day	5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 5

Form: Biomarker-Urine (NNN, NNAL) (1)

Data signed: (hfarmer1) 26 Mar 2015 14:19:00

Generated On: 20 Jul 2016 12:09:14

Urine End Day

6

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 5

Form: Biomarker-Urine (NNN, NNAL) (2)

Data signed: (hfarmer1) 26 Mar 2015 14:19:00

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05112460000107
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-JAN-24
Timepoint-minutes	
Urine Start Day	5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 5

Form: Biomarker-Urine (NNN, NNAL) (2)

Data signed: (hfarmer1) 26 Mar 2015 14:19:00

Generated On: 20 Jul 2016 12:09:14

Urine End Day

6

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 5

Form: Biomarker-Urine (HEMA)

Data signed: (hfarmer1) 26 Mar 2015 14:19:00

Generated On: 20 Jul 2016 12:09:14

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 5

Form: Biomarker-Urine (HEMA) (1)

Data signed: (hfarmer1) 26 Mar 2015 14:19:00

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05112470000107
Analyte	HEMA
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	AA99128-05
Date of Collection	2014-JAN-24
Timepoint-minutes	
Urine Start Day	5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 5

Form: Biomarker-Urine (HEMA) (1)

Data signed: (hfarmer1) 26 Mar 2015 14:19:00

Generated On: 20 Jul 2016 12:09:14

Urine End Day

6

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 5

Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)

Data signed: (hfarmer1) 26 Mar 2015 14:19:03

Generated On: 20 Jul 2016 12:09:14

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 5

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(1)**

Data signed: (hfarmer1) 26 Mar 2015 14:19:03

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05112480000085
Analyte	COT
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	AA99128-06
Date of Collection	2014-JAN-24
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 5

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(1)**

Data signed: (hfarmer1) 26 Mar 2015 14:19:03

Generated On: 20 Jul 2016 12:09:14

Urine Start Day	5
<hr/>	
Urine End Day	6
<hr/>	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 5

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(2)**

Data signed: (hfarmer1) 26 Mar 2015 14:19:03

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05112480000085
Analyte	COT-GLUC
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	AA99128-06
Date of Collection	2014-JAN-24
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 5

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(2)**

Data signed: (hfarmer1) 26 Mar 2015 14:19:03

Generated On: 20 Jul 2016 12:09:14

Urine Start Day	5
<hr/>	
Urine End Day	6
<hr/>	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 5

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(3)**

Data signed: (hfarmer1) 26 Mar 2015 14:19:03

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05112480000085
Analyte	NIC
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	AA99128-06
Date of Collection	2014-JAN-24
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 5

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(3)**

Data signed: (hfarmer1) 26 Mar 2015 14:19:03

Generated On: 20 Jul 2016 12:09:14

Urine Start Day	5
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Urine End Day	6
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 5

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(4)**

Data signed: (hfarmer1) 26 Mar 2015 14:19:03

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05112480000085
Analyte	NIC-GLUC
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	AA99128-06
Date of Collection	2014-JAN-24
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 5

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(4)**

Data signed: (hfarmer1) 26 Mar 2015 14:19:03

Generated On: 20 Jul 2016 12:09:14

Urine Start Day	5
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Urine End Day	6
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 5

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(5)**

Data signed: (hfarmer1) 26 Mar 2015 14:19:03

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05112480000085
Analyte	THCOT
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	AA99128-06
Date of Collection	2014-JAN-24
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 5

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(5)**

Data signed: (hfarmer1) 26 Mar 2015 14:19:03

Generated On: 20 Jul 2016 12:09:14

Urine Start Day	5
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Urine End Day	6
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 5

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(6)**

Data signed: (hfarmer1) 26 Mar 2015 14:19:03

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05112480000085
Analyte	THCOT-GLUC
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	AA99128-06
Date of Collection	2014-JAN-24
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 5

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(6)**

Data signed: (hfarmer1) 26 Mar 2015 14:19:03

Generated On: 20 Jul 2016 12:09:14

Urine Start Day	5
<hr/>	
Urine End Day	6
<hr/>	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 5

Form: Biomarker-Urine (3-OH BaP)

Data signed: (hfarmer1) 26 Mar 2015 14:19:04

Generated On: 20 Jul 2016 12:09:14

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 5

Form: Biomarker-Urine (3-OH BaP) (1)

Data signed: (hfarmer1) 26 Mar 2015 14:19:04

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05112490000107
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-JAN-24
Timepoint-minutes	
Urine Start Day	5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 5

Form: Biomarker-Urine (3-OH BaP) (1)

Data signed: (hfarmer1) 26 Mar 2015 14:19:04

Generated On: 20 Jul 2016 12:09:14

Urine End Day

6

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 5

Form: Biomarker-Plasma (Caffeine, Paraxanthine)

Generated On: 20 Jul 2016 12:09:14

Sample type

PLASMA

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 5

Form: Biomarker-Plasma (Caffeine, Paraxanthine) (1)

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05112500000029
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Analyte	CAFFEINE
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Sample type	PLASMA
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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)	6
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Day of Visit	5
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Celerion Study Number	AA99128-08
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Date of Collection	2014-JAN-21
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Timepoint-minutes	0
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Urine Start Day	
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 5

Form: Biomarker-Plasma (Caffeine, Paraxanthine) (1)

Generated On: 20 Jul 2016 12:09:14

Urine End Day	5
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 5

Form: Biomarker-Plasma (Caffeine, Paraxanthine) (2)

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05112500000029
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Analyte	PARAXANTHINE
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Sample type	PLASMA
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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)	6
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Day of Visit	5
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Celerion Study Number	AA99128-08
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Date of Collection	2014-JAN-21
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Timepoint-minutes	0
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Urine Start Day	
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 5

Form: Biomarker-Plasma (Caffeine, Paraxanthine) (2)

Generated On: 20 Jul 2016 12:09:14

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 5

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP)

Data signed: (hfarmer1) 26 Mar 2015 14:19:04

Generated On: 20 Jul 2016 12:09:14

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 5

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (1)

Data signed: (hfarmer1) 26 Mar 2015 14:19:04

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05112510000107
Analyte	1-NA
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	AA99128-09
Date of Collection	2014-JAN-24
Timepoint-minutes	
Urine Start Day	5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 5

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (1)

Data signed: (hfarmer1) 26 Mar 2015 14:19:04

Generated On: 20 Jul 2016 12:09:14

Urine End Day

6

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 5

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (2)

Data signed: (hfarmer1) 26 Mar 2015 14:19:04

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05112510000107
Analyte	2-NA
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	AA99128-09
Date of Collection	2014-JAN-24
Timepoint-minutes	
Urine Start Day	5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 5

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (2)

Data signed: (hfarmer1) 26 Mar 2015 14:19:04

Generated On: 20 Jul 2016 12:09:14

Urine End Day

6

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 5

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (3)

Data signed: (hfarmer1) 26 Mar 2015 14:19:04

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05112510000107
Analyte	4-ABP
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	AA99128-09
Date of Collection	2014-JAN-24
Timepoint-minutes	
Urine Start Day	5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 5

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (3)

Data signed: (hfarmer1) 26 Mar 2015 14:19:04

Generated On: 20 Jul 2016 12:09:14

Urine End Day

6

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 5

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (4)

Data signed: (hfarmer1) 26 Mar 2015 14:19:04

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05112510000107
Analyte	O-TOL
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	AA99128-09
Date of Collection	2014-JAN-24
Timepoint-minutes	
Urine Start Day	5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 5

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (4)

Data signed: (hfarmer1) 26 Mar 2015 14:19:04

Generated On: 20 Jul 2016 12:09:14

Urine End Day

6

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 5

Form: Biomarker-Urine (11-dTXb2)

Data signed: (hfarmer1) 26 Mar 2015 14:19:01

Generated On: 20 Jul 2016 12:09:14

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 5

Form: Biomarker-Urine (11-dTXb2) (1)

Data signed: (hfarmer1) 26 Mar 2015 14:19:01

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05112530000067
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-JAN-24
Timepoint-minutes	
Urine Start Day	5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 5

Form: Biomarker-Urine (11-dTXb2) (1)

Data signed: (hfarmer1) 26 Mar 2015 14:19:01

Generated On: 20 Jul 2016 12:09:14

Urine End Day

6

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 5

Form: Biomarker-Urine (iPF2a-III)

Data signed: (hfarmer1) 26 Mar 2015 14:19:01

Generated On: 20 Jul 2016 12:09:14

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 5

Form: Biomarker-Urine (iPF2a-III) (1)

Data signed: (hfarmer1) 26 Mar 2015 14:19:01

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05112540000067
Analyte	IPF2A-III
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	AA99128-12
Date of Collection	2014-JAN-24
Timepoint-minutes	
Urine Start Day	5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 5

Form: Biomarker-Urine (iPF2a-III) (1)

Data signed: (hfarmer1) 26 Mar 2015 14:19:01

Generated On: 20 Jul 2016 12:09:14

Urine End Day

6

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 5

Form: Biomarker-Urine (Ames)

Data signed: (hfarmer1) 26 Mar 2015 14:19:04

Generated On: 20 Jul 2016 12:09:14

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 5

Form: Biomarker-Urine (Ames) (1)

Data signed: (hfarmer1) 26 Mar 2015 14:19:04

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05113320000026
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-JAN-24
Timepoint-minutes	
Urine Start Day	5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 5

Form: Biomarker-Urine (Ames) (1)

Data signed: (hfarmer1) 26 Mar 2015 14:19:04

Generated On: 20 Jul 2016 12:09:14

Urine End Day

6

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 5

Form: Biomarker-Urine (1-OHP)

Data signed: (hfarmer1) 26 Mar 2015 14:19:04

Generated On: 20 Jul 2016 12:09:14

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 5

Form: Biomarker-Urine (1-OHP) (1)

Data signed: (hfarmer1) 26 Mar 2015 14:19:04

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05115190001196
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-JAN-24
Timepoint-minutes	
Urine Start Day	5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 5

Form: Biomarker-Urine (1-OHP) (1)

Data signed: (hfarmer1) 26 Mar 2015 14:19:04

Generated On: 20 Jul 2016 12:09:14

Urine End Day

6

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 5

Form: Biomarker-Urine (SPMA, SBMA)

Data signed: (hfarmer1) 26 Mar 2015 14:19:01

Generated On: 20 Jul 2016 12:09:14

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 5

Form: Biomarker-Urine (SPMA, SBMA) (1)

Data signed: (hfarmer1) 26 Mar 2015 14:19:01

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05115170000107
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-JAN-24
Timepoint-minutes	
Urine Start Day	5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 5

Form: Biomarker-Urine (SPMA, SBMA) (1)

Data signed: (hfarmer1) 26 Mar 2015 14:19:01

Generated On: 20 Jul 2016 12:09:14

Urine End Day

6

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 5

Form: Biomarker-Urine (SPMA, SBMA) (2)

Data signed: (hfarmer1) 26 Mar 2015 14:19:01

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05115170000107
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-JAN-24
Timepoint-minutes	
Urine Start Day	5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 5

Form: Biomarker-Urine (SPMA, SBMA) (2)

Data signed: (hfarmer1) 26 Mar 2015 14:19:01

Generated On: 20 Jul 2016 12:09:14

Urine End Day

6

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 5

Form: Biomarker-Urine (MHBMA)

Data signed: (hfarmer1) 26 Mar 2015 14:19:01

Generated On: 20 Jul 2016 12:09:14

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 5

Form: Biomarker-Urine (MHBMA) (1)

Data signed: (hfarmer1) 26 Mar 2015 14:19:01

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05115180000107
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-JAN-24
Timepoint-minutes	
Urine Start Day	5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 5

Form: Biomarker-Urine (MHBMA) (1)

Data signed: (hfarmer1) 26 Mar 2015 14:19:01

Generated On: 20 Jul 2016 12:09:14

Urine End Day

6

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 5

Form: Biomarker-Urine (Creatinine)

Data signed: (hfarmer1) 26 Mar 2015 14:19:04

Generated On: 20 Jul 2016 12:09:14

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 5

Form: Biomarker-Urine (Creatinine) (1)

Data signed: (hfarmer1) 26 Mar 2015 14:19:04

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05115160000107
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-JAN-24
Timepoint-minutes	
Urine Start Day	5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 5

Form: Biomarker-Urine (Creatinine) (1)

Data signed: (hfarmer1) 26 Mar 2015 14:19:04

Generated On: 20 Jul 2016 12:09:14

Urine End Day

6

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot)

Data signed: (hfarmer1) 26 Mar 2015 14:19:01

Generated On: 20 Jul 2016 12:09:14

Sample type

PLASMA

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (1)

Data signed: (hfarmer1) 26 Mar 2015 14:19:01

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05112430000139
Analyte	COT
Sample type	PLASMA
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	AA99128-01
Date of Collection	2014-JAN-24
Timepoint-minutes	-15
Urine Start Day	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (1)

Data signed: (hfarmer1) 26 Mar 2015 14:19:01

Generated On: 20 Jul 2016 12:09:14

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (2)

Data signed: (hfarmer1) 26 Mar 2015 14:19:01

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05112430000139
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Analyte	NIC
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Sample type	PLASMA
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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
----------------	-----------------------

Detection method	LC-MS/MS
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Planned time point (Hour)	0
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Day of Visit	5
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Celerion Study Number	AA99128-01
-----------------------	------------

Date of Collection	2014-JAN-24
--------------------	-------------

Timepoint-minutes	-15
-------------------	-----

Urine Start Day	
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (2)

Data signed: (hfarmer1) 26 Mar 2015 14:19:01

Generated On: 20 Jul 2016 12:09:14

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (3)

Data signed: (hfarmer1) 26 Mar 2015 14:19:01

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05112430000140
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Analyte	COT
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Sample type	PLASMA
-------------	--------

Result	.
--------	---

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

Lab Status	OTHER
------------	-------

Sample comment	ANALYSIS NOT REQUIRED
----------------	-----------------------

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	2
---------------------------	---

Day of Visit	5
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Celerion Study Number	AA99128-01
-----------------------	------------

Date of Collection	2014-JAN-24
--------------------	-------------

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: 1062**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (3)

Data signed: (hfarmer1) 26 Mar 2015 14:19:01

Generated On: 20 Jul 2016 12:09:14

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (4)

Data signed: (hfarmer1) 26 Mar 2015 14:19:01

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05112430000140
Analyte	NIC
Sample type	PLASMA
Result	.
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	2
Day of Visit	5
Celerion Study Number	AA99128-01
Date of Collection	2014-JAN-24
Timepoint-minutes	0
Urine Start Day	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (4)

Data signed: (hfarmer1) 26 Mar 2015 14:19:01

Generated On: 20 Jul 2016 12:09:14

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (5)

Data signed: (hfarmer1) 26 Mar 2015 14:19:01

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05112430000141
Analyte	COT
Sample type	PLASMA
Result	.
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	4
Day of Visit	5
Celerion Study Number	AA99128-01
Date of Collection	2014-JAN-24
Timepoint-minutes	0
Urine Start Day	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (5)

Data signed: (hfarmer1) 26 Mar 2015 14:19:01

Generated On: 20 Jul 2016 12:09:14

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (6)

Data signed: (hfarmer1) 26 Mar 2015 14:19:01

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05112430000141
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Analyte	NIC
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Sample type	PLASMA
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Result	.
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Result Unit	NG/ML
-------------	-------

Lab Status	OTHER
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Sample comment	ANALYSIS NOT REQUIRED
----------------	-----------------------

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	4
---------------------------	---

Day of Visit	5
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Celerion Study Number	AA99128-01
-----------------------	------------

Date of Collection	2014-JAN-24
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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: 1062**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (6)

Data signed: (hfarmer1) 26 Mar 2015 14:19:01

Generated On: 20 Jul 2016 12:09:14

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (7)

Data signed: (hfarmer1) 26 Mar 2015 14:19:01

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05112430000142
Analyte	COT
Sample type	PLASMA
Result	.
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	6
Day of Visit	5
Celerion Study Number	AA99128-01
Date of Collection	2014-JAN-24
Timepoint-minutes	0
Urine Start Day	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (7)

Data signed: (hfarmer1) 26 Mar 2015 14:19:01

Generated On: 20 Jul 2016 12:09:14

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (8)

Data signed: (hfarmer1) 26 Mar 2015 14:19:01

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05112430000142
Analyte	NIC
Sample type	PLASMA
Result	.
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	6
Day of Visit	5
Celerion Study Number	AA99128-01
Date of Collection	2014-JAN-24
Timepoint-minutes	0
Urine Start Day	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (8)

Data signed: (hfarmer1) 26 Mar 2015 14:19:01

Generated On: 20 Jul 2016 12:09:14

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (9)

Data signed: (hfarmer1) 26 Mar 2015 14:19:01

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05112430000143
Analyte	COT
Sample type	PLASMA
Result	.
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	8
Day of Visit	5
Celerion Study Number	AA99128-01
Date of Collection	2014-JAN-24
Timepoint-minutes	0
Urine Start Day	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (9)

Data signed: (hfarmer1) 26 Mar 2015 14:19:01

Generated On: 20 Jul 2016 12:09:14

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (10)

Data signed: (hfarmer1) 26 Mar 2015 14:19:01

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05112430000143
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Analyte	NIC
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Sample type	PLASMA
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Result	.
--------	---

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

Planned time point (Hour)	8
---------------------------	---

Day of Visit	5
--------------	---

Celerion Study Number	AA99128-01
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Date of Collection	2014-JAN-24
--------------------	-------------

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: 1062**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (10)

Data signed: (hfarmer1) 26 Mar 2015 14:19:01

Generated On: 20 Jul 2016 12:09:14

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (11)

Data signed: (hfarmer1) 26 Mar 2015 14:19:01

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05112430000144
Analyte	COT
Sample type	PLASMA
Result	.
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	10
Day of Visit	5
Celerion Study Number	AA99128-01
Date of Collection	2014-JAN-24
Timepoint-minutes	0
Urine Start Day	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (11)

Data signed: (hfarmer1) 26 Mar 2015 14:19:01

Generated On: 20 Jul 2016 12:09:14

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (12)

Data signed: (hfarmer1) 26 Mar 2015 14:19:01

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05112430000144
Analyte	NIC
Sample type	PLASMA
Result	.
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	10
Day of Visit	5
Celerion Study Number	AA99128-01
Date of Collection	2014-JAN-24
Timepoint-minutes	0
Urine Start Day	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (12)

Data signed: (hfarmer1) 26 Mar 2015 14:19:01

Generated On: 20 Jul 2016 12:09:14

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (13)

Data signed: (hfarmer1) 26 Mar 2015 14:19:01

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05112430000145
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Analyte	COT
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Sample type	PLASMA
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Result	.
--------	---

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

Lab Status	OTHER
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Sample comment	ANALYSIS NOT REQUIRED
----------------	-----------------------

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	12
---------------------------	----

Day of Visit	5
--------------	---

Celerion Study Number	AA99128-01
-----------------------	------------

Date of Collection	2014-JAN-24
--------------------	-------------

Timepoint-minutes	0
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Urine Start Day	
-----------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (13)

Data signed: (hfarmer1) 26 Mar 2015 14:19:01

Generated On: 20 Jul 2016 12:09:14

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (14)

Data signed: (hfarmer1) 26 Mar 2015 14:19:01

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05112430000145
Analyte	NIC
Sample type	PLASMA
Result	.
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	12
Day of Visit	5
Celerion Study Number	AA99128-01
Date of Collection	2014-JAN-24
Timepoint-minutes	0
Urine Start Day	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (14)

Data signed: (hfarmer1) 26 Mar 2015 14:19:01

Generated On: 20 Jul 2016 12:09:14

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (15)

Data signed: (hfarmer1) 26 Mar 2015 14:19:01

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05112430000146
Analyte	COT
Sample type	PLASMA
Result	.
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	14
Day of Visit	5
Celerion Study Number	AA99128-01
Date of Collection	2014-JAN-24
Timepoint-minutes	0
Urine Start Day	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (15)

Data signed: (hfarmer1) 26 Mar 2015 14:19:01

Generated On: 20 Jul 2016 12:09:14

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (16)

Data signed: (hfarmer1) 26 Mar 2015 14:19:01

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05112430000146
----------------	----------------

Analyte	NIC
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Sample type	PLASMA
-------------	--------

Result	.
--------	---

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

Lab Status	OTHER
------------	-------

Sample comment	ANALYSIS NOT REQUIRED
----------------	-----------------------

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	14
---------------------------	----

Day of Visit	5
--------------	---

Celerion Study Number	AA99128-01
-----------------------	------------

Date of Collection	2014-JAN-24
--------------------	-------------

Timepoint-minutes	0
-------------------	---

Urine Start Day	
-----------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (16)

Data signed: (hfarmer1) 26 Mar 2015 14:19:01

Generated On: 20 Jul 2016 12:09:14

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (17)

Data signed: (hfarmer1) 26 Mar 2015 14:19:01

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05112430000147
----------------	----------------

Analyte	COT
---------	-----

Sample type	PLASMA
-------------	--------

Result	.
--------	---

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

Lab Status	OTHER
------------	-------

Sample comment	ANALYSIS NOT REQUIRED
----------------	-----------------------

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	16
---------------------------	----

Day of Visit	5
--------------	---

Celerion Study Number	AA99128-01
-----------------------	------------

Date of Collection	2014-JAN-24
--------------------	-------------

Timepoint-minutes	0
-------------------	---

Urine Start Day	
-----------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (17)

Data signed: (hfarmer1) 26 Mar 2015 14:19:01

Generated On: 20 Jul 2016 12:09:14

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (18)

Data signed: (hfarmer1) 26 Mar 2015 14:19:01

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05112430000147
----------------	----------------

Analyte	NIC
---------	-----

Sample type	PLASMA
-------------	--------

Result	.
--------	---

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

Lab Status	OTHER
------------	-------

Sample comment	ANALYSIS NOT REQUIRED
----------------	-----------------------

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	16
---------------------------	----

Day of Visit	5
--------------	---

Celerion Study Number	AA99128-01
-----------------------	------------

Date of Collection	2014-JAN-24
--------------------	-------------

Timepoint-minutes	0
-------------------	---

Urine Start Day	
-----------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (18)

Data signed: (hfarmer1) 26 Mar 2015 14:19:01

Generated On: 20 Jul 2016 12:09:14

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 6

Form: Date of Visit

Data signed: (hfarmer1) 26 Mar 2015 14:19:05

Generated On: 20 Jul 2016 12:09:14

Date of Visit

25 JAN 2014
DD/MMM/YYYY

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 6

Form: Plasma Nicotine Samples <Day 6> (1)

Data signed: (hfarmer1) 26 Mar 2015 14:19:05

Generated On: 20 Jul 2016 12:09:14

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	25 JAN 2014
---------------------	-------------

Scheduled Time	T0 + 20H <input checked="" type="radio"/>
----------------	---

Time hour:min 24-hour clock	02:42
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 6

Form: Plasma Nicotine Samples <Day 6> (2)

Data signed: (hfarmer1) 26 Mar 2015 14:19:05

Generated On: 20 Jul 2016 12:09:14

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	25 JAN 2014
---------------------	-------------

Scheduled Time	T0 + 24H <input checked="" type="radio"/>
----------------	---

Time hour:min 24-hour clock	06:42
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 6

Form: Plasma Cotinine Samples <Day 6> (1)

Data signed: (hfarmer1) 26 Mar 2015 14:19:05

Generated On: 20 Jul 2016 12:09:14

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	25 JAN 2014
---------------------	-------------

Scheduled Time	T0 + 20H <input checked="" type="radio"/>
----------------	---

Time hour:min 24-hour clock	02:42
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 6

Form: Plasma Cotinine Samples <Day 6> (2)

Data signed: (hfarmer1) 26 Mar 2015 14:19:05

Generated On: 20 Jul 2016 12:09:14

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	25 JAN 2014
---------------------	-------------

Scheduled Time	T0 + 24H <input checked="" type="radio"/>
----------------	---

Time hour:min 24-hour clock	06:42
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 6

Form: CoHb Blood Sample <prior to gas transfer and product>

Data signed: (hfarmer1) 26 Mar 2015 14:19:05

Generated On: 20 Jul 2016 12:09:14

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	25 JAN 2014
---------------------	-------------

Timepoint	Prior to gas transfer assessment and prior to product use <input checked="" type="radio"/>
-----------	--

Time hour:min 24-hour clock	06:42
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 6

Form: Oxysterols

Data signed: (hfarmer1) 26 Mar 2015 14:19:05

Generated On: 20 Jul 2016 12:09:14

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	25 JAN 2014
---------------------	-------------

Time hour:min 24-hour clock	06:42
--------------------------------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1062

Folder: Day 6

Form: CYP2A6 activity Sample

Data signed: (hfarmer1) 26 Mar 2015 14:19:04

Generated On: 20 Jul 2016 12:09:14

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

25 JAN 2014

06:42

trans-3'-hydroxyc
otinine

25 JAN 2014

06:42

cotinine

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 6

Form: Risk Marker: sICAM-1

Data signed: (hfarmer1) 26 Mar 2015 14:19:04

Generated On: 20 Jul 2016 12:09:14

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	25 JAN 2014
---------------------	-------------

Time hour:min 24-hour clock	06:42
--------------------------------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1062

Folder: Day 6

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Data signed: (hfarmer1) 26 Mar 2015 14:19:06

Generated On: 20 Jul 2016 12:09:14

Date of Birth

(b) (6)

Date of assessment
DD/MMM/YYYY

2014 JAN 25
DD/MMM/YYYY

Time of assessment

06:20
hour:min 24-hour clock

Assessment Status

Completed ☒

Please indicate for each of the items below, how you have been feeling over the past 24 hours

How have you been feeling over the past 24 hours?

Slight ☒

1. Angry, irritable, frustrated

How have you been feeling over the past 24 hours?

None ☐

2. Anxious, nervous

How have you been feeling over the past 24 hours?

Slight ☒

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: 1062**

Folder: Day 6

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Data signed: (hfarmer1) 26 Mar 2015 14:19:06

Generated On: 20 Jul 2016 12:09:14

How have you been feeling over the past 24 hours? None ☐

5. Difficulty concentrating

How have you been feeling over the past 24 hours? Mild ☐

6. Increased appetite, hungry, weight gain

How have you been feeling over the past 24 hours? Slight ☐

7. Insomnia, sleep problems, awakening at night

How have you been feeling over the past 24 hours? Slight ☐

8. Restless

How have you been feeling over the past 24 hours? Slight ☐

9. Impatient

How have you been feeling over the past 24 hours? None ☐

10. Constipation

How have you been feeling over the past 24 hours? None ☐

11. Dizziness

How have you been feeling over the past 24 hours? Slight ☐

12. Coughing

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 6

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Data signed: (hfarmer1) 26 Mar 2015 14:19:06

Generated On: 20 Jul 2016 12:09:14

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: 1062

Folder: Day 6

Form: Cough Assessment

Data signed: (hfarmer1) 26 Mar 2015 14:19:06

Generated On: 20 Jul 2016 12:09:14

Date of Birth

(b) (6)

Date of assessment
DD/MMM/YYYY

2014 JAN 25
DD/MMM/YYYY

Time of assessment

06:18
hour:min 24-hour clock

Assessment Status

Completed ☒

Have you experienced a regular need to cough e.g.
coughing several times in the last 24 hrs?

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: 1062**

Folder: Day 6

Form: Bio-banking (Transcriptomics)

Data signed: (hfarmer1) 26 Mar 2015 14:19:05

Generated On: 20 Jul 2016 12:09:14

Was a Bio-banking sample for transcriptomics taken?

Yes ☒

Time of Sample Collection

06:42
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: 1062**

Folder: Day 6

Form: Bio-banking (Biomarkers of exposure and risk markers)

Data signed: (hfarmer1) 26 Mar 2015 14:19:05

Generated On: 20 Jul 2016 12:09:14

Was a Bio-banking sample for biomarkers of exposure
and risk markers taken?

Yes ☒

Time of Sample Collection

06:42
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: 1062**

Folder: Day 6

Form: Bio-banking (nasal epithelial collection/buccal collection)

Data signed: (hfarmer1) 26 Mar 2015 14:19:05

Generated On: 20 Jul 2016 12:09:14

Was a Bio-banking sample for nasal epithelial collection/buccal collection taken?	Yes <input type="radio"/>
---	---------------------------

Time of Buccal Collection	10:51
	hour:min 24-hour clock

Time of Nasal Epithelial Collection	10:48
	hour:min 24-hour clock

Was the subject fasting for at least 30 minutes at time of sample collection?	Yes <input type="radio"/>
---	---------------------------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 6

Form: Lab_BU_COHB (1)

Data signed: (hfarmer1) 26 Mar 2015 14:19:07

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05115150000140
Analyte	CARBOXYHEMOGLOBIN
Sample type	BLOOD
Result	.
Result Unit	%
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
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	2015-JAN-25
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 6

Form: Lab_BU_COHB (1)

Data signed: (hfarmer1) 26 Mar 2015 14:19:07

Generated On: 20 Jul 2016 12:09:14

Start Day (24 hour urine only)

End Day (24 hour Urine Only)

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 6

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)

Data signed: (hfarmer1) 26 Mar 2015 14:19:06

Generated On: 20 Jul 2016 12:09:14

Date of Birth

(b) (6)

Date of assessment

2014 JAN 25
DD/MMM/YYYY

DD/MMM/YYYY

Time of assessment

06:21
hour:min 24-hour clock

Assessment Status

Completed ☐

1. Was smoking satisfying?

Not at all ☐

2. Did cigarettes taste good?

Very little ☐

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

Very little ☐

4. Did smoking calm you down?

Very little ☐

5. Did smoking make you feel more awake?

Not at all ☐

6. Did smoking make you feel less irritable?

Very little ☐

7. Did smoking help you concentrate?

Not at all ☐

8. Did smoking reduce your hunger for food?

Not at all ☐

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 6

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)

Data signed: (hfarmer1) 26 Mar 2015 14:19:06

Generated On: 20 Jul 2016 12:09:14

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

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

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

12. Did you enjoy smoking? Very little ☐

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 6

Form: Questionnaire on smoking urges (QSU)

Data signed: (hfarmer1) 26 Mar 2015 14:19:05

Generated On: 20 Jul 2016 12:09:14

Type	QSU
Date of Birth	(b) (6)
Date of assessment DD/MMM/YYYY	2014 JAN 25
Time of assessment hour:min 24-hour clock	06:21
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	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	Disagree <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: 1062**

Folder: Day 6

Form: Questionnaire on smoking urges (QSU)

Data signed: (hfarmer1) 26 Mar 2015 14:19:05

Generated On: 20 Jul 2016 12:09:14

7. A cigarette would taste good now Agree ☐

8. I would do almost anything for a cigarette now Disagree ☐

9. Smoking would make me less depressed Disagree ☐

10. I am going to smoke as soon as possible Agree ☐

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 6

Form: Risk Markers(CCLS) (1)

Data signed: (hfarmer1) 26 Mar 2015 14:19:06

Generated On: 20 Jul 2016 12:09:14

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	1062
----------------------	------

Subject Sex	M
-------------	---

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

Visit Name	DAY6
------------	------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	V225832
--------------	---------

Actual Collection Date	2014 01 25
------------------------	------------

Actual Collection Time	06:42
------------------------	-------

Specimen Condition	
--------------------	--

Battery ID	IM2293
------------	--------

Battery Name	SICAM-1
--------------	---------

Lab Test ID	IMT1768
-------------	---------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1062

Folder: Day 6

Form: Risk Markers(CCLS) (1)

Data signed: (hfarmer1) 26 Mar 2015 14:19:06

Generated On: 20 Jul 2016 12:09:14

Lab Test Name	SICAM-1-RUO
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	112.6
Reported Numeric Result	112.6
Reference Range low	98.8
Reference Range high	320.0
Range Units	NG/ML
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 6

Form: Risk Markers(CCLS) (1)

Data signed: (hfarmer1) 26 Mar 2015 14:19:06

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Day 6

Form: Biomarker-Plasma (Nic, Cot, tHCot)

Generated On: 20 Jul 2016 12:09:14

Sample type

PLASMA

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 6

Form: Biomarker-Plasma (Nic, Cot, tHCot) (1)

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05112430000148
----------------	----------------

Analyte	COT
---------	-----

Sample type	PLASMA
-------------	--------

Result	.
--------	---

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

Lab Status	OTHER
------------	-------

Sample comment	ANALYSIS NOT REQUIRED
----------------	-----------------------

Detection method	LC-MS/MS
------------------	----------

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

Day of Visit	6
--------------	---

Celerion Study Number	AA99128-01
-----------------------	------------

Date of Collection	2014-JAN-25
--------------------	-------------

Timepoint-minutes	0
-------------------	---

Urine Start Day	
-----------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 6

Form: Biomarker-Plasma (Nic, Cot, tHCot) (1)

Generated On: 20 Jul 2016 12:09:14

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 6

Form: Biomarker-Plasma (Nic, Cot, tHCot) (2)

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05112430000148
----------------	----------------

Analyte	NIC
---------	-----

Sample type	PLASMA
-------------	--------

Result	.
--------	---

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

Lab Status	OTHER
------------	-------

Sample comment	ANALYSIS NOT REQUIRED
----------------	-----------------------

Detection method	LC-MS/MS
------------------	----------

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

Day of Visit	6
--------------	---

Celerion Study Number	AA99128-01
-----------------------	------------

Date of Collection	2014-JAN-25
--------------------	-------------

Timepoint-minutes	0
-------------------	---

Urine Start Day	
-----------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 6

Form: Biomarker-Plasma (Nic, Cot, tHCot) (2)

Generated On: 20 Jul 2016 12:09:14

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 6

Form: Biomarker-Plasma (Nic, Cot, tHCot) (3)

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05112430000149
----------------	----------------

Analyte	COT
---------	-----

Sample type	PLASMA
-------------	--------

Result	.
--------	---

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

Lab Status	OTHER
------------	-------

Sample comment	ANALYSIS NOT REQUIRED
----------------	-----------------------

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	24
---------------------------	----

Day of Visit	6
--------------	---

Celerion Study Number	AA99128-01
-----------------------	------------

Date of Collection	2014-JAN-25
--------------------	-------------

Timepoint-minutes	0
-------------------	---

Urine Start Day	
-----------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 6

Form: Biomarker-Plasma (Nic, Cot, tHCot) (3)

Generated On: 20 Jul 2016 12:09:14

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 6

Form: Biomarker-Plasma (Nic, Cot, tHCot) (4)

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05112430000149
----------------	----------------

Analyte	NIC
---------	-----

Sample type	PLASMA
-------------	--------

Result	.
--------	---

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

Lab Status	OTHER
------------	-------

Sample comment	ANALYSIS NOT REQUIRED
----------------	-----------------------

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	24
---------------------------	----

Day of Visit	6
--------------	---

Celerion Study Number	AA99128-01
-----------------------	------------

Date of Collection	2014-JAN-25
--------------------	-------------

Timepoint-minutes	0
-------------------	---

Urine Start Day	
-----------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 6

Form: Biomarker-Plasma (Nic, Cot, tHCot) (4)

Generated On: 20 Jul 2016 12:09:14

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 6

Form: Biomarker-Plasma (Nic, Cot, tHCot) (5)

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05112520000029
----------------	----------------

Analyte	COT
---------	-----

Sample type	PLASMA
-------------	--------

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	6
--------------	---

Celerion Study Number	AA99128-10
-----------------------	------------

Date of Collection	2014-JAN-22
--------------------	-------------

Timepoint-minutes	0
-------------------	---

Urine Start Day	
-----------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 6

Form: Biomarker-Plasma (Nic, Cot, tHCot) (5)

Generated On: 20 Jul 2016 12:09:14

Urine End Day

6

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 6

Form: Biomarker-Plasma (Nic, Cot, tHCot) (6)

Generated On: 20 Jul 2016 12:09:14

Sample Barcode	05112520000029
----------------	----------------

Analyte	THCOT
---------	-------

Sample type	PLASMA
-------------	--------

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	6
--------------	---

Celerion Study Number	AA99128-10
-----------------------	------------

Date of Collection	2014-JAN-22
--------------------	-------------

Timepoint-minutes	0
-------------------	---

Urine Start Day	
-----------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Day 6

Form: Biomarker-Plasma (Nic, Cot, tHCot) (6)

Generated On: 20 Jul 2016 12:09:14

Urine End Day

6

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Discharge (Confinement)

Form: Date of Discharge

Data signed: (hfarmer1) 26 Mar 2015 14:19:10

Generated On: 20 Jul 2016 12:09:14

Date of Visit

25 JAN 2014
DD/MMM/YYYY

Discharge Time

11:47
hour:min 24-hour clock

Is the subject continuing in the ambulatory period?

Yes ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Discharge (Confinement)

Form: Vital Signs

Data signed: (hfarmer1) 26 Mar 2015 14:19:10

Generated On: 20 Jul 2016 12:09:14

Were Vitals Signs assessed? Yes ☒

If No, please specify the reason: _____

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

Time of assessment 09:43
hour:min 24-hour clock

Pulse rate 61
beats per minute

Respiratory rate 14
breaths per minute

Blood Pressure (systolic) 115
mmHg

Blood Pressure (diastolic) 72
mmHg

Vital Signs Position of Subject Supine ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Discharge (Confinement)

Form: Advice on the risk of smoking and debriefing

Data signed: (hfarmer1) 26 Mar 2015 14:19:10

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Discharge (Confinement)

Form: Physical Examination

Data signed: (hfarmer1) 26 Mar 2015 14:19:07

Generated On: 20 Jul 2016 12:09:14

Was the physical examination performed?

Yes ☒

If No, please specify the reason:

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Discharge (Confinement)

Form: Physical Examination (1)

Data signed: (hfarmer1) 26 Mar 2015 14:19:07

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Discharge (Confinement)

Form: Physical Examination (2)

Data signed: (hfarmer1) 26 Mar 2015 14:19:07

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Discharge (Confinement)

Form: Physical Examination (3)

Data signed: (hfarmer1) 26 Mar 2015 14:19:07

Generated On: 20 Jul 2016 12:09:14

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: 1062

Folder: Discharge (Confinement)

Form: Physical Examination (4)

Data signed: (hfarmer1) 26 Mar 2015 14:19:07

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Discharge (Confinement)

Form: Physical Examination (5)

Data signed: (hfarmer1) 26 Mar 2015 14:19:07

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Discharge (Confinement)

Form: Physical Examination (6)

Data signed: (hfarmer1) 26 Mar 2015 14:19:07

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Discharge (Confinement)

Form: Physical Examination (7)

Data signed: (hfarmer1) 26 Mar 2015 14:19:07

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Discharge (Confinement)

Form: Physical Examination (8)

Data signed: (hfarmer1) 26 Mar 2015 14:19:07

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Discharge (Confinement)

Form: Physical Examination (9)

Data signed: (hfarmer1) 26 Mar 2015 14:19:07

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Discharge (Confinement)

Form: Physical Examination (10)

Data signed: (hfarmer1) 26 Mar 2015 14:19:07

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Discharge (Confinement)

Form: Physical Examination (11)

Data signed: (hfarmer1) 26 Mar 2015 14:19:07

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Discharge (Confinement)

Form: Physical Examination (12)

Data signed: (hfarmer1) 26 Mar 2015 14:19:07

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Discharge (Confinement)

Form: Physical Examination (13)

Data signed: (hfarmer1) 26 Mar 2015 14:19:07

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Discharge (Confinement)

Form: Physical Examination (14)

Data signed: (hfarmer1) 26 Mar 2015 14:19:07

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Discharge (Confinement)

Form: Physical Examination (15)

Data signed: (hfarmer1) 26 Mar 2015 14:19:07

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Discharge (Confinement)

Form: Physical Examination (16)

Data signed: (hfarmer1) 26 Mar 2015 14:19:07

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Discharge (Confinement)

Form: Physical Examination (17)

Data signed: (hfarmer1) 26 Mar 2015 14:19:07

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Discharge (Confinement)

Form: Physical Examination (18)

Data signed: (hfarmer1) 26 Mar 2015 14:19:07

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Discharge (Confinement)

Form: Physical Examination (19)

Data signed: (hfarmer1) 26 Mar 2015 14:19:07

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Discharge (Confinement)

Form: Weight

Data signed: (hfarmer1) 26 Mar 2015 14:19:11

Generated On: 20 Jul 2016 12:09:14

Measurement(s) assessed?

Yes ☒

If No, please specify the reason: _____

Date of Assessment

25 JAN 2014
DD/MMM/YYYY

Time of assessment

10:03
hour:min 24-hour clock

Weight

77.6
kg

BMI

24.0

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Discharge (Confinement)

Form: ECG (12-Lead Standard)

Data signed: (hfarmer1) 26 Mar 2015 14:19:07

Generated On: 20 Jul 2016 12:09:14

Was the ECG performed? Yes ☒

If No, please specify the reason: _____

Position Supine ☒

Heart Rate 63
beats per minute

QRS Interval 106
msec

QT Interval 371
msec

QTcB Interval 380
msec

PR Interval 148
msec

QTcF Interval 377
msec

Interpretation Normal ☒

If Abnormal, Clinical Significance _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Discharge (Confinement)

Form: ECG (12-Lead Standard)

Data signed: (hfarmer1) 26 Mar 2015 14:19:07

Generated On: 20 Jul 2016 12:09:14

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

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1062

Folder: Discharge (Confinement)

Form: Gas Transfer

Data signed: (hcoleman1) 18 Jun 2015 19:58:07

Generated On: 20 Jul 2016 12:09:14

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: 1062

Folder: Discharge (Confinement)

Form: Lung Volume Measurements

Data signed: (hcoleman1) 18 Jun 2015 19:58:07

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Discharge (Confinement)

Form: Spirometry with a short-acting bronchodilator

Data signed: (hcoleman1) 18 Jun 2015 19:58:07

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Discharge (Confinement)

Form: Spirometry with a short-acting bronchodilator

Data signed: (hcoleman1) 18 Jun 2015 19:58:07

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Discharge (Confinement)

Form: Haematology

Data signed: (hfarmer1) 26 Mar 2015 14:19:07

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Discharge (Confinement)

Form: Clinical Chemistry

Data signed: (hfarmer1) 26 Mar 2015 14:19:07

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Discharge (Confinement)

Form: Urine analysis

Data signed: (hfarmer1) 26 Mar 2015 14:19:07

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Discharge (Confinement)

Form: CO Breath Test

Data signed: (hfarmer1) 26 Mar 2015 14:19:07

Generated On: 20 Jul 2016 12:09:14

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

If Not Done, please specify the reason: _____

Actual Time of Assessment	09:45
	hour:min 24-hour clock

Result	7
	ppm

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (1)

Data signed: (hfarmer1) 26 Mar 2015 14:19:11

Generated On: 20 Jul 2016 12:09:14

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	V225832
--------------	---------

Actual Collection Date	2014 01 25
------------------------	------------

Actual Collection Time	06:42
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	RC1029
------------	--------

Battery Name	TRIGLYCERIDES
--------------	---------------

Lab Test ID	RCT19
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (1)

Data signed: (hfarmer1) 26 Mar 2015 14:19:11

Generated On: 20 Jul 2016 12:09:14

Lab Test Name	TRIGLYCERIDES (GPO)
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	120
Reported Numeric Result	120
Reference Range low	55
Reference Range high	327
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: 1062**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (1)

Data signed: (hfarmer1) 26 Mar 2015 14:19:11

Generated On: 20 Jul 2016 12:09:14

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (2)

Data signed: (hfarmer1) 26 Mar 2015 14:19:11

Generated On: 20 Jul 2016 12:09:14

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	V225832
--------------	---------

Actual Collection Date	2014 01 25
------------------------	------------

Actual Collection Time	06:42
------------------------	-------

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: 1062

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (2)

Data signed: (hfarmer1) 26 Mar 2015 14:19:11

Generated On: 20 Jul 2016 12:09:14

Lab Test Name	FASTING GLUCOSE
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	75
Reported Numeric Result	75
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: 1062**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (2)

Data signed: (hfarmer1) 26 Mar 2015 14:19:11

Generated On: 20 Jul 2016 12:09:14

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (3)

Data signed: (hfarmer1) 26 Mar 2015 14:19:11

Generated On: 20 Jul 2016 12:09:14

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	<hr/>
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Subject Sex	M
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Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	V225832
--------------	---------

Actual Collection Date	2014 01 25
------------------------	------------

Actual Collection Time	06:42
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	RC272
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Battery Name	TOTAL CHOLESTEROL
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Lab Test ID	RCT20
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1062

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (3)

Data signed: (hfarmer1) 26 Mar 2015 14:19:11

Generated On: 20 Jul 2016 12:09:14

Lab Test Name	CHOLESTEROL (HIGH PERFORMANCE)
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	198
Reported Numeric Result	198
Reference Range low	162
Reference Range high	280
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: 1062**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (3)

Data signed: (hfarmer1) 26 Mar 2015 14:19:11

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (4)

Data signed: (hfarmer1) 26 Mar 2015 14:19:11

Generated On: 20 Jul 2016 12:09:14

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6)

Visit Name _____

Visit Type Scheduled ☒

Accession ID V225832

Actual Collection Date 2014 01 25

Actual Collection Time 06:42

Specimen Condition _____

Battery ID RC9255

Battery Name CHEMISTRY PANEL

Lab Test ID RCT1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (4)

Data signed: (hfarmer1) 26 Mar 2015 14:19:11

Generated On: 20 Jul 2016 12:09:14

Lab Test Name	TOTAL BILIRUBIN
Test ID	
Test Status	Done <input checked="" type="checkbox"/>
Reported Text Result	0.5
Reported Numeric Result	0.5
Reference Range low	0.2
Reference Range high	1.2
Range Units	MG/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (4)

Data signed: (hfarmer1) 26 Mar 2015 14:19:11

Generated On: 20 Jul 2016 12:09:14

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (5)

Data signed: (hfarmer1) 26 Mar 2015 14:19:11

Generated On: 20 Jul 2016 12:09:14

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"/>
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Accession ID	V225832
--------------	---------

Actual Collection Date	2014 01 25
------------------------	------------

Actual Collection Time	06:42
------------------------	-------

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

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1062

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (5)

Data signed: (hfarmer1) 26 Mar 2015 14:19:11

Generated On: 20 Jul 2016 12:09:14

Lab Test Name	TOTAL PROTEIN
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	6.5
Reported Numeric Result	6.5
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: 1062**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (5)

Data signed: (hfarmer1) 26 Mar 2015 14:19:11

Generated On: 20 Jul 2016 12:09:14

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (6)

Data signed: (hfarmer1) 26 Mar 2015 14:19:11

Generated On: 20 Jul 2016 12:09:14

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"/>
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Accession ID	V225832
--------------	---------

Actual Collection Date	2014 01 25
------------------------	------------

Actual Collection Time	06:42
------------------------	-------

Specimen Condition	<hr/>
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Battery ID	RC9255
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Battery Name	CHEMISTRY PANEL
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Lab Test ID	RCT13
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (6)

Data signed: (hfarmer1) 26 Mar 2015 14:19:11

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (6)

Data signed: (hfarmer1) 26 Mar 2015 14:19:11

Generated On: 20 Jul 2016 12:09:14

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (7)

Data signed: (hfarmer1) 26 Mar 2015 14:19:11

Generated On: 20 Jul 2016 12:09:14

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	V225832
--------------	---------

Actual Collection Date	2014 01 25
------------------------	------------

Actual Collection Time	06:42
------------------------	-------

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: 1062

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (7)

Data signed: (hfarmer1) 26 Mar 2015 14:19:11

Generated On: 20 Jul 2016 12:09:14

Lab Test Name	ALKALINE PHOSPHATASE
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	81
Reported Numeric Result	81
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: 1062**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (7)

Data signed: (hfarmer1) 26 Mar 2015 14:19:11

Generated On: 20 Jul 2016 12:09:14

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (8)

Data signed: (hfarmer1) 26 Mar 2015 14:19:11

Generated On: 20 Jul 2016 12:09:14

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	V225832
--------------	---------

Actual Collection Date	2014 01 25
------------------------	------------

Actual Collection Time	06:42
------------------------	-------

Specimen Condition	<hr/>
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Battery ID	RC9255
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Battery Name	CHEMISTRY PANEL
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Lab Test ID	RCT1408
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1062

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (8)

Data signed: (hfarmer1) 26 Mar 2015 14:19:11

Generated On: 20 Jul 2016 12:09:14

Lab Test Name	LDH
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	84
Reported Numeric Result	84
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: 1062**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (8)

Data signed: (hfarmer1) 26 Mar 2015 14:19:11

Generated On: 20 Jul 2016 12:09:14

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (9)

Data signed: (hfarmer1) 26 Mar 2015 14:19:11

Generated On: 20 Jul 2016 12:09:14

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	V225832
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Actual Collection Date	2014 01 25
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Actual Collection Time	06:42
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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	RCT15
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1062

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (9)

Data signed: (hfarmer1) 26 Mar 2015 14:19:11

Generated On: 20 Jul 2016 12:09:14

Lab Test Name	SERUM SODIUM
Test ID	
Test Status	Done <input type="checkbox"/>
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: 1062**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (9)

Data signed: (hfarmer1) 26 Mar 2015 14:19:11

Generated On: 20 Jul 2016 12:09:14

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (10)

Data signed: (hfarmer1) 26 Mar 2015 14:19:11

Generated On: 20 Jul 2016 12:09:14

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	V225832
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Actual Collection Date	2014 01 25
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Actual Collection Time	06:42
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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: 1062

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (10)

Data signed: (hfarmer1) 26 Mar 2015 14:19:11

Generated On: 20 Jul 2016 12:09:14

Lab Test Name	SERUM POTASSIUM
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	4.9
Reported Numeric Result	4.9
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: 1062**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (10)

Data signed: (hfarmer1) 26 Mar 2015 14:19:11

Generated On: 20 Jul 2016 12:09:14

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (11)

Data signed: (hfarmer1) 26 Mar 2015 14:19:11

Generated On: 20 Jul 2016 12:09:14

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	V225832
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Actual Collection Date	2014 01 25
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Actual Collection Time	06:42
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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	RCT29
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (11)

Data signed: (hfarmer1) 26 Mar 2015 14:19:11

Generated On: 20 Jul 2016 12:09:14

Lab Test Name	DIRECT BILIRUBIN
Test ID	
Test Status	Done <input 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: 1062**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (11)

Data signed: (hfarmer1) 26 Mar 2015 14:19:11

Generated On: 20 Jul 2016 12:09:14

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (12)

Data signed: (hfarmer1) 26 Mar 2015 14:19:11

Generated On: 20 Jul 2016 12:09:14

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	V225832
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Actual Collection Date	2014 01 25
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Actual Collection Time	06:42
------------------------	-------

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: 1062

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (12)

Data signed: (hfarmer1) 26 Mar 2015 14:19:11

Generated On: 20 Jul 2016 12:09:14

Lab Test Name	GGT
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	13
Reported Numeric Result	13
Reference Range low	10
Reference Range high	61
Range Units	U/L
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (12)

Data signed: (hfarmer1) 26 Mar 2015 14:19:11

Generated On: 20 Jul 2016 12:09:14

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (13)

Data signed: (hfarmer1) 26 Mar 2015 14:19:11

Generated On: 20 Jul 2016 12:09:14

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	V225832
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Actual Collection Date	2014 01 25
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Actual Collection Time	06:42
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Specimen Condition	<hr/>
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Battery ID	RC9255
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Battery Name	CHEMISTRY PANEL
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Lab Test ID	RCT392
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1062

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (13)

Data signed: (hfarmer1) 26 Mar 2015 14:19:11

Generated On: 20 Jul 2016 12:09:14

Lab Test Name	CREATININE (RATE BLANKED)
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Test ID	<hr/>
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Test Status	Done <input type="checkbox"/>
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Reported Text Result	1.3
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Reported Numeric Result	1.3
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Reference Range low	0.5
---------------------	-----

Reference Range high	1.2
----------------------	-----

Range Units	MG/DL
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Conventional Text Result	<hr/>
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Conventional Numeric Result	<hr/>
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Conventional Reference Range Low	<hr/>
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Conventional Reference Range High	<hr/>
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Conventional Units	<hr/>
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SI Text Result	<hr/>
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (13)

Data signed: (hfarmer1) 26 Mar 2015 14:19:11

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (14)

Data signed: (hfarmer1) 26 Mar 2015 14:19:11

Generated On: 20 Jul 2016 12:09:14

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	V225832
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Actual Collection Date	2014 01 25
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Actual Collection Time	06:42
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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: 1062

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (14)

Data signed: (hfarmer1) 26 Mar 2015 14:19:11

Generated On: 20 Jul 2016 12:09:14

Lab Test Name	ALT (SGPT)
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	11
Reported Numeric Result	11
Reference Range low	6
Reference Range high	43
Range Units	U/L
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (14)

Data signed: (hfarmer1) 26 Mar 2015 14:19:11

Generated On: 20 Jul 2016 12:09:14

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (15)

Data signed: (hfarmer1) 26 Mar 2015 14:19:11

Generated On: 20 Jul 2016 12:09:14

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	V225832
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Actual Collection Date	2014 01 25
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Actual Collection Time	06:42
------------------------	-------

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: 1062

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (15)

Data signed: (hfarmer1) 26 Mar 2015 14:19:11

Generated On: 20 Jul 2016 12:09:14

Lab Test Name	AST (SGOT)
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	10
Reported Numeric Result	10
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: 1062**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (15)

Data signed: (hfarmer1) 26 Mar 2015 14:19:11

Generated On: 20 Jul 2016 12:09:14

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Low ☒

Clinically Significant?

No ☒

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (16)

Data signed: (hfarmer1) 26 Mar 2015 14:19:11

Generated On: 20 Jul 2016 12:09:14

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	V225832
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Actual Collection Date	2014 01 25
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Actual Collection Time	06:42
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Specimen Condition	<hr/>
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Battery ID	RC9255
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Battery Name	CHEMISTRY PANEL
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Lab Test ID	RCT6
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1062

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (16)

Data signed: (hfarmer1) 26 Mar 2015 14:19:11

Generated On: 20 Jul 2016 12:09:14

Lab Test Name	UREA NITROGEN
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	16
Reported Numeric Result	16
Reference Range low	4
Reference Range high	24
Range Units	MG/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (16)

Data signed: (hfarmer1) 26 Mar 2015 14:19:11

Generated On: 20 Jul 2016 12:09:14

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (17)

Data signed: (hfarmer1) 26 Mar 2015 14:19:11

Generated On: 20 Jul 2016 12:09:14

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	V225832
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Actual Collection Date	2014 01 25
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Actual Collection Time	06:42
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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: 1062**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (17)

Data signed: (hfarmer1) 26 Mar 2015 14:19:11

Generated On: 20 Jul 2016 12:09:14

Lab Test Name	MONOCYTES
Test ID	
Test Status	Done <input type="checkbox"/>
Reported Text Result	0.28
Reported Numeric Result	0.28
Reference Range low	0.12
Reference Range high	0.92
Range Units	X10^3/UL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (17)

Data signed: (hfarmer1) 26 Mar 2015 14:19:11

Generated On: 20 Jul 2016 12:09:14

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (18)

Data signed: (hfarmer1) 26 Mar 2015 14:19:11

Generated On: 20 Jul 2016 12:09:14

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	V225832
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Actual Collection Date	2014 01 25
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Actual Collection Time	06:42
------------------------	-------

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: 1062

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (18)

Data signed: (hfarmer1) 26 Mar 2015 14:19:11

Generated On: 20 Jul 2016 12:09:14

Lab Test Name	MCH
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	32
Reported Numeric Result	32
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: 1062**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (18)

Data signed: (hfarmer1) 26 Mar 2015 14:19:11

Generated On: 20 Jul 2016 12:09:14

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (19)

Data signed: (hfarmer1) 26 Mar 2015 14:19:11

Generated On: 20 Jul 2016 12:09:14

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	V225832
--------------	---------

Actual Collection Date	2014 01 25
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Actual Collection Time	06:42
------------------------	-------

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: 1062**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (19)

Data signed: (hfarmer1) 26 Mar 2015 14:19:11

Generated On: 20 Jul 2016 12:09:14

Lab Test Name	MCHC
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	35
Reported Numeric Result	35
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: 1062**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (19)

Data signed: (hfarmer1) 26 Mar 2015 14:19:11

Generated On: 20 Jul 2016 12:09:14

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (20)

Data signed: (hfarmer1) 26 Mar 2015 14:19:11

Generated On: 20 Jul 2016 12:09:14

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	V225832
--------------	---------

Actual Collection Date	2014 01 25
------------------------	------------

Actual Collection Time	06:42
------------------------	-------

Specimen Condition	<hr/>
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Battery ID	HM1604
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Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
--------------	-----------------------------------

Lab Test ID	HMT11
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1062

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (20)

Data signed: (hfarmer1) 26 Mar 2015 14:19:11

Generated On: 20 Jul 2016 12:09:14

Lab Test Name	EOSINOPHILS
Test ID	
Test Status	Done <input checked="" 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: 1062**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (20)

Data signed: (hfarmer1) 26 Mar 2015 14:19:11

Generated On: 20 Jul 2016 12:09:14

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (21)

Data signed: (hfarmer1) 26 Mar 2015 14:19:11

Generated On: 20 Jul 2016 12:09:14

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	V225832
--------------	---------

Actual Collection Date	2014 01 25
------------------------	------------

Actual Collection Time	06:42
------------------------	-------

Specimen Condition	<hr/>
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Battery ID	HM1604
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Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
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Lab Test ID	HMT12
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1062

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (21)

Data signed: (hfarmer1) 26 Mar 2015 14:19:11

Generated On: 20 Jul 2016 12:09:14

Lab Test Name	BASOPHILS
Test ID	
Test Status	Done <input checked="" type="checkbox"/>
Reported Text Result	0.05
Reported Numeric Result	0.05
Reference Range low	0.00
Reference Range high	0.20
Range Units	X10^3/UL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (21)

Data signed: (hfarmer1) 26 Mar 2015 14:19:11

Generated On: 20 Jul 2016 12:09:14

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (22)

Data signed: (hfarmer1) 26 Mar 2015 14:19:11

Generated On: 20 Jul 2016 12:09:14

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	V225832
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Actual Collection Date	2014 01 25
------------------------	------------

Actual Collection Time	06:42
------------------------	-------

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: 1062**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (22)

Data signed: (hfarmer1) 26 Mar 2015 14:19:11

Generated On: 20 Jul 2016 12:09:14

Lab Test Name	PLATELETS
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	246
Reported Numeric Result	246
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: 1062**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (22)

Data signed: (hfarmer1) 26 Mar 2015 14:19:11

Generated On: 20 Jul 2016 12:09:14

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (23)

Data signed: (hfarmer1) 26 Mar 2015 14:19:11

Generated On: 20 Jul 2016 12:09:14

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	V225832
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Actual Collection Date	2014 01 25
------------------------	------------

Actual Collection Time	06:42
------------------------	-------

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: 1062

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (23)

Data signed: (hfarmer1) 26 Mar 2015 14:19:11

Generated On: 20 Jul 2016 12:09:14

Lab Test Name	NEUTROPHILS (%)
Test ID	
Test Status	Done <input checked="" type="checkbox"/>
Reported Text Result	65.2
Reported Numeric Result	65.2
Reference Range low	40.5
Reference Range high	75.0
Range Units	%
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (23)

Data signed: (hfarmer1) 26 Mar 2015 14:19:11

Generated On: 20 Jul 2016 12:09:14

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (24)

Data signed: (hfarmer1) 26 Mar 2015 14:19:11

Generated On: 20 Jul 2016 12:09:14

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	V225832
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Actual Collection Date	2014 01 25
------------------------	------------

Actual Collection Time	06:42
------------------------	-------

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: 1062

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (24)

Data signed: (hfarmer1) 26 Mar 2015 14:19:11

Generated On: 20 Jul 2016 12:09:14

Lab Test Name	LYMPHOCYTES (%)
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	28.4
Reported Numeric Result	28.4
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: 1062**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (24)

Data signed: (hfarmer1) 26 Mar 2015 14:19:11

Generated On: 20 Jul 2016 12:09:14

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (25)

Data signed: (hfarmer1) 26 Mar 2015 14:19:11

Generated On: 20 Jul 2016 12:09:14

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	V225832
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Actual Collection Date	2014 01 25
------------------------	------------

Actual Collection Time	06:42
------------------------	-------

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: 1062

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (25)

Data signed: (hfarmer1) 26 Mar 2015 14:19:11

Generated On: 20 Jul 2016 12:09:14

Lab Test Name	MONOCYTES (%)
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	4.0
Reported Numeric Result	4.0
Reference Range low	2.6
Reference Range high	10.1
Range Units	%
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (25)

Data signed: (hfarmer1) 26 Mar 2015 14:19:11

Generated On: 20 Jul 2016 12:09:14

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1062

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (26)

Data signed: (hfarmer1) 26 Mar 2015 14:19:11

Generated On: 20 Jul 2016 12:09:14

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	V225832
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Actual Collection Date	2014 01 25
------------------------	------------

Actual Collection Time	06:42
------------------------	-------

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: 1062**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (26)

Data signed: (hfarmer1) 26 Mar 2015 14:19:11

Generated On: 20 Jul 2016 12:09:14

Lab Test Name	EOSINOPHILS (%)
Test ID	
Test Status	Done <input type="checkbox"/>
Reported Text Result	1.6
Reported Numeric Result	1.6
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: 1062**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (26)

Data signed: (hfarmer1) 26 Mar 2015 14:19:11

Generated On: 20 Jul 2016 12:09:14

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (27)

Data signed: (hfarmer1) 26 Mar 2015 14:19:11

Generated On: 20 Jul 2016 12:09:14

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	V225832
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Actual Collection Date	2014 01 25
------------------------	------------

Actual Collection Time	06:42
------------------------	-------

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: 1062

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (27)

Data signed: (hfarmer1) 26 Mar 2015 14:19:11

Generated On: 20 Jul 2016 12:09:14

Lab Test Name	BASOPHILS (%)
Test ID	
Test Status	Done <input type="checkbox"/>
Reported Text Result	0.7
Reported Numeric Result	0.7
Reference Range low	0.0
Reference Range high	2.0
Range Units	%
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (27)

Data signed: (hfarmer1) 26 Mar 2015 14:19:11

Generated On: 20 Jul 2016 12:09:14

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (28)

Data signed: (hfarmer1) 26 Mar 2015 14:19:11

Generated On: 20 Jul 2016 12:09:14

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	V225832
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Actual Collection Date	2014 01 25
------------------------	------------

Actual Collection Time	06:42
------------------------	-------

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: 1062

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (28)

Data signed: (hfarmer1) 26 Mar 2015 14:19:11

Generated On: 20 Jul 2016 12:09:14

Lab Test Name	HEMATOCRIT
Test ID	
Test Status	Done <input 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: 1062**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (28)

Data signed: (hfarmer1) 26 Mar 2015 14:19:11

Generated On: 20 Jul 2016 12:09:14

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (29)

Data signed: (hfarmer1) 26 Mar 2015 14:19:11

Generated On: 20 Jul 2016 12:09:14

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	V225832
--------------	---------

Actual Collection Date	2014 01 25
------------------------	------------

Actual Collection Time	06:42
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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: 1062

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (29)

Data signed: (hfarmer1) 26 Mar 2015 14:19:11

Generated On: 20 Jul 2016 12:09:14

Lab Test Name	RBC
Test ID	
Test Status	Done <input checked="" type="checkbox"/>
Reported Text Result	5.0
Reported Numeric Result	5.0
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: 1062**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (29)

Data signed: (hfarmer1) 26 Mar 2015 14:19:11

Generated On: 20 Jul 2016 12:09:14

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (30)

Data signed: (hfarmer1) 26 Mar 2015 14:19:11

Generated On: 20 Jul 2016 12:09:14

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	<hr/>
----------------------	-------

Subject Sex	M
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Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	V225832
--------------	---------

Actual Collection Date	2014 01 25
------------------------	------------

Actual Collection Time	06:42
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

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: 1062**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (30)

Data signed: (hfarmer1) 26 Mar 2015 14:19:11

Generated On: 20 Jul 2016 12:09:14

Lab Test Name	MCV
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	91
Reported Numeric Result	91
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: 1062**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (30)

Data signed: (hfarmer1) 26 Mar 2015 14:19:11

Generated On: 20 Jul 2016 12:09:14

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (31)

Data signed: (hfarmer1) 26 Mar 2015 14:19:11

Generated On: 20 Jul 2016 12:09:14

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	V225832
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Actual Collection Date	2014 01 25
------------------------	------------

Actual Collection Time	06:42
------------------------	-------

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: 1062**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (31)

Data signed: (hfarmer1) 26 Mar 2015 14:19:11

Generated On: 20 Jul 2016 12:09:14

Lab Test Name	HEMOGLOBIN
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	15.7
Reported Numeric Result	15.7
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: 1062**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (31)

Data signed: (hfarmer1) 26 Mar 2015 14:19:11

Generated On: 20 Jul 2016 12:09:14

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (32)

Data signed: (hfarmer1) 26 Mar 2015 14:19:11

Generated On: 20 Jul 2016 12:09:14

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	V225832
--------------	---------

Actual Collection Date	2014 01 25
------------------------	------------

Actual Collection Time	06:42
------------------------	-------

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: 1062

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (32)

Data signed: (hfarmer1) 26 Mar 2015 14:19:11

Generated On: 20 Jul 2016 12:09:14

Lab Test Name	WBC
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	7.01
Reported Numeric Result	7.01
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: 1062**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (32)

Data signed: (hfarmer1) 26 Mar 2015 14:19:11

Generated On: 20 Jul 2016 12:09:14

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (33)

Data signed: (hfarmer1) 26 Mar 2015 14:19:11

Generated On: 20 Jul 2016 12:09:14

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	V225832
--------------	---------

Actual Collection Date	2014 01 25
------------------------	------------

Actual Collection Time	06:42
------------------------	-------

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: 1062

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (33)

Data signed: (hfarmer1) 26 Mar 2015 14:19:11


Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (33)

Data signed: (hfarmer1) 26 Mar 2015 14:19:11

Generated On: 20 Jul 2016 12:09:14

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (34)

Data signed: (hfarmer1) 26 Mar 2015 14:19:11

Generated On: 20 Jul 2016 12:09:14

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	V225832
--------------	---------

Actual Collection Date	2014 01 25
------------------------	------------

Actual Collection Time	06:42
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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: 1062**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (34)

Data signed: (hfarmer1) 26 Mar 2015 14:19:11

Generated On: 20 Jul 2016 12:09:14

Lab Test Name	NEUTROPHILS
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	4.57
Reported Numeric Result	4.57
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: 1062**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (34)

Data signed: (hfarmer1) 26 Mar 2015 14:19:11

Generated On: 20 Jul 2016 12:09:14

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (35)

Data signed: (hfarmer1) 26 Mar 2015 14:19:11

Generated On: 20 Jul 2016 12:09:14

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	V225832
--------------	---------

Actual Collection Date	2014 01 25
------------------------	------------

Actual Collection Time	06:42
------------------------	-------

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: 1062**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (35)

Data signed: (hfarmer1) 26 Mar 2015 14:19:11

Generated On: 20 Jul 2016 12:09:14

Lab Test Name	LYMPHOCYTES
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	2.00
Reported Numeric Result	2.00
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: 1062**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (35)

Data signed: (hfarmer1) 26 Mar 2015 14:19:11

Generated On: 20 Jul 2016 12:09:14

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (36)

Data signed: (hfarmer1) 26 Mar 2015 14:19:11

Generated On: 20 Jul 2016 12:09:14

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	V225832
--------------	---------

Actual Collection Date	2014 01 25
------------------------	------------

Actual Collection Time	06:42
------------------------	-------

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: 1062**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (36)

Data signed: (hfarmer1) 26 Mar 2015 14:19:11


Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (36)

Data signed: (hfarmer1) 26 Mar 2015 14:19:11

Generated On: 20 Jul 2016 12:09:14

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (37)

Data signed: (hfarmer1) 26 Mar 2015 14:19:11

Generated On: 20 Jul 2016 12:09:14

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	V225832
--------------	---------

Actual Collection Date	2014 01 25
------------------------	------------

Actual Collection Time	06:42
------------------------	-------

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: 1062**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (37)

Data signed: (hfarmer1) 26 Mar 2015 14:19:11

Generated On: 20 Jul 2016 12:09:14

Lab Test Name	UR SPECIFIC GRAVITY
Test ID	
Test Status	Done <input checked="" 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: 1062**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (37)

Data signed: (hfarmer1) 26 Mar 2015 14:19:11

Generated On: 20 Jul 2016 12:09:14

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (38)

Data signed: (hfarmer1) 26 Mar 2015 14:19:11

Generated On: 20 Jul 2016 12:09:14

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	V225832
--------------	---------

Actual Collection Date	2014 01 25
------------------------	------------

Actual Collection Time	06:42
------------------------	-------

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: 1062

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (38)

Data signed: (hfarmer1) 26 Mar 2015 14:19:11

Generated On: 20 Jul 2016 12:09:14

Lab Test Name	UR PH
Test ID	
Test Status	Done <input checked="" 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: 1062**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (38)

Data signed: (hfarmer1) 26 Mar 2015 14:19:11

Generated On: 20 Jul 2016 12:09:14

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (39)

Data signed: (hfarmer1) 26 Mar 2015 14:19:11

Generated On: 20 Jul 2016 12:09:14

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	V225832
--------------	---------

Actual Collection Date	2014 01 25
------------------------	------------

Actual Collection Time	06:42
------------------------	-------

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: 1062**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (39)

Data signed: (hfarmer1) 26 Mar 2015 14:19:11


Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (39)

Data signed: (hfarmer1) 26 Mar 2015 14:19:11

Generated On: 20 Jul 2016 12:09:14

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (40)

Data signed: (hfarmer1) 26 Mar 2015 14:19:11

Generated On: 20 Jul 2016 12:09:14

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	V225832
--------------	---------

Actual Collection Date	2014 01 25
------------------------	------------

Actual Collection Time	06:42
------------------------	-------

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: 1062

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (40)

Data signed: (hfarmer1) 26 Mar 2015 14:19:11


Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (40)

Data signed: (hfarmer1) 26 Mar 2015 14:19:11

Generated On: 20 Jul 2016 12:09:14

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (41)

Data signed: (hfarmer1) 26 Mar 2015 14:19:11

Generated On: 20 Jul 2016 12:09:14

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	V225832
--------------	---------

Actual Collection Date	2014 01 25
------------------------	------------

Actual Collection Time	06:42
------------------------	-------

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: 1062

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (41)

Data signed: (hfarmer1) 26 Mar 2015 14:19:11


Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (41)

Data signed: (hfarmer1) 26 Mar 2015 14:19:11

Generated On: 20 Jul 2016 12:09:14

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (42)

Data signed: (hfarmer1) 26 Mar 2015 14:19:11

Generated On: 20 Jul 2016 12:09:14

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	V225832
--------------	---------

Actual Collection Date	2014 01 25
------------------------	------------

Actual Collection Time	06:42
------------------------	-------

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: 1062**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (42)

Data signed: (hfarmer1) 26 Mar 2015 14:19:11

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (42)

Data signed: (hfarmer1) 26 Mar 2015 14:19:11

Generated On: 20 Jul 2016 12:09:14

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Discharge (Ambulatory)

Form: Date of Discharge

Data signed: (hfarmer1) 26 Mar 2015 14:19:27

Generated On: 20 Jul 2016 12:09:14

Date of Visit

31 JAN 2014
DD/MMM/YYYY

Discharge Time

10:35
hour:min 24-hour clock

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Discharge (Ambulatory)

Form: Vital Signs

Data signed: (hfarmer1) 26 Mar 2015 14:19:27

Generated On: 20 Jul 2016 12:09:14

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

31 JAN 2014
DD/MMM/YYYY

Time of assessment

10:12
hour:min 24-hour clock

Pulse rate

62
beats per minute

Respiratory rate

16
breaths per minute

Blood Pressure (systolic)

120
mmHg

Blood Pressure (diastolic)

80
mmHg

Vital Signs Position of Subject

Supine ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Discharge (Ambulatory)

Form: Advice on the risk of smoking and debriefing

Data signed: (hfarmer1) 26 Mar 2015 14:19:27

Generated On: 20 Jul 2016 12:09:14

Date	31 JAN 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: 1062**

Folder: Discharge (Ambulatory)

Form: Physical Examination

Data signed: (hfarmer1) 26 Mar 2015 14:19:26

Generated On: 20 Jul 2016 12:09:14

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of Assessment

31 JAN 2014
DD/MMM/YYYY

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Discharge (Ambulatory)

Form: Physical Examination (1)

Data signed: (hfarmer1) 26 Mar 2015 14:19:26

Generated On: 20 Jul 2016 12:09:14

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of Assessment 31 JAN 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: 1062**

Folder: Discharge (Ambulatory)

Form: Physical Examination (2)

Data signed: (hfarmer1) 26 Mar 2015 14:19:26

Generated On: 20 Jul 2016 12:09:14

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of Assessment

31 JAN 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: 1062**

Folder: Discharge (Ambulatory)

Form: Physical Examination (3)

Data signed: (hfarmer1) 26 Mar 2015 14:19:26

Generated On: 20 Jul 2016 12:09:14

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of Assessment 31 JAN 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: 1062**

Folder: Discharge (Ambulatory)

Form: Physical Examination (4)

Data signed: (hfarmer1) 26 Mar 2015 14:19:26

Generated On: 20 Jul 2016 12:09:14

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of Assessment

31 JAN 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: 1062**

Folder: Discharge (Ambulatory)

Form: Physical Examination (5)

Data signed: (hfarmer1) 26 Mar 2015 14:19:26

Generated On: 20 Jul 2016 12:09:14

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of Assessment 31 JAN 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: 1062**

Folder: Discharge (Ambulatory)

Form: Physical Examination (6)

Data signed: (hfarmer1) 26 Mar 2015 14:19:26

Generated On: 20 Jul 2016 12:09:14

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of Assessment 31 JAN 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: 1062**

Folder: Discharge (Ambulatory)

Form: Physical Examination (7)

Data signed: (hfarmer1) 26 Mar 2015 14:19:26

Generated On: 20 Jul 2016 12:09:14

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of Assessment

31 JAN 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: 1062**

Folder: Discharge (Ambulatory)

Form: Physical Examination (8)

Data signed: (hfarmer1) 26 Mar 2015 14:19:26

Generated On: 20 Jul 2016 12:09:14

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of Assessment 31 JAN 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: 1062**

Folder: Discharge (Ambulatory)

Form: Physical Examination (9)

Data signed: (hfarmer1) 26 Mar 2015 14:19:26

Generated On: 20 Jul 2016 12:09:14

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of Assessment 31 JAN 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: 1062**

Folder: Discharge (Ambulatory)

Form: Physical Examination (10)

Data signed: (hfarmer1) 26 Mar 2015 14:19:26

Generated On: 20 Jul 2016 12:09:14

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of Assessment 31 JAN 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: 1062**

Folder: Discharge (Ambulatory)

Form: Physical Examination (11)

Data signed: (hfarmer1) 26 Mar 2015 14:19:26

Generated On: 20 Jul 2016 12:09:14

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of Assessment

31 JAN 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: 1062**

Folder: Discharge (Ambulatory)

Form: Physical Examination (12)

Data signed: (hfarmer1) 26 Mar 2015 14:19:26

Generated On: 20 Jul 2016 12:09:14

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of Assessment 31 JAN 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: 1062**

Folder: Discharge (Ambulatory)

Form: Physical Examination (13)

Data signed: (hfarmer1) 26 Mar 2015 14:19:26

Generated On: 20 Jul 2016 12:09:14

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of Assessment 31 JAN 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: 1062**

Folder: Discharge (Ambulatory)

Form: Physical Examination (14)

Data signed: (hfarmer1) 26 Mar 2015 14:19:26

Generated On: 20 Jul 2016 12:09:14

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of Assessment 31 JAN 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: 1062**

Folder: Discharge (Ambulatory)

Form: Physical Examination (15)

Data signed: (hfarmer1) 26 Mar 2015 14:19:26

Generated On: 20 Jul 2016 12:09:14

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of Assessment

31 JAN 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: 1062**

Folder: Discharge (Ambulatory)

Form: Physical Examination (16)

Data signed: (hfarmer1) 26 Mar 2015 14:19:26

Generated On: 20 Jul 2016 12:09:14

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of Assessment

31 JAN 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: 1062**

Folder: Discharge (Ambulatory)

Form: Physical Examination (17)

Data signed: (hfarmer1) 26 Mar 2015 14:19:26

Generated On: 20 Jul 2016 12:09:14

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of Assessment

31 JAN 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: 1062**

Folder: Discharge (Ambulatory)

Form: Physical Examination (18)

Data signed: (hfarmer1) 26 Mar 2015 14:19:26

Generated On: 20 Jul 2016 12:09:14

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of Assessment

31 JAN 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: 1062**

Folder: Discharge (Ambulatory)

Form: Physical Examination (19)

Data signed: (hfarmer1) 26 Mar 2015 14:19:26

Generated On: 20 Jul 2016 12:09:14

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of Assessment

31 JAN 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: 1062**

Folder: Discharge (Ambulatory)

Form: Weight

Data signed: (hfarmer1) 26 Mar 2015 14:19:27

Generated On: 20 Jul 2016 12:09:14

Measurement(s) assessed?

Yes ☒

If No, please specify the reason: _____

Date of Assessment

31 JAN 2014
DD/MMM/YYYY

Time of assessment

10:15
hour:min 24-hour clock

Weight

77.0
kg

Waist circumference

180
cm

BMI

23.8

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Discharge (Ambulatory)

Form: ECG (12-Lead Standard)

Data signed: (hfarmer1) 26 Mar 2015 14:19:25

Generated On: 20 Jul 2016 12:09:14

Was the ECG performed?

Yes ☒

If No, please specify the reason: _____

Date of Assessment

31 JAN 2014
DD/MMM/YYYY

Position

Supine ☒

Heart Rate

57
beats per minute

QRS Interval

103
msec

QT Interval

376
msec

QTcB Interval

368
msec

PR Interval

144
msec

QTcF Interval

370
msec

Interpretation

Normal ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Discharge (Ambulatory)

Form: ECG (12-Lead Standard)

Data signed: (hfarmer1) 26 Mar 2015 14:19:25

Generated On: 20 Jul 2016 12:09:14

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: 1062

Folder: Discharge (Ambulatory)

Form: Gas Transfer

Data signed: (hfarmer1) 26 Mar 2015 14:19:27

Generated On: 20 Jul 2016 12:09:14

Was the Gas Transfer performed?

No ☒

If No, please specify the reason:

SUBJECT EARLY TERM ON
31JAN 2014.DID NOT STAY
FOR THIS PROCEDURE

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: 1062

Folder: Discharge (Ambulatory)

Form: Lung Volume Measurements

Data signed: (hfarmer1) 26 Mar 2015 14:19:27

Generated On: 20 Jul 2016 12:09:14

Were the Lung Volume Measurements performed?

No ☒

If No, please specify the reason:

SUBJECT WAS A EARLY TERM
DID NOT STAY FOR THIS
PROCEDURE

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Discharge (Ambulatory)

Form: Lung Volume Measurements

Data signed: (hfarmer1) 26 Mar 2015 14:19:27

Generated On: 20 Jul 2016 12:09:14

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

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1062

Folder: Discharge (Ambulatory)

Form: Spirometry with a short-acting bronchodilator

Data signed: (hfarmer1) 26 Mar 2015 14:19:27

Generated On: 20 Jul 2016 12:09:14

Was the Spirometry with a short-acting bronchodilator performed?

No ☒

If No, please specify the reason:

THE SUBJECT WAS UNABLE
TO STAY FOR ASSESSMENTS
DUE TO TRANSPORTATION
ISSUES

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: 1062**

Folder: Discharge (Ambulatory)

Form: Spirometry with a short-acting bronchodilator

Data signed: (hfarmer1) 26 Mar 2015 14:19:27

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Discharge (Ambulatory)

Form: Haematology

Data signed: (hfarmer1) 26 Mar 2015 14:19:25

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Discharge (Ambulatory)

Form: Clinical Chemistry

Data signed: (hfarmer1) 26 Mar 2015 14:19:25

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Discharge (Ambulatory)

Form: Urine analysis

Data signed: (hfarmer1) 26 Mar 2015 14:19:25

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Discharge (Ambulatory)

Form: CoHb Blood Sample <prior to gas transfer and product>

Data signed: (hcoleman1) 18 Jun 2015 19:58:07

Generated On: 20 Jul 2016 12:09:14

Not Done	True
----------	------

If Not Done, please specify the reason:	NOT REQUIRED FOR EARLY TERM PROCEDURES
---	---

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

Timepoint	Prior to gas transfer assessment and prior to product use <input checked="" type="radio"/>
-----------	--

Time hour:min 24-hour clock	
--------------------------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (1)

Data signed: (hfarmer1) 26 Mar 2015 14:19:27

Generated On: 20 Jul 2016 12:09:14

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	<hr/>
----------------------	-------

Subject Sex	M
-------------	---

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

Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	V225852
--------------	---------

Actual Collection Date	2014 01 31
------------------------	------------

Actual Collection Time	09:47
------------------------	-------

Specimen Condition	<hr/>
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Battery ID	RC1029
------------	--------

Battery Name	TRIGLYCERIDES
--------------	---------------

Lab Test ID	RCT19
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (1)

Data signed: (hfarmer1) 26 Mar 2015 14:19:27

Generated On: 20 Jul 2016 12:09:14

Lab Test Name	TRIGLYCERIDES (GPO)
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	149
Reported Numeric Result	149
Reference Range low	55
Reference Range high	327
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: 1062**

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (1)

Data signed: (hfarmer1) 26 Mar 2015 14:19:27

Generated On: 20 Jul 2016 12:09:14

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (2)

Data signed: (hfarmer1) 26 Mar 2015 14:19:27

Generated On: 20 Jul 2016 12:09:14

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6)

Visit Name _____

Visit Type Scheduled ☒

Accession ID V225852

Actual Collection Date 2014 01 31

Actual Collection Time 09:47

Specimen Condition _____

Battery ID RC1092

Battery Name FASTING GLUCOSE

Lab Test ID RCT142

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (2)

Data signed: (hfarmer1) 26 Mar 2015 14:19:27

Generated On: 20 Jul 2016 12:09:14

Lab Test Name	FASTING GLUCOSE
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	89
Reported Numeric Result	89
Reference Range low	70
Reference Range high	100
Range Units	MG/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (2)

Data signed: (hfarmer1) 26 Mar 2015 14:19:27

Generated On: 20 Jul 2016 12:09:14

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (3)

Data signed: (hfarmer1) 26 Mar 2015 14:19:27

Generated On: 20 Jul 2016 12:09:14

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6)

Visit Name _____

Visit Type Scheduled ☒

Accession ID V225852

Actual Collection Date 2014 01 31

Actual Collection Time 09:47

Specimen Condition _____

Battery ID RC272

Battery Name TOTAL CHOLESTEROL

Lab Test ID RCT20

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (3)

Data signed: (hfarmer1) 26 Mar 2015 14:19:27

Generated On: 20 Jul 2016 12:09:14

Lab Test Name	CHOLESTEROL (HIGH PERFORMANCE)
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	183
Reported Numeric Result	183
Reference Range low	162
Reference Range high	280
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: 1062**

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (3)

Data signed: (hfarmer1) 26 Mar 2015 14:19:27

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (4)

Data signed: (hfarmer1) 26 Mar 2015 14:19:27

Generated On: 20 Jul 2016 12:09:14

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	V225852
--------------	---------

Actual Collection Date	2014 01 31
------------------------	------------

Actual Collection Time	09:47
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	RC9255
------------	--------

Battery Name	CHEMISTRY PANEL
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Lab Test ID	RCT1
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (4)

Data signed: (hfarmer1) 26 Mar 2015 14:19:27

Generated On: 20 Jul 2016 12:09:14

Lab Test Name	TOTAL BILIRUBIN
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	0.2
Reported Numeric Result	0.2
Reference Range low	0.2
Reference Range high	1.2
Range Units	MG/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (4)

Data signed: (hfarmer1) 26 Mar 2015 14:19:27

Generated On: 20 Jul 2016 12:09:14

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (5)

Data signed: (hfarmer1) 26 Mar 2015 14:19:27

Generated On: 20 Jul 2016 12:09:14

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	V225852
--------------	---------

Actual Collection Date	2014 01 31
------------------------	------------

Actual Collection Time	09:47
------------------------	-------

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: 1062

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (5)

Data signed: (hfarmer1) 26 Mar 2015 14:19:27

Generated On: 20 Jul 2016 12:09:14

Lab Test Name	TOTAL PROTEIN
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	6.6
Reported Numeric Result	6.6
Reference Range low	6.1
Reference Range high	8.4
Range Units	G/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (5)

Data signed: (hfarmer1) 26 Mar 2015 14:19:27

Generated On: 20 Jul 2016 12:09:14

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (6)

Data signed: (hfarmer1) 26 Mar 2015 14:19:27

Generated On: 20 Jul 2016 12:09:14

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	V225852
--------------	---------

Actual Collection Date	2014 01 31
------------------------	------------

Actual Collection Time	09:47
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	RC9255
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Battery Name	CHEMISTRY PANEL
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Lab Test ID	RCT13
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1062

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (6)

Data signed: (hfarmer1) 26 Mar 2015 14:19:27

Generated On: 20 Jul 2016 12:09:14

Lab Test Name	ALBUMIN
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	3.9
Reported Numeric Result	3.9
Reference Range low	3.3
Reference Range high	4.9
Range Units	G/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (6)

Data signed: (hfarmer1) 26 Mar 2015 14:19:27

Generated On: 20 Jul 2016 12:09:14

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (7)

Data signed: (hfarmer1) 26 Mar 2015 14:19:27

Generated On: 20 Jul 2016 12:09:14

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	V225852
--------------	---------

Actual Collection Date	2014 01 31
------------------------	------------

Actual Collection Time	09:47
------------------------	-------

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: 1062

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (7)

Data signed: (hfarmer1) 26 Mar 2015 14:19:27

Generated On: 20 Jul 2016 12:09:14

Lab Test Name	ALKALINE PHOSPHATASE
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	85
Reported Numeric Result	85
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: 1062**

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (7)

Data signed: (hfarmer1) 26 Mar 2015 14:19:27

Generated On: 20 Jul 2016 12:09:14

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (8)

Data signed: (hfarmer1) 26 Mar 2015 14:19:27

Generated On: 20 Jul 2016 12:09:14

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	V225852
--------------	---------

Actual Collection Date	2014 01 31
------------------------	------------

Actual Collection Time	09:47
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	RC9255
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Battery Name	CHEMISTRY PANEL
--------------	-----------------

Lab Test ID	RCT1408
-------------	---------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1062

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (8)

Data signed: (hfarmer1) 26 Mar 2015 14:19:27

Generated On: 20 Jul 2016 12:09:14

Lab Test Name	LDH
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	103
Reported Numeric Result	103
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: 1062**

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (8)

Data signed: (hfarmer1) 26 Mar 2015 14:19:27

Generated On: 20 Jul 2016 12:09:14

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (9)

Data signed: (hfarmer1) 26 Mar 2015 14:19:27

Generated On: 20 Jul 2016 12:09:14

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	V225852
--------------	---------

Actual Collection Date	2014 01 31
------------------------	------------

Actual Collection Time	09:47
------------------------	-------

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: 1062

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (9)

Data signed: (hfarmer1) 26 Mar 2015 14:19:27

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (9)

Data signed: (hfarmer1) 26 Mar 2015 14:19:27

Generated On: 20 Jul 2016 12:09:14

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (10)

Data signed: (hfarmer1) 26 Mar 2015 14:19:27

Generated On: 20 Jul 2016 12:09:14

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	V225852
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Actual Collection Date	2014 01 31
------------------------	------------

Actual Collection Time	09:47
------------------------	-------

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: 1062

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (10)

Data signed: (hfarmer1) 26 Mar 2015 14:19:27

Generated On: 20 Jul 2016 12:09:14

Lab Test Name	SERUM POTASSIUM
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	4.3
Reported Numeric Result	4.3
Reference Range low	3.4
Reference Range high	5.4
Range Units	MEQ/L
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (10)

Data signed: (hfarmer1) 26 Mar 2015 14:19:27

Generated On: 20 Jul 2016 12:09:14

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (11)

Data signed: (hfarmer1) 26 Mar 2015 14:19:27

Generated On: 20 Jul 2016 12:09:14

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	V225852
--------------	---------

Actual Collection Date	2014 01 31
------------------------	------------

Actual Collection Time	09:47
------------------------	-------

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: 1062

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (11)

Data signed: (hfarmer1) 26 Mar 2015 14:19:27

Generated On: 20 Jul 2016 12:09:14

Lab Test Name	DIRECT BILIRUBIN
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	<0.1
Reported Numeric Result	
Reference Range low	0.0
Reference Range high	0.4
Range Units	MG/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (11)

Data signed: (hfarmer1) 26 Mar 2015 14:19:27

Generated On: 20 Jul 2016 12:09:14

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (12)

Data signed: (hfarmer1) 26 Mar 2015 14:19:27

Generated On: 20 Jul 2016 12:09:14

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	<hr/>
----------------------	-------

Subject Sex	M
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Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	V225852
--------------	---------

Actual Collection Date	2014 01 31
------------------------	------------

Actual Collection Time	09:47
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	RC9255
------------	--------

Battery Name	CHEMISTRY PANEL
--------------	-----------------

Lab Test ID	RCT3
-------------	------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1062

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (12)

Data signed: (hfarmer1) 26 Mar 2015 14:19:27

Generated On: 20 Jul 2016 12:09:14

Lab Test Name	GGT
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	14
Reported Numeric Result	14
Reference Range low	10
Reference Range high	61
Range Units	U/L
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (12)

Data signed: (hfarmer1) 26 Mar 2015 14:19:27

Generated On: 20 Jul 2016 12:09:14

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (13)

Data signed: (hfarmer1) 26 Mar 2015 14:19:27

Generated On: 20 Jul 2016 12:09:14

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	<hr/>
----------------------	-------

Subject Sex	M
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Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	V225852
--------------	---------

Actual Collection Date	2014 01 31
------------------------	------------

Actual Collection Time	09:47
------------------------	-------

Specimen Condition	<hr/>
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Battery ID	RC9255
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Battery Name	CHEMISTRY PANEL
--------------	-----------------

Lab Test ID	RCT392
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (13)

Data signed: (hfarmer1) 26 Mar 2015 14:19:27

Generated On: 20 Jul 2016 12:09:14

Lab Test Name	CREATININE (RATE BLANKED)
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Test ID	<hr/>
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Test Status	Done 
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Reported Text Result	1.1
----------------------	-----

Reported Numeric Result	1.1
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Reference Range low	0.5
---------------------	-----

Reference Range high	1.2
----------------------	-----

Range Units	MG/DL
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Conventional Text Result	<hr/>
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Conventional Numeric Result	<hr/>
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Conventional Reference Range Low	<hr/>
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Conventional Reference Range High	<hr/>
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Conventional Units	<hr/>
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SI Text Result	<hr/>
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (13)

Data signed: (hfarmer1) 26 Mar 2015 14:19:27

Generated On: 20 Jul 2016 12:09:14

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (14)

Data signed: (hfarmer1) 26 Mar 2015 14:19:27

Generated On: 20 Jul 2016 12:09:14

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	V225852
--------------	---------

Actual Collection Date	2014 01 31
------------------------	------------

Actual Collection Time	09:47
------------------------	-------

Specimen Condition	<hr/>
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Battery ID	RC9255
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Battery Name	CHEMISTRY PANEL
--------------	-----------------

Lab Test ID	RCT4
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1062

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (14)

Data signed: (hfarmer1) 26 Mar 2015 14:19:27

Generated On: 20 Jul 2016 12:09:14

Lab Test Name	ALT (SGPT)
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	11
Reported Numeric Result	11
Reference Range low	6
Reference Range high	43
Range Units	U/L
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (14)

Data signed: (hfarmer1) 26 Mar 2015 14:19:27

Generated On: 20 Jul 2016 12:09:14

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (15)

Data signed: (hfarmer1) 26 Mar 2015 14:19:27

Generated On: 20 Jul 2016 12:09:14

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	V225852
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Actual Collection Date	2014 01 31
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Actual Collection Time	09:47
------------------------	-------

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: 1062

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (15)

Data signed: (hfarmer1) 26 Mar 2015 14:19:27

Generated On: 20 Jul 2016 12:09:14

Lab Test Name	AST (SGOT)
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	13
Reported Numeric Result	13
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: 1062**

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (15)

Data signed: (hfarmer1) 26 Mar 2015 14:19:27

Generated On: 20 Jul 2016 12:09:14

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (16)

Data signed: (hfarmer1) 26 Mar 2015 14:19:27

Generated On: 20 Jul 2016 12:09:14

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6)

Visit Name _____

Visit Type Scheduled ☒

Accession ID V225852

Actual Collection Date 2014 01 31

Actual Collection Time 09:47

Specimen Condition _____

Battery ID RC9255

Battery Name CHEMISTRY PANEL

Lab Test ID RCT6

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1062

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (16)

Data signed: (hfarmer1) 26 Mar 2015 14:19:27

Generated On: 20 Jul 2016 12:09:14

Lab Test Name	UREA NITROGEN
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	11
Reported Numeric Result	11
Reference Range low	4
Reference Range high	24
Range Units	MG/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (16)

Data signed: (hfarmer1) 26 Mar 2015 14:19:27

Generated On: 20 Jul 2016 12:09:14

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (17)

Data signed: (hfarmer1) 26 Mar 2015 14:19:27

Generated On: 20 Jul 2016 12:09:14

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	V225852
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Actual Collection Date	2014 01 31
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Actual Collection Time	09:47
------------------------	-------

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: 1062

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (17)

Data signed: (hfarmer1) 26 Mar 2015 14:19:27

Generated On: 20 Jul 2016 12:09:14

Lab Test Name	MONOCYTES
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	0.34
Reported Numeric Result	0.34
Reference Range low	0.12
Reference Range high	0.92
Range Units	X10^3/UL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (17)

Data signed: (hfarmer1) 26 Mar 2015 14:19:27

Generated On: 20 Jul 2016 12:09:14

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (18)

Data signed: (hfarmer1) 26 Mar 2015 14:19:27

Generated On: 20 Jul 2016 12:09:14

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	V225852
--------------	---------

Actual Collection Date	2014 01 31
------------------------	------------

Actual Collection Time	09:47
------------------------	-------

Specimen Condition	<hr/>
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Battery ID	HM1604
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Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
--------------	-----------------------------------

Lab Test ID	HMT100
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1062

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (18)

Data signed: (hfarmer1) 26 Mar 2015 14:19:27

Generated On: 20 Jul 2016 12:09:14

Lab Test Name	MCH
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	31
Reported Numeric Result	31
Reference Range low	26
Reference Range high	34
Range Units	PG
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (18)

Data signed: (hfarmer1) 26 Mar 2015 14:19:27

Generated On: 20 Jul 2016 12:09:14

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (19)

Data signed: (hfarmer1) 26 Mar 2015 14:19:27

Generated On: 20 Jul 2016 12:09:14

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	V225852
--------------	---------

Actual Collection Date	2014 01 31
------------------------	------------

Actual Collection Time	09:47
------------------------	-------

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: 1062**

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (19)

Data signed: (hfarmer1) 26 Mar 2015 14:19:27

Generated On: 20 Jul 2016 12:09:14

Lab Test Name	MCHC
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	33
Reported Numeric Result	33
Reference Range low	31
Reference Range high	38
Range Units	G/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (19)

Data signed: (hfarmer1) 26 Mar 2015 14:19:27

Generated On: 20 Jul 2016 12:09:14

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (20)

Data signed: (hfarmer1) 26 Mar 2015 14:19:27

Generated On: 20 Jul 2016 12:09:14

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	V225852
--------------	---------

Actual Collection Date	2014 01 31
------------------------	------------

Actual Collection Time	09:47
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	HM1604
------------	--------

Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
--------------	-----------------------------------

Lab Test ID	HMT11
-------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (20)

Data signed: (hfarmer1) 26 Mar 2015 14:19:27

Generated On: 20 Jul 2016 12:09:14

Lab Test Name	EOSINOPHILS
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	0.09
Reported Numeric Result	0.09
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: 1062**

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (20)

Data signed: (hfarmer1) 26 Mar 2015 14:19:27

Generated On: 20 Jul 2016 12:09:14

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (21)

Data signed: (hfarmer1) 26 Mar 2015 14:19:27

Generated On: 20 Jul 2016 12:09:14

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	V225852
--------------	---------

Actual Collection Date	2014 01 31
------------------------	------------

Actual Collection Time	09:47
------------------------	-------

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: 1062

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (21)

Data signed: (hfarmer1) 26 Mar 2015 14:19:27

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (21)

Data signed: (hfarmer1) 26 Mar 2015 14:19:27

Generated On: 20 Jul 2016 12:09:14

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (22)

Data signed: (hfarmer1) 26 Mar 2015 14:19:27

Generated On: 20 Jul 2016 12:09:14

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	V225852
--------------	---------

Actual Collection Date	2014 01 31
------------------------	------------

Actual Collection Time	09:47
------------------------	-------

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: 1062

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (22)

Data signed: (hfarmer1) 26 Mar 2015 14:19:27

Generated On: 20 Jul 2016 12:09:14

Lab Test Name	PLATELETS
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	255
Reported Numeric Result	255
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: 1062**

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (22)

Data signed: (hfarmer1) 26 Mar 2015 14:19:27

Generated On: 20 Jul 2016 12:09:14

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (23)

Data signed: (hfarmer1) 26 Mar 2015 14:19:27

Generated On: 20 Jul 2016 12:09:14

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	V225852
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Actual Collection Date	2014 01 31
------------------------	------------

Actual Collection Time	09:47
------------------------	-------

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: 1062

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (23)

Data signed: (hfarmer1) 26 Mar 2015 14:19:27

Generated On: 20 Jul 2016 12:09:14

Lab Test Name	NEUTROPHILS (%)
Test ID	
Test Status	Done <input type="checkbox"/>
Reported Text Result	70.6
Reported Numeric Result	70.6
Reference Range low	40.5
Reference Range high	75.0
Range Units	%
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (23)

Data signed: (hfarmer1) 26 Mar 2015 14:19:27

Generated On: 20 Jul 2016 12:09:14

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (24)

Data signed: (hfarmer1) 26 Mar 2015 14:19:27

Generated On: 20 Jul 2016 12:09:14

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	V225852
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Actual Collection Date	2014 01 31
------------------------	------------

Actual Collection Time	09:47
------------------------	-------

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: 1062

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (24)

Data signed: (hfarmer1) 26 Mar 2015 14:19:27

Generated On: 20 Jul 2016 12:09:14

Lab Test Name	LYMPHOCYTES (%)
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	23.2
Reported Numeric Result	23.2
Reference Range low	15.4
Reference Range high	48.5
Range Units	%
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (24)

Data signed: (hfarmer1) 26 Mar 2015 14:19:27

Generated On: 20 Jul 2016 12:09:14

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (25)

Data signed: (hfarmer1) 26 Mar 2015 14:19:27

Generated On: 20 Jul 2016 12:09:14

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	V225852
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Actual Collection Date	2014 01 31
------------------------	------------

Actual Collection Time	09:47
------------------------	-------

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: 1062

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (25)

Data signed: (hfarmer1) 26 Mar 2015 14:19:27

Generated On: 20 Jul 2016 12:09:14

Lab Test Name	MONOCYTES (%)
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	4.4
Reported Numeric Result	4.4
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: 1062**

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (25)

Data signed: (hfarmer1) 26 Mar 2015 14:19:27

Generated On: 20 Jul 2016 12:09:14

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (26)

Data signed: (hfarmer1) 26 Mar 2015 14:19:27

Generated On: 20 Jul 2016 12:09:14

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	V225852
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Actual Collection Date	2014 01 31
------------------------	------------

Actual Collection Time	09:47
------------------------	-------

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: 1062**

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (26)

Data signed: (hfarmer1) 26 Mar 2015 14:19:27

Generated On: 20 Jul 2016 12:09:14

Lab Test Name	EOSINOPHILS (%)
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	1.2
Reported Numeric Result	1.2
Reference Range low	0.0
Reference Range high	6.8
Range Units	%
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (26)

Data signed: (hfarmer1) 26 Mar 2015 14:19:27

Generated On: 20 Jul 2016 12:09:14

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (27)

Data signed: (hfarmer1) 26 Mar 2015 14:19:27

Generated On: 20 Jul 2016 12:09:14

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	V225852
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Actual Collection Date	2014 01 31
------------------------	------------

Actual Collection Time	09:47
------------------------	-------

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: 1062

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (27)

Data signed: (hfarmer1) 26 Mar 2015 14:19:27

Generated On: 20 Jul 2016 12:09:14

Lab Test Name	BASOPHILS (%)
Test ID	
Test Status	Done <input 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: 1062**

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (27)

Data signed: (hfarmer1) 26 Mar 2015 14:19:27

Generated On: 20 Jul 2016 12:09:14

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (28)

Data signed: (hfarmer1) 26 Mar 2015 14:19:27

Generated On: 20 Jul 2016 12:09:14

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	V225852
--------------	---------

Actual Collection Date	2014 01 31
------------------------	------------

Actual Collection Time	09:47
------------------------	-------

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: 1062

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (28)

Data signed: (hfarmer1) 26 Mar 2015 14:19:27

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (28)

Data signed: (hfarmer1) 26 Mar 2015 14:19:27

Generated On: 20 Jul 2016 12:09:14

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (29)

Data signed: (hfarmer1) 26 Mar 2015 14:19:27

Generated On: 20 Jul 2016 12:09:14

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	V225852
--------------	---------

Actual Collection Date	2014 01 31
------------------------	------------

Actual Collection Time	09:47
------------------------	-------

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: 1062

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (29)

Data signed: (hfarmer1) 26 Mar 2015 14:19:27

Generated On: 20 Jul 2016 12:09:14

Lab Test Name	RBC
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	5.0
Reported Numeric Result	5.0
Reference Range low	4.5
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: 1062**

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (29)

Data signed: (hfarmer1) 26 Mar 2015 14:19:27

Generated On: 20 Jul 2016 12:09:14

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (30)

Data signed: (hfarmer1) 26 Mar 2015 14:19:27

Generated On: 20 Jul 2016 12:09:14

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	V225852
--------------	---------

Actual Collection Date	2014 01 31
------------------------	------------

Actual Collection Time	09:47
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

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: 1062

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (30)

Data signed: (hfarmer1) 26 Mar 2015 14:19:27

Generated On: 20 Jul 2016 12:09:14

Lab Test Name	MCV
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	93
Reported Numeric Result	93
Reference Range low	79
Reference Range high	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: 1062**

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (30)

Data signed: (hfarmer1) 26 Mar 2015 14:19:27

Generated On: 20 Jul 2016 12:09:14

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (31)

Data signed: (hfarmer1) 26 Mar 2015 14:19:27

Generated On: 20 Jul 2016 12:09:14

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	V225852
--------------	---------

Actual Collection Date	2014 01 31
------------------------	------------

Actual Collection Time	09:47
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	HM1604
------------	--------

Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
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Lab Test ID	HMT40
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (31)

Data signed: (hfarmer1) 26 Mar 2015 14:19:27

Generated On: 20 Jul 2016 12:09:14

Lab Test Name	HEMOGLOBIN
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	15.5
Reported Numeric Result	15.5
Reference Range low	12.7
Reference Range high	18.1
Range Units	G/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (31)

Data signed: (hfarmer1) 26 Mar 2015 14:19:27

Generated On: 20 Jul 2016 12:09:14

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (32)

Data signed: (hfarmer1) 26 Mar 2015 14:19:27

Generated On: 20 Jul 2016 12:09:14

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	V225852
--------------	---------

Actual Collection Date	2014 01 31
------------------------	------------

Actual Collection Time	09:47
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

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: 1062**

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (32)

Data signed: (hfarmer1) 26 Mar 2015 14:19:27

Generated On: 20 Jul 2016 12:09:14

Lab Test Name	WBC
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	7.61
Reported Numeric Result	7.61
Reference Range low	3.80
Reference Range high	10.70
Range Units	X10^3/UL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (32)

Data signed: (hfarmer1) 26 Mar 2015 14:19:27

Generated On: 20 Jul 2016 12:09:14

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (33)

Data signed: (hfarmer1) 26 Mar 2015 14:19:27

Generated On: 20 Jul 2016 12:09:14

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	V225852
--------------	---------

Actual Collection Date	2014 01 31
------------------------	------------

Actual Collection Time	09:47
------------------------	-------

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: 1062**

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (33)

Data signed: (hfarmer1) 26 Mar 2015 14:19:27


Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (33)

Data signed: (hfarmer1) 26 Mar 2015 14:19:27

Generated On: 20 Jul 2016 12:09:14

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (34)

Data signed: (hfarmer1) 26 Mar 2015 14:19:27

Generated On: 20 Jul 2016 12:09:14

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	V225852
--------------	---------

Actual Collection Date	2014 01 31
------------------------	------------

Actual Collection Time	09:47
------------------------	-------

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: 1062**

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (34)

Data signed: (hfarmer1) 26 Mar 2015 14:19:27

Generated On: 20 Jul 2016 12:09:14

Lab Test Name	NEUTROPHILS
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	5.37
Reported Numeric Result	5.37
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: 1062**

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (34)

Data signed: (hfarmer1) 26 Mar 2015 14:19:27

Generated On: 20 Jul 2016 12:09:14

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (35)

Data signed: (hfarmer1) 26 Mar 2015 14:19:27

Generated On: 20 Jul 2016 12:09:14

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	V225852
--------------	---------

Actual Collection Date	2014 01 31
------------------------	------------

Actual Collection Time	09:47
------------------------	-------

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: 1062**

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (35)

Data signed: (hfarmer1) 26 Mar 2015 14:19:27

Generated On: 20 Jul 2016 12:09:14

Lab Test Name	LYMPHOCYTES
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	1.77
Reported Numeric Result	1.77
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: 1062**

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (35)

Data signed: (hfarmer1) 26 Mar 2015 14:19:27

Generated On: 20 Jul 2016 12:09:14

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (36)

Data signed: (hfarmer1) 26 Mar 2015 14:19:27

Generated On: 20 Jul 2016 12:09:14

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	V225852
--------------	---------

Actual Collection Date	2014 01 31
------------------------	------------

Actual Collection Time	09:47
------------------------	-------

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: 1062**

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (36)

Data signed: (hfarmer1) 26 Mar 2015 14:19:27


Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (36)

Data signed: (hfarmer1) 26 Mar 2015 14:19:27

Generated On: 20 Jul 2016 12:09:14

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (37)

Data signed: (hfarmer1) 26 Mar 2015 14:19:27

Generated On: 20 Jul 2016 12:09:14

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	V225852
--------------	---------

Actual Collection Date	2014 01 31
------------------------	------------

Actual Collection Time	09:47
------------------------	-------

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: 1062

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (37)

Data signed: (hfarmer1) 26 Mar 2015 14:19:27

Generated On: 20 Jul 2016 12:09:14

Lab Test Name	UR SPECIFIC GRAVITY
Test ID	
Test Status	Done <input type="radio"/>
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: 1062**

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (37)

Data signed: (hfarmer1) 26 Mar 2015 14:19:27

Generated On: 20 Jul 2016 12:09:14

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (38)

Data signed: (hfarmer1) 26 Mar 2015 14:19:27

Generated On: 20 Jul 2016 12:09:14

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	V225852
--------------	---------

Actual Collection Date	2014 01 31
------------------------	------------

Actual Collection Time	09:47
------------------------	-------

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: 1062

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (38)

Data signed: (hfarmer1) 26 Mar 2015 14:19:27

Generated On: 20 Jul 2016 12:09:14

Lab Test Name	UR PH
Test ID	
Test Status	Done <input type="checkbox"/>
Reported Text Result	6.5
Reported Numeric Result	6.5
Reference Range low	5.0
Reference Range high	8.0
Range Units	
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (38)

Data signed: (hfarmer1) 26 Mar 2015 14:19:27

Generated On: 20 Jul 2016 12:09:14

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (39)

Data signed: (hfarmer1) 26 Mar 2015 14:19:27

Generated On: 20 Jul 2016 12:09:14

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	V225852
--------------	---------

Actual Collection Date	2014 01 31
------------------------	------------

Actual Collection Time	09:47
------------------------	-------

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: 1062**

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (39)

Data signed: (hfarmer1) 26 Mar 2015 14:19:27

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (39)

Data signed: (hfarmer1) 26 Mar 2015 14:19:27

Generated On: 20 Jul 2016 12:09:14

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (40)

Data signed: (hfarmer1) 26 Mar 2015 14:19:27

Generated On: 20 Jul 2016 12:09:14

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	V225852
--------------	---------

Actual Collection Date	2014 01 31
------------------------	------------

Actual Collection Time	09:47
------------------------	-------

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: 1062

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (40)

Data signed: (hfarmer1) 26 Mar 2015 14:19:27


Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (40)

Data signed: (hfarmer1) 26 Mar 2015 14:19:27

Generated On: 20 Jul 2016 12:09:14

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (41)

Data signed: (hfarmer1) 26 Mar 2015 14:19:27

Generated On: 20 Jul 2016 12:09:14

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	V225852
--------------	---------

Actual Collection Date	2014 01 31
------------------------	------------

Actual Collection Time	09:47
------------------------	-------

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: 1062**

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (41)

Data signed: (hfarmer1) 26 Mar 2015 14:19:27


Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (41)

Data signed: (hfarmer1) 26 Mar 2015 14:19:27

Generated On: 20 Jul 2016 12:09:14

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (42)

Data signed: (hfarmer1) 26 Mar 2015 14:19:27

Generated On: 20 Jul 2016 12:09:14

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	V225852
--------------	---------

Actual Collection Date	2014 01 31
------------------------	------------

Actual Collection Time	09:47
------------------------	-------

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: 1062**

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (42)

Data signed: (hfarmer1) 26 Mar 2015 14:19:27


Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Discharge (Ambulatory)

Form: Lab_BU_CCLS (42)

Data signed: (hfarmer1) 26 Mar 2015 14:19:27

Generated On: 20 Jul 2016 12:09:14

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Product Use

Form: Product administration-mCC

Data signed: (hfarmer1) 26 Mar 2015 14:19:40

Generated On: 20 Jul 2016 12:09:14

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Product Use

Form: Product administration-mCC (1)

Data signed: (hfarmer1) 26 Mar 2015 14:19:40

Generated On: 20 Jul 2016 12:09:14

Date of product use DD/MMM/YYYY	18 JAN 2014
------------------------------------	-------------

Visit	Day -1 <input checked="" type="radio"/>
-------	---

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	07:13
----------------------	-------

Time of butt return	07:20
---------------------	-------

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: 1062

Folder: Product Use

Form: Product administration-mCC (1)

Data signed: (hfarmer1) 26 Mar 2015 14:19:40

Generated On: 20 Jul 2016 12:09:14

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Product Use

Form: Product administration-mCC (2)

Data signed: (hfarmer1) 26 Mar 2015 14:19:40

Generated On: 20 Jul 2016 12:09:14

Date of product use DD/MMM/YYYY	18 JAN 2014
------------------------------------	-------------

Visit	Day -1 <input checked="" type="radio"/>
-------	---

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	08:55
----------------------	-------

Time of butt return	09:11
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1062

Folder: Product Use

Form: Product administration-mCC (2)

Data signed: (hfarmer1) 26 Mar 2015 14:19:40

Generated On: 20 Jul 2016 12:09:14

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Product Use

Form: Product administration-mCC (3)

Data signed: (hfarmer1) 26 Mar 2015 14:19:40

Generated On: 20 Jul 2016 12:09:14

Date of product use DD/MMM/YYYY	18 JAN 2014
------------------------------------	-------------

Visit	Day -1 <input checked="" type="radio"/>
-------	---

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	09:55
----------------------	-------

Time of butt return	10:02
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1062

Folder: Product Use

Form: Product administration-mCC (3)

Data signed: (hfarmer1) 26 Mar 2015 14:19:40

Generated On: 20 Jul 2016 12:09:14

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Product Use

Form: Product administration-mCC (4)

Data signed: (hfarmer1) 26 Mar 2015 14:19:40

Generated On: 20 Jul 2016 12:09:14

Date of product use DD/MMM/YYYY	18 JAN 2014
------------------------------------	-------------

Visit	Day -1 <input checked="" type="radio"/>
-------	---

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	11:02
----------------------	-------

Time of butt return	11:11
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1062

Folder: Product Use

Form: Product administration-mCC (4)

Data signed: (hfarmer1) 26 Mar 2015 14:19:40

Generated On: 20 Jul 2016 12:09:14

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Product Use

Form: Product administration-mCC (5)

Data signed: (hfarmer1) 26 Mar 2015 14:19:40

Generated On: 20 Jul 2016 12:09:14

Date of product use DD/MMM/YYYY	18 JAN 2014
------------------------------------	-------------

Visit	Day -1 <input checked="" type="radio"/>
-------	---

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	13:29
----------------------	-------

Time of butt return	13:38
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1062

Folder: Product Use

Form: Product administration-mCC (5)

Data signed: (hfarmer1) 26 Mar 2015 14:19:40

Generated On: 20 Jul 2016 12:09:14

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Product Use

Form: Product administration-mCC (6)

Data signed: (hfarmer1) 26 Mar 2015 14:19:40

Generated On: 20 Jul 2016 12:09:14

Date of product use DD/MMM/YYYY	18 JAN 2014
------------------------------------	-------------

Visit	Day -1 <input checked="" type="radio"/>
-------	---

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	15:52
----------------------	-------

Time of butt return	16:02
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1062

Folder: Product Use

Form: Product administration-mCC (6)

Data signed: (hfarmer1) 26 Mar 2015 14:19:40

Generated On: 20 Jul 2016 12:09:14

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Product Use

Form: Product administration-mCC (7)

Data signed: (hfarmer1) 26 Mar 2015 14:19:40

Generated On: 20 Jul 2016 12:09:14

Date of product use DD/MMM/YYYY	18 JAN 2014
------------------------------------	-------------

Visit	Day -1 <input checked="" type="radio"/>
-------	---

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	18:23
----------------------	-------

Time of butt return	18:38
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1062

Folder: Product Use

Form: Product administration-mCC (7)

Data signed: (hfarmer1) 26 Mar 2015 14:19:40

Generated On: 20 Jul 2016 12:09:14

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Product Use

Form: Product administration-mCC (8)

Data signed: (hfarmer1) 26 Mar 2015 14:19:40

Generated On: 20 Jul 2016 12:09:14

Date of product use DD/MMM/YYYY	18 JAN 2014
------------------------------------	-------------

Visit	Day -1 <input checked="" type="radio"/>
-------	---

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	19:45
----------------------	-------

Time of butt return	19:54
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1062

Folder: Product Use

Form: Product administration-mCC (8)

Data signed: (hfarmer1) 26 Mar 2015 14:19:40

Generated On: 20 Jul 2016 12:09:14

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Product Use

Form: Product administration-mCC (9)

Data signed: (hfarmer1) 26 Mar 2015 14:19:40

Generated On: 20 Jul 2016 12:09:14

Date of product use DD/MMM/YYYY	18 JAN 2014
------------------------------------	-------------

Visit	Day -1 <input checked="" type="radio"/>
-------	---

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	21:22
----------------------	-------

Time of butt return	21:32
---------------------	-------

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: 1062

Folder: Product Use

Form: Product administration-mCC (9)

Data signed: (hfarmer1) 26 Mar 2015 14:19:40

Generated On: 20 Jul 2016 12:09:14

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Product Use

Form: Product administration-mCC (10)

Data signed: (hfarmer1) 26 Mar 2015 14:19:40

Generated On: 20 Jul 2016 12:09:14

Date of product use DD/MMM/YYYY	18 JAN 2014
------------------------------------	-------------

Visit	Day -1 <input checked="" type="radio"/>
-------	---

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	22:15
----------------------	-------

Time of butt return	22:21
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1062

Folder: Product Use

Form: Product administration-mCC (10)

Data signed: (hfarmer1) 26 Mar 2015 14:19:40

Generated On: 20 Jul 2016 12:09:14

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Product Use

Form: Product administration-mCC (11)

Data signed: (hfarmer1) 26 Mar 2015 14:19:40

Generated On: 20 Jul 2016 12:09:14

Date of product use DD/MMM/YYYY	19 JAN 2014
------------------------------------	-------------

Visit	Day 0 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	08:53
----------------------	-------

Time of butt return	09:02
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	159
---------------------	-----

SODIM sample holder number	0540
----------------------------	------

SODIM file number	08DY0159COHB10540001
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1062

Folder: Product Use

Form: Product administration-mCC (11)

Data signed: (hfarmer1) 26 Mar 2015 14:19:40

Generated On: 20 Jul 2016 12:09:14

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Product Use

Form: Product administration-mCC (12)

Data signed: (hfarmer1) 26 Mar 2015 14:19:40

Generated On: 20 Jul 2016 12:09:14

Date of product use DD/MMM/YYYY	19 JAN 2014
------------------------------------	-------------

Visit	Day 0 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	09:50
----------------------	-------

Time of butt return	10:01
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	159
---------------------	-----

SODIM sample holder number	0540
----------------------------	------

SODIM file number	08DY0159COHB10540002
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1062

Folder: Product Use

Form: Product administration-mCC (12)

Data signed: (hfarmer1) 26 Mar 2015 14:19:40

Generated On: 20 Jul 2016 12:09:14

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Product Use

Form: Product administration-mCC (13)

Data signed: (hfarmer1) 26 Mar 2015 14:19:40

Generated On: 20 Jul 2016 12:09:14

Date of product use DD/MMM/YYYY	19 JAN 2014
------------------------------------	-------------

Visit	Day 0 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	11:43
----------------------	-------

Time of butt return	11:51
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	159
---------------------	-----

SODIM sample holder number	0540
----------------------------	------

SODIM file number	08DY0159COHB10540003
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1062

Folder: Product Use

Form: Product administration-mCC (13)

Data signed: (hfarmer1) 26 Mar 2015 14:19:40

Generated On: 20 Jul 2016 12:09:14

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Product Use

Form: Product administration-mCC (14)

Data signed: (hfarmer1) 26 Mar 2015 14:19:40

Generated On: 20 Jul 2016 12:09:14

Date of product use DD/MMM/YYYY	19 JAN 2014
------------------------------------	-------------

Visit	Day 0 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	13:42
----------------------	-------

Time of butt return	13:56
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	159
---------------------	-----

SODIM sample holder number	0540
----------------------------	------

SODIM file number	08DY0159COHB10540004
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1062

Folder: Product Use

Form: Product administration-mCC (14)

Data signed: (hfarmer1) 26 Mar 2015 14:19:40

Generated On: 20 Jul 2016 12:09:14

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Product Use

Form: Product administration-mCC (15)

Data signed: (hfarmer1) 26 Mar 2015 14:19:40

Generated On: 20 Jul 2016 12:09:14

Date of product use DD/MMM/YYYY	19 JAN 2014
------------------------------------	-------------

Visit	Day 0 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	14:45
----------------------	-------

Time of butt return	14:52
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	159
---------------------	-----

SODIM sample holder number	0540
----------------------------	------

SODIM file number	08DY0159COHB10540005
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1062

Folder: Product Use

Form: Product administration-mCC (15)

Data signed: (hfarmer1) 26 Mar 2015 14:19:40

Generated On: 20 Jul 2016 12:09:14

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Product Use

Form: Product administration-mCC (16)

Data signed: (hfarmer1) 26 Mar 2015 14:19:40

Generated On: 20 Jul 2016 12:09:14

Date of product use DD/MMM/YYYY	19 JAN 2014
------------------------------------	-------------

Visit	Day 0 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	16:40
----------------------	-------

Time of butt return	16:50
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	159
---------------------	-----

SODIM sample holder number	0540
----------------------------	------

SODIM file number	08DY0159COHB10540006
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1062

Folder: Product Use

Form: Product administration-mCC (16)

Data signed: (hfarmer1) 26 Mar 2015 14:19:40

Generated On: 20 Jul 2016 12:09:14

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Product Use

Form: Product administration-mCC (17)

Data signed: (hfarmer1) 26 Mar 2015 14:19:40

Generated On: 20 Jul 2016 12:09:14

Date of product use DD/MMM/YYYY	19 JAN 2014
------------------------------------	-------------

Visit	Day 0 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	19:18
----------------------	-------

Time of butt return	19:29
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	159
---------------------	-----

SODIM sample holder number	0540
----------------------------	------

SODIM file number	08DY0159COHB10540007
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1062

Folder: Product Use

Form: Product administration-mCC (17)

Data signed: (hfarmer1) 26 Mar 2015 14:19:40

Generated On: 20 Jul 2016 12:09:14

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Product Use

Form: Product administration-mCC (18)

Data signed: (hfarmer1) 26 Mar 2015 14:19:40

Generated On: 20 Jul 2016 12:09:14

Date of product use DD/MMM/YYYY	19 JAN 2014
------------------------------------	-------------

Visit	Day 0 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	20:15
----------------------	-------

Time of butt return	20:24
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	159
---------------------	-----

SODIM sample holder number	0540
----------------------------	------

SODIM file number	08DY0159COHB10540008
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1062

Folder: Product Use

Form: Product administration-mCC (18)

Data signed: (hfarmer1) 26 Mar 2015 14:19:40

Generated On: 20 Jul 2016 12:09:14

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Product Use

Form: Product administration-mCC (19)

Data signed: (hfarmer1) 26 Mar 2015 14:19:40

Generated On: 20 Jul 2016 12:09:14

Date of product use DD/MMM/YYYY	19 JAN 2014
------------------------------------	-------------

Visit	Day 0 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	21:57
----------------------	-------

Time of butt return	22:07
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	159
---------------------	-----

SODIM sample holder number	0540
----------------------------	------

SODIM file number	08DY0159COHB10540009
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1062

Folder: Product Use

Form: Product administration-mCC (19)

Data signed: (hfarmer1) 26 Mar 2015 14:19:40

Generated On: 20 Jul 2016 12:09:14

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Product Use

Form: Product administration-mCC (20)

Data signed: (hfarmer1) 26 Mar 2015 14:19:40

Generated On: 20 Jul 2016 12:09:14

Date of product use DD/MMM/YYYY	19 JAN 2014
------------------------------------	-------------

Visit	Day 0 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	22:32
----------------------	-------

Time of butt return	22:43
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	159
---------------------	-----

SODIM sample holder number	0540
----------------------------	------

SODIM file number	08DY0159COHB10540010
-------------------	----------------------

Comment	_____
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1062

Folder: Product Use

Form: Product administration-mCC (20)

Data signed: (hfarmer1) 26 Mar 2015 14:19:40

Generated On: 20 Jul 2016 12:09:14

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Product Use

Form: Product administration-THS menthol

Data signed: (hfarmer1) 26 Mar 2015 14:19:42

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Product Use

Form: Product administration-THS menthol (1)

Data signed: (hfarmer1) 26 Mar 2015 14:19:42

Generated On: 20 Jul 2016 12:09:14

Date of product use DD/MMM/YYYY	20 JAN 2014
------------------------------------	-------------

Visit	Day 1 <input checked="" type="radio"/>
-------	--

Type of Product Use	THS 2.2 Menthol <input checked="" type="radio"/>
---------------------	--

If type of Product Use different from the randomization
please explain _____

Time of distribution	07:14
----------------------	-------

Time of product return	07:25
------------------------	-------

SODIM device number	159
---------------------	-----

SODIM sample holder number	1125
----------------------------	------

Tobacco plug kit number	T1809
-------------------------	-------

Tobacco plug vial number	01
--------------------------	----

SODIM file number	08DY0159COHB11125001
-------------------	----------------------

Comment	_____
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Batch Number	B08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1062

Folder: Product Use

Form: Product administration-THS menthol (1)

Data signed: (hfarmer1) 26 Mar 2015 14:19:42

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Product Use

Form: Product administration-THS menthol (2)

Data signed: (hfarmer1) 26 Mar 2015 14:19:42

Generated On: 20 Jul 2016 12:09:14

Date of product use DD/MMM/YYYY	20 JAN 2014
------------------------------------	-------------

Visit	Day 1 <input checked="" type="radio"/>
-------	--

Type of Product Use	THS 2.2 Menthol <input checked="" type="radio"/>
---------------------	--

If type of Product Use different from the randomization
please explain _____

Time of distribution	09:05
----------------------	-------

Time of product return	09:13
------------------------	-------

SODIM device number	159
---------------------	-----

SODIM sample holder number	1125
----------------------------	------

Tobacco plug kit number	T1809
-------------------------	-------

Tobacco plug vial number	02
--------------------------	----

SODIM file number	08DY0159COHB11125002
-------------------	----------------------

Comment	_____
---------	-------

Batch Number	B08545
--------------	--------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1062

Folder: Product Use

Form: Product administration-THS menthol (2)

Data signed: (hfarmer1) 26 Mar 2015 14:19:42

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Product Use

Form: Product administration-THS menthol (3)

Data signed: (hfarmer1) 26 Mar 2015 14:19:42

Generated On: 20 Jul 2016 12:09:14

Date of product use DD/MMM/YYYY	20 JAN 2014
------------------------------------	-------------

Visit	Day 1 <input checked="" type="radio"/>
-------	--

Type of Product Use	THS 2.2 Menthol <input checked="" type="radio"/>
---------------------	--

If type of Product Use different from the randomization
please explain _____

Time of distribution	11:08
----------------------	-------

Time of product return	11:16
------------------------	-------

SODIM device number	159
---------------------	-----

SODIM sample holder number	1125
----------------------------	------

Tobacco plug kit number	T1809
-------------------------	-------

Tobacco plug vial number	03
--------------------------	----

SODIM file number	08DY0159COHB11125003
-------------------	----------------------

Comment	_____
---------	-------

Batch Number	B08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1062

Folder: Product Use

Form: Product administration-THS menthol (3)

Data signed: (hfarmer1) 26 Mar 2015 14:19:42

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Product Use

Form: Product administration-THS menthol (4)

Data signed: (hfarmer1) 26 Mar 2015 14:19:42

Generated On: 20 Jul 2016 12:09:14

Date of product use DD/MMM/YYYY	20 JAN 2014
------------------------------------	-------------

Visit	Day 1 <input checked="" type="radio"/>
-------	--

Type of Product Use	THS 2.2 Menthol <input checked="" type="radio"/>
---------------------	--

If type of Product Use different from the randomization
please explain _____

Time of distribution	13:57
----------------------	-------

Time of product return	14:05
------------------------	-------

SODIM device number	159
---------------------	-----

SODIM sample holder number	1125
----------------------------	------

Tobacco plug kit number	T1809
-------------------------	-------

Tobacco plug vial number	04
--------------------------	----

SODIM file number	08DY0159COHB11125004
-------------------	----------------------

Comment	_____
---------	-------

Batch Number	B08545
--------------	--------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1062

Folder: Product Use

Form: Product administration-THS menthol (4)

Data signed: (hfarmer1) 26 Mar 2015 14:19:42

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Product Use

Form: Product administration-THS menthol (5)

Data signed: (hfarmer1) 26 Mar 2015 14:19:42

Generated On: 20 Jul 2016 12:09:14

Date of product use DD/MMM/YYYY	20 JAN 2014
------------------------------------	-------------

Visit	Day 1 <input checked="" type="radio"/>
-------	--

Type of Product Use	THS 2.2 Menthol <input checked="" type="radio"/>
---------------------	--

If type of Product Use different from the randomization
please explain _____

Time of distribution	15:13
----------------------	-------

Time of product return	15:27
------------------------	-------

SODIM device number	159
---------------------	-----

SODIM sample holder number	1125
----------------------------	------

Tobacco plug kit number	T1809
-------------------------	-------

Tobacco plug vial number	05
--------------------------	----

SODIM file number	08DY0159COHB11125005
-------------------	----------------------

Comment	_____
---------	-------

Batch Number	B08545
--------------	--------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1062

Folder: Product Use

Form: Product administration-THS menthol (5)

Data signed: (hfarmer1) 26 Mar 2015 14:19:42

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Product Use

Form: Product administration-THS menthol (6)

Data signed: (hfarmer1) 26 Mar 2015 14:19:42

Generated On: 20 Jul 2016 12:09:14

Date of product use DD/MMM/YYYY	20 JAN 2014
------------------------------------	-------------

Visit	Day 1 <input checked="" type="radio"/>
-------	--

Type of Product Use	THS 2.2 Menthol <input checked="" type="radio"/>
---------------------	--

If type of Product Use different from the randomization
please explain _____

Time of distribution	16:31
----------------------	-------

Time of product return	16:49
------------------------	-------

SODIM device number	159
---------------------	-----

SODIM sample holder number	1125
----------------------------	------

Tobacco plug kit number	T1809
-------------------------	-------

Tobacco plug vial number	06
--------------------------	----

SODIM file number	08DY0159COHB11125006
-------------------	----------------------

Comment	_____
---------	-------

Batch Number	B08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1062

Folder: Product Use

Form: Product administration-THS menthol (6)

Data signed: (hfarmer1) 26 Mar 2015 14:19:42

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Product Use

Form: Product administration-THS menthol (7)

Data signed: (hfarmer1) 26 Mar 2015 14:19:42

Generated On: 20 Jul 2016 12:09:14

Date of product use DD/MMM/YYYY	20 JAN 2014
------------------------------------	-------------

Visit	Day 1 <input checked="" type="radio"/>
-------	--

Type of Product Use	THS 2.2 Menthol <input checked="" type="radio"/>
---------------------	--

If type of Product Use different from the randomization
please explain _____

Time of distribution	18:08
----------------------	-------

Time of product return	18:22
------------------------	-------

SODIM device number	159
---------------------	-----

SODIM sample holder number	1125
----------------------------	------

Tobacco plug kit number	T1809
-------------------------	-------

Tobacco plug vial number	07
--------------------------	----

SODIM file number	08DY0159COHB11125007
-------------------	----------------------

Comment	_____
---------	-------

Batch Number	B08545
--------------	--------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1062

Folder: Product Use

Form: Product administration-THS menthol (7)

Data signed: (hfarmer1) 26 Mar 2015 14:19:42

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Product Use

Form: Product administration-THS menthol (8)

Data signed: (hfarmer1) 26 Mar 2015 14:19:42

Generated On: 20 Jul 2016 12:09:14

Date of product use DD/MMM/YYYY	20 JAN 2014
------------------------------------	-------------

Visit	Day 1 <input checked="" type="radio"/>
-------	--

Type of Product Use	THS 2.2 Menthol <input checked="" type="radio"/>
---------------------	--

If type of Product Use different from the randomization
please explain _____

Time of distribution	19:50
----------------------	-------

Time of product return	20:01
------------------------	-------

SODIM device number	159
---------------------	-----

SODIM sample holder number	1125
----------------------------	------

Tobacco plug kit number	T1809
-------------------------	-------

Tobacco plug vial number	08
--------------------------	----

SODIM file number	08DY0159COHB11125008
-------------------	----------------------

Comment	_____
---------	-------

Batch Number	B08545
--------------	--------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1062

Folder: Product Use

Form: Product administration-THS menthol (8)

Data signed: (hfarmer1) 26 Mar 2015 14:19:42

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Product Use

Form: Product administration-THS menthol (9)

Data signed: (hfarmer1) 26 Mar 2015 14:19:42

Generated On: 20 Jul 2016 12:09:14

Date of product use DD/MMM/YYYY	20 JAN 2014
------------------------------------	-------------

Visit	Day 1 <input checked="" type="radio"/>
-------	--

Type of Product Use	THS 2.2 Menthol <input checked="" type="radio"/>
---------------------	--

If type of Product Use different from the randomization
please explain _____

Time of distribution	21:08
----------------------	-------

Time of product return	21:19
------------------------	-------

SODIM device number	159
---------------------	-----

SODIM sample holder number	1125
----------------------------	------

Tobacco plug kit number	T1809
-------------------------	-------

Tobacco plug vial number	09
--------------------------	----

SODIM file number	08DY0159COHB11125009
-------------------	----------------------

Comment	_____
---------	-------

Batch Number	B08545
--------------	--------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1062

Folder: Product Use

Form: Product administration-THS menthol (9)

Data signed: (hfarmer1) 26 Mar 2015 14:19:42

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Product Use

Form: Product administration-THS menthol (10)

Data signed: (hfarmer1) 26 Mar 2015 14:19:42

Generated On: 20 Jul 2016 12:09:14

Date of product use DD/MMM/YYYY	20 JAN 2014
------------------------------------	-------------

Visit	Day 1 <input checked="" type="radio"/>
-------	--

Type of Product Use	THS 2.2 Menthol <input checked="" type="radio"/>
---------------------	--

If type of Product Use different from the randomization
please explain _____

Time of distribution	22:23
----------------------	-------

Time of product return	22:34
------------------------	-------

SODIM device number	159
---------------------	-----

SODIM sample holder number	1125
----------------------------	------

Tobacco plug kit number	T1809
-------------------------	-------

Tobacco plug vial number	10
--------------------------	----

SODIM file number	08DY0159COHB11125010
-------------------	----------------------

Comment	_____
---------	-------

Batch Number	B08545
--------------	--------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1062

Folder: Product Use

Form: Product administration-THS menthol (10)

Data signed: (hfarmer1) 26 Mar 2015 14:19:42

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Product Use

Form: Product administration-THS menthol (11)

Data signed: (hfarmer1) 26 Mar 2015 14:19:42

Generated On: 20 Jul 2016 12:09:14

Date of product use DD/MMM/YYYY	21 JAN 2014
------------------------------------	-------------

Visit	Day 2 <input checked="" type="radio"/>
-------	--

Type of Product Use	THS 2.2 Menthol <input checked="" type="radio"/>
---------------------	--

If type of Product Use different from the randomization
please explain _____

Time of distribution	07:15
----------------------	-------

Time of product return	07:23
------------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

Tobacco plug kit number	T1821
-------------------------	-------

Tobacco plug vial number	01
--------------------------	----

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

Batch Number	B08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1062

Folder: Product Use

Form: Product administration-THS menthol (11)

Data signed: (hfarmer1) 26 Mar 2015 14:19:42

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Product Use

Form: Product administration-THS menthol (12)

Data signed: (hfarmer1) 26 Mar 2015 14:19:42

Generated On: 20 Jul 2016 12:09:14

Date of product use DD/MMM/YYYY	21 JAN 2014
------------------------------------	-------------

Visit	Day 2 <input checked="" type="radio"/>
-------	--

Type of Product Use	THS 2.2 Menthol <input checked="" type="radio"/>
---------------------	--

If type of Product Use different from the randomization
please explain _____

Time of distribution	08:54
----------------------	-------

Time of product return	08:55
------------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

Tobacco plug kit number	T1821
-------------------------	-------

Tobacco plug vial number	02
--------------------------	----

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

Batch Number	B08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1062

Folder: Product Use

Form: Product administration-THS menthol (12)

Data signed: (hfarmer1) 26 Mar 2015 14:19:42

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Product Use

Form: Product administration-THS menthol (13)

Data signed: (hfarmer1) 26 Mar 2015 14:19:42

Generated On: 20 Jul 2016 12:09:14

Date of product use DD/MMM/YYYY	21 JAN 2014
------------------------------------	-------------

Visit	Day 2 <input checked="" type="radio"/>
-------	--

Type of Product Use	THS 2.2 Menthol <input checked="" type="radio"/>
---------------------	--

If type of Product Use different from the randomization
please explain _____

Time of distribution	09:01
----------------------	-------

Time of product return	09:06
------------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

Tobacco plug kit number	T1821
-------------------------	-------

Tobacco plug vial number	03
--------------------------	----

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

Batch Number	B08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1062

Folder: Product Use

Form: Product administration-THS menthol (13)

Data signed: (hfarmer1) 26 Mar 2015 14:19:42

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Product Use

Form: Product administration-THS menthol (14)

Data signed: (hfarmer1) 26 Mar 2015 14:19:42

Generated On: 20 Jul 2016 12:09:14

Date of product use DD/MMM/YYYY	21 JAN 2014
------------------------------------	-------------

Visit	Day 2 <input checked="" type="radio"/>
-------	--

Type of Product Use	THS 2.2 Menthol <input checked="" type="radio"/>
---------------------	--

If type of Product Use different from the randomization
please explain

Time of distribution	09:55
----------------------	-------

Time of product return	10:03
------------------------	-------

SODIM device number	
---------------------	--

SODIM sample holder number	
----------------------------	--

Tobacco plug kit number	T1821
-------------------------	-------

Tobacco plug vial number	04
--------------------------	----

SODIM file number	
-------------------	--

Comment	
---------	--

Batch Number	B08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1062

Folder: Product Use

Form: Product administration-THS menthol (14)

Data signed: (hfarmer1) 26 Mar 2015 14:19:42

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Product Use

Form: Product administration-THS menthol (15)

Data signed: (hfarmer1) 26 Mar 2015 14:19:42

Generated On: 20 Jul 2016 12:09:14

Date of product use DD/MMM/YYYY	21 JAN 2014
------------------------------------	-------------

Visit	Day 2 <input checked="" type="radio"/>
-------	--

Type of Product Use	THS 2.2 Menthol <input checked="" type="radio"/>
---------------------	--

If type of Product Use different from the randomization
please explain _____

Time of distribution	12:25
----------------------	-------

Time of product return	12:35
------------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

Tobacco plug kit number	T1821
-------------------------	-------

Tobacco plug vial number	05
--------------------------	----

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

Batch Number	B08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1062

Folder: Product Use

Form: Product administration-THS menthol (15)

Data signed: (hfarmer1) 26 Mar 2015 14:19:42

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Product Use

Form: Product administration-THS menthol (16)

Data signed: (hfarmer1) 26 Mar 2015 14:19:42

Generated On: 20 Jul 2016 12:09:14

Date of product use DD/MMM/YYYY	21 JAN 2014
------------------------------------	-------------

Visit	Day 2 <input checked="" type="radio"/>
-------	--

Type of Product Use	THS 2.2 Menthol <input checked="" type="radio"/>
---------------------	--

If type of Product Use different from the randomization
please explain _____

Time of distribution	13:45
----------------------	-------

Time of product return	13:51
------------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

Tobacco plug kit number	T1821
-------------------------	-------

Tobacco plug vial number	06
--------------------------	----

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

Batch Number	B08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1062

Folder: Product Use

Form: Product administration-THS menthol (16)

Data signed: (hfarmer1) 26 Mar 2015 14:19:42

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Product Use

Form: Product administration-THS menthol (17)

Data signed: (hfarmer1) 26 Mar 2015 14:19:42

Generated On: 20 Jul 2016 12:09:14

Date of product use DD/MMM/YYYY	21 JAN 2014
------------------------------------	-------------

Visit	Day 2 <input checked="" type="radio"/>
-------	--

Type of Product Use	THS 2.2 Menthol <input checked="" type="radio"/>
---------------------	--

If type of Product Use different from the randomization
please explain _____

Time of distribution	13:55
----------------------	-------

Time of product return	14:01
------------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

Tobacco plug kit number	T1821
-------------------------	-------

Tobacco plug vial number	07
--------------------------	----

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

Batch Number	B08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1062

Folder: Product Use

Form: Product administration-THS menthol (17)

Data signed: (hfarmer1) 26 Mar 2015 14:19:42

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Product Use

Form: Product administration-THS menthol (18)

Data signed: (hfarmer1) 26 Mar 2015 14:19:42

Generated On: 20 Jul 2016 12:09:14

Date of product use DD/MMM/YYYY	21 JAN 2014
------------------------------------	-------------

Visit	Day 2 <input checked="" type="radio"/>
-------	--

Type of Product Use	THS 2.2 Menthol <input checked="" type="radio"/>
---------------------	--

If type of Product Use different from the randomization
please explain _____

Time of distribution	14:53
----------------------	-------

Time of product return	15:11
------------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

Tobacco plug kit number	T1821
-------------------------	-------

Tobacco plug vial number	08
--------------------------	----

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

Batch Number	B08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1062

Folder: Product Use

Form: Product administration-THS menthol (18)

Data signed: (hfarmer1) 26 Mar 2015 14:19:42

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Product Use

Form: Product administration-THS menthol (19)

Data signed: (hfarmer1) 26 Mar 2015 14:19:42

Generated On: 20 Jul 2016 12:09:14

Date of product use DD/MMM/YYYY	21 JAN 2014
------------------------------------	-------------

Visit	Day 2 <input checked="" type="radio"/>
-------	--

Type of Product Use	THS 2.2 Menthol <input checked="" type="radio"/>
---------------------	--

If type of Product Use different from the randomization
please explain

Time of distribution	15:44
----------------------	-------

Time of product return	15:57
------------------------	-------

SODIM device number	<hr/>
---------------------	-------

SODIM sample holder number	<hr/>
----------------------------	-------

Tobacco plug kit number	T1821
-------------------------	-------

Tobacco plug vial number	09
--------------------------	----

SODIM file number	<hr/>
-------------------	-------

Comment	<hr/>
---------	-------

Batch Number	B08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1062

Folder: Product Use

Form: Product administration-THS menthol (19)

Data signed: (hfarmer1) 26 Mar 2015 14:19:42

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Product Use

Form: Product administration-THS menthol (20)

Data signed: (hfarmer1) 26 Mar 2015 14:19:42

Generated On: 20 Jul 2016 12:09:14

Date of product use DD/MMM/YYYY	21 JAN 2014
------------------------------------	-------------

Visit	Day 2 <input checked="" type="radio"/>
-------	--

Type of Product Use	THS 2.2 Menthol <input checked="" type="radio"/>
---------------------	--

If type of Product Use different from the randomization
please explain

Time of distribution	17:02
----------------------	-------

Time of product return	17:10
------------------------	-------

SODIM device number	<hr/>
---------------------	-------

SODIM sample holder number	<hr/>
----------------------------	-------

Tobacco plug kit number	T1821
-------------------------	-------

Tobacco plug vial number	10
--------------------------	----

SODIM file number	<hr/>
-------------------	-------

Comment	<hr/>
---------	-------

Batch Number	B08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1062

Folder: Product Use

Form: Product administration-THS menthol (20)

Data signed: (hfarmer1) 26 Mar 2015 14:19:42

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Product Use

Form: Product administration-THS menthol (21)

Data signed: (hfarmer1) 26 Mar 2015 14:19:42

Generated On: 20 Jul 2016 12:09:14

Date of product use DD/MMM/YYYY	21 JAN 2014
------------------------------------	-------------

Visit	Day 2 <input checked="" type="radio"/>
-------	--

Type of Product Use	THS 2.2 Menthol <input checked="" type="radio"/>
---------------------	--

If type of Product Use different from the randomization
please explain

Time of distribution	17:33
----------------------	-------

Time of product return	17:41
------------------------	-------

SODIM device number	
---------------------	--

SODIM sample holder number	
----------------------------	--

Tobacco plug kit number	T1821
-------------------------	-------

Tobacco plug vial number	11
--------------------------	----

SODIM file number	
-------------------	--

Comment	
---------	--

Batch Number	B08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1062

Folder: Product Use

Form: Product administration-THS menthol (21)

Data signed: (hfarmer1) 26 Mar 2015 14:19:42

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Product Use

Form: Product administration-THS menthol (22)

Data signed: (hfarmer1) 26 Mar 2015 14:19:42

Generated On: 20 Jul 2016 12:09:14

Date of product use DD/MMM/YYYY	21 JAN 2014
------------------------------------	-------------

Visit	Day 2 <input checked="" type="radio"/>
-------	--

Type of Product Use	THS 2.2 Menthol <input checked="" type="radio"/>
---------------------	--

If type of Product Use different from the randomization
please explain _____

Time of distribution	19:51
----------------------	-------

Time of product return	20:02
------------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

Tobacco plug kit number	T1821
-------------------------	-------

Tobacco plug vial number	12
--------------------------	----

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

Batch Number	B08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1062

Folder: Product Use

Form: Product administration-THS menthol (22)

Data signed: (hfarmer1) 26 Mar 2015 14:19:42

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Product Use

Form: Product administration-THS menthol (23)

Data signed: (hfarmer1) 26 Mar 2015 14:19:42

Generated On: 20 Jul 2016 12:09:14

Date of product use DD/MMM/YYYY	21 JAN 2014
------------------------------------	-------------

Visit	Day 2 <input checked="" type="radio"/>
-------	--

Type of Product Use	THS 2.2 Menthol <input checked="" type="radio"/>
---------------------	--

If type of Product Use different from the randomization
please explain

Time of distribution	21:31
----------------------	-------

Time of product return	21:43
------------------------	-------

SODIM device number	
---------------------	--

SODIM sample holder number	
----------------------------	--

Tobacco plug kit number	T1821
-------------------------	-------

Tobacco plug vial number	13
--------------------------	----

SODIM file number	
-------------------	--

Comment	
---------	--

Batch Number	B08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1062

Folder: Product Use

Form: Product administration-THS menthol (23)

Data signed: (hfarmer1) 26 Mar 2015 14:19:42

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Product Use

Form: Product administration-THS menthol (24)

Data signed: (hfarmer1) 26 Mar 2015 14:19:42

Generated On: 20 Jul 2016 12:09:14

Date of product use DD/MMM/YYYY	21 JAN 2014
------------------------------------	-------------

Visit	Day 2 <input checked="" type="radio"/>
-------	--

Type of Product Use	THS 2.2 Menthol <input checked="" type="radio"/>
---------------------	--

If type of Product Use different from the randomization
please explain _____

Time of distribution	22:08
----------------------	-------

Time of product return	22:14
------------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

Tobacco plug kit number	T1821
-------------------------	-------

Tobacco plug vial number	14
--------------------------	----

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

Batch Number	B08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1062

Folder: Product Use

Form: Product administration-THS menthol (24)

Data signed: (hfarmer1) 26 Mar 2015 14:19:42

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Product Use

Form: Product administration-THS menthol (25)

Data signed: (hfarmer1) 26 Mar 2015 14:19:42

Generated On: 20 Jul 2016 12:09:14

Date of product use DD/MMM/YYYY	21 JAN 2014
------------------------------------	-------------

Visit	Day 2 <input checked="" type="radio"/>
-------	--

Type of Product Use	THS 2.2 Menthol <input checked="" type="radio"/>
---------------------	--

If type of Product Use different from the randomization
please explain _____

Time of distribution	22:30
----------------------	-------

Time of product return	22:37
------------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

Tobacco plug kit number	T1821
-------------------------	-------

Tobacco plug vial number	15
--------------------------	----

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

Batch Number	B08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1062

Folder: Product Use

Form: Product administration-THS menthol (25)

Data signed: (hfarmer1) 26 Mar 2015 14:19:42

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Product Use

Form: Product administration-THS menthol (26)

Data signed: (hfarmer1) 26 Mar 2015 14:19:42

Generated On: 20 Jul 2016 12:09:14

Date of product use DD/MMM/YYYY	22 JAN 2014
------------------------------------	-------------

Visit	Day 3 <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 _____

Time of distribution	06:50
----------------------	-------

Time of product return	07:00
------------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

Tobacco plug kit number	T1825
-------------------------	-------

Tobacco plug vial number	01
--------------------------	----

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

Batch Number	B08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1062

Folder: Product Use

Form: Product administration-THS menthol (26)

Data signed: (hfarmer1) 26 Mar 2015 14:19:42

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Product Use

Form: Product administration-THS menthol (27)

Data signed: (hfarmer1) 26 Mar 2015 14:19:42

Generated On: 20 Jul 2016 12:09:14

Date of product use DD/MMM/YYYY	22 JAN 2014
------------------------------------	-------------

Visit	Day 3 <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

Time of distribution	09:32
----------------------	-------

Time of product return	09:40
------------------------	-------

SODIM device number	<hr/>
---------------------	-------

SODIM sample holder number	<hr/>
----------------------------	-------

Tobacco plug kit number	T1825
-------------------------	-------

Tobacco plug vial number	02
--------------------------	----

SODIM file number	<hr/>
-------------------	-------

Comment	<hr/>
---------	-------

Batch Number	B08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1062

Folder: Product Use

Form: Product administration-THS menthol (27)

Data signed: (hfarmer1) 26 Mar 2015 14:19:42

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Product Use

Form: Product administration-THS menthol (28)

Data signed: (hfarmer1) 26 Mar 2015 14:19:42

Generated On: 20 Jul 2016 12:09:14

Date of product use DD/MMM/YYYY	22 JAN 2014
------------------------------------	-------------

Visit	Day 3 <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 _____

Time of distribution	10:33
----------------------	-------

Time of product return	10:37
------------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

Tobacco plug kit number	T1825
-------------------------	-------

Tobacco plug vial number	03
--------------------------	----

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

Batch Number	B08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1062

Folder: Product Use

Form: Product administration-THS menthol (28)

Data signed: (hfarmer1) 26 Mar 2015 14:19:42

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Product Use

Form: Product administration-THS menthol (29)

Data signed: (hfarmer1) 26 Mar 2015 14:19:42

Generated On: 20 Jul 2016 12:09:14

Date of product use DD/MMM/YYYY	22 JAN 2014
------------------------------------	-------------

Visit	Day 3 <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

Time of distribution	11:53
----------------------	-------

Time of product return	12:04
------------------------	-------

SODIM device number	<hr/>
---------------------	-------

SODIM sample holder number	<hr/>
----------------------------	-------

Tobacco plug kit number	T1825
-------------------------	-------

Tobacco plug vial number	04
--------------------------	----

SODIM file number	<hr/>
-------------------	-------

Comment	<hr/>
---------	-------

Batch Number	B08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1062

Folder: Product Use

Form: Product administration-THS menthol (29)

Data signed: (hfarmer1) 26 Mar 2015 14:19:42

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Product Use

Form: Product administration-THS menthol (30)

Data signed: (hfarmer1) 26 Mar 2015 14:19:42

Generated On: 20 Jul 2016 12:09:14

Date of product use DD/MMM/YYYY	22 JAN 2014
------------------------------------	-------------

Visit	Day 3 <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

Time of distribution	12:31
----------------------	-------

Time of product return	12:42
------------------------	-------

SODIM device number	<hr/>
---------------------	-------

SODIM sample holder number	<hr/>
----------------------------	-------

Tobacco plug kit number	T1825
-------------------------	-------

Tobacco plug vial number	05
--------------------------	----

SODIM file number	<hr/>
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Comment	<hr/>
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Batch Number	B08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1062

Folder: Product Use

Form: Product administration-THS menthol (30)

Data signed: (hfarmer1) 26 Mar 2015 14:19:42

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Product Use

Form: Product administration-THS menthol (31)

Data signed: (hfarmer1) 26 Mar 2015 14:19:42

Generated On: 20 Jul 2016 12:09:14

Date of product use DD/MMM/YYYY	22 JAN 2014
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Visit	Day 3 <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

Time of distribution	13:23
----------------------	-------

Time of product return	13:33
------------------------	-------

SODIM device number	
---------------------	--

SODIM sample holder number	
----------------------------	--

Tobacco plug kit number	T1825
-------------------------	-------

Tobacco plug vial number	06
--------------------------	----

SODIM file number	
-------------------	--

Comment	
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Batch Number	B08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1062

Folder: Product Use

Form: Product administration-THS menthol (31)

Data signed: (hfarmer1) 26 Mar 2015 14:19:42

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Product Use

Form: Product administration-THS menthol (32)

Data signed: (hfarmer1) 26 Mar 2015 14:19:42

Generated On: 20 Jul 2016 12:09:14

Date of product use DD/MMM/YYYY	22 JAN 2014
------------------------------------	-------------

Visit	Day 3 <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

Time of distribution	14:14
----------------------	-------

Time of product return	14:24
------------------------	-------

SODIM device number	<hr/>
---------------------	-------

SODIM sample holder number	<hr/>
----------------------------	-------

Tobacco plug kit number	T1825
-------------------------	-------

Tobacco plug vial number	07
--------------------------	----

SODIM file number	<hr/>
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Comment	<hr/>
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Batch Number	B08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1062

Folder: Product Use

Form: Product administration-THS menthol (32)

Data signed: (hfarmer1) 26 Mar 2015 14:19:42

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Product Use

Form: Product administration-THS menthol (33)

Data signed: (hfarmer1) 26 Mar 2015 14:19:42

Generated On: 20 Jul 2016 12:09:14

Date of product use DD/MMM/YYYY	22 JAN 2014
------------------------------------	-------------

Visit	Day 3 <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

Time of distribution	15:44
----------------------	-------

Time of product return	15:52
------------------------	-------

SODIM device number	<hr/>
---------------------	-------

SODIM sample holder number	<hr/>
----------------------------	-------

Tobacco plug kit number	T1825
-------------------------	-------

Tobacco plug vial number	08
--------------------------	----

SODIM file number	<hr/>
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Comment	<hr/>
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Batch Number	B08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1062

Folder: Product Use

Form: Product administration-THS menthol (33)

Data signed: (hfarmer1) 26 Mar 2015 14:19:42

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Product Use

Form: Product administration-THS menthol (34)

Data signed: (hfarmer1) 26 Mar 2015 14:19:42

Generated On: 20 Jul 2016 12:09:14

Date of product use DD/MMM/YYYY	22 JAN 2014
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Visit	Day 3 <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 _____

Time of distribution	17:17
----------------------	-------

Time of product return	17:26
------------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

Tobacco plug kit number	T1825
-------------------------	-------

Tobacco plug vial number	09
--------------------------	----

SODIM file number	_____
-------------------	-------

Comment	_____
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Batch Number	B08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1062

Folder: Product Use

Form: Product administration-THS menthol (34)

Data signed: (hfarmer1) 26 Mar 2015 14:19:42

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Product Use

Form: Product administration-THS menthol (35)

Data signed: (hfarmer1) 26 Mar 2015 14:19:42

Generated On: 20 Jul 2016 12:09:14

Date of product use DD/MMM/YYYY	22 JAN 2014
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Visit	Day 3 <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

Time of distribution	20:22
----------------------	-------

Time of product return	20:31
------------------------	-------

SODIM device number	<hr/>
---------------------	-------

SODIM sample holder number	<hr/>
----------------------------	-------

Tobacco plug kit number	T1825
-------------------------	-------

Tobacco plug vial number	10
--------------------------	----

SODIM file number	<hr/>
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Comment	<hr/>
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Batch Number	B08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1062

Folder: Product Use

Form: Product administration-THS menthol (35)

Data signed: (hfarmer1) 26 Mar 2015 14:19:42

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Product Use

Form: Product administration-THS menthol (36)

Data signed: (hfarmer1) 26 Mar 2015 14:19:42

Generated On: 20 Jul 2016 12:09:14

Date of product use DD/MMM/YYYY	22 JAN 2014
------------------------------------	-------------

Visit	Day 3 <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 _____

Time of distribution	20:54
----------------------	-------

Time of product return	21:08
------------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

Tobacco plug kit number	T1825
-------------------------	-------

Tobacco plug vial number	11
--------------------------	----

SODIM file number	_____
-------------------	-------

Comment	_____
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Batch Number	B08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1062

Folder: Product Use

Form: Product administration-THS menthol (36)

Data signed: (hfarmer1) 26 Mar 2015 14:19:42

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Product Use

Form: Product administration-THS menthol (37)

Data signed: (hfarmer1) 26 Mar 2015 14:19:42

Generated On: 20 Jul 2016 12:09:14

Date of product use DD/MMM/YYYY	22 JAN 2014
------------------------------------	-------------

Visit	Day 3 <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

Time of distribution	21:50
----------------------	-------

Time of product return	21:58
------------------------	-------

SODIM device number	<hr/>
---------------------	-------

SODIM sample holder number	<hr/>
----------------------------	-------

Tobacco plug kit number	T1825
-------------------------	-------

Tobacco plug vial number	12
--------------------------	----

SODIM file number	<hr/>
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Comment	<hr/>
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Batch Number	B08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1062

Folder: Product Use

Form: Product administration-THS menthol (37)

Data signed: (hfarmer1) 26 Mar 2015 14:19:42

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Product Use

Form: Product administration-THS menthol (38)

Data signed: (hfarmer1) 26 Mar 2015 14:19:42

Generated On: 20 Jul 2016 12:09:14

Date of product use DD/MMM/YYYY	22 JAN 2014
------------------------------------	-------------

Visit	Day 3 <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 _____

Time of distribution	22:30
----------------------	-------

Time of product return	22:39
------------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

Tobacco plug kit number	T1825
-------------------------	-------

Tobacco plug vial number	13
--------------------------	----

SODIM file number	_____
-------------------	-------

Comment	_____
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Batch Number	B08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1062

Folder: Product Use

Form: Product administration-THS menthol (38)

Data signed: (hfarmer1) 26 Mar 2015 14:19:42

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Product Use

Form: Product administration-THS menthol (39)

Data signed: (hfarmer1) 26 Mar 2015 14:19:42

Generated On: 20 Jul 2016 12:09:14

Date of product use DD/MMM/YYYY	23 JAN 2014
------------------------------------	-------------

Visit	Day 4 <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 _____

Time of distribution	06:34
----------------------	-------

Time of product return	06:44
------------------------	-------

SODIM device number	159
---------------------	-----

SODIM sample holder number	1125
----------------------------	------

Tobacco plug kit number	T1834
-------------------------	-------

Tobacco plug vial number	01
--------------------------	----

SODIM file number	08DY0159COHB11125011
-------------------	----------------------

Comment	_____
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Batch Number	B08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1062

Folder: Product Use

Form: Product administration-THS menthol (39)

Data signed: (hfarmer1) 26 Mar 2015 14:19:42

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Product Use

Form: Product administration-THS menthol (40)

Data signed: (hfarmer1) 26 Mar 2015 14:19:42

Generated On: 20 Jul 2016 12:09:14

Date of product use DD/MMM/YYYY	23 JAN 2014
------------------------------------	-------------

Visit	Day 4 <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 _____

Time of distribution	07:29
----------------------	-------

Time of product return	07:34
------------------------	-------

SODIM device number	159
---------------------	-----

SODIM sample holder number	1125
----------------------------	------

Tobacco plug kit number	T1834
-------------------------	-------

Tobacco plug vial number	02
--------------------------	----

SODIM file number	08DY0159COHB11125012
-------------------	----------------------

Comment	_____
---------	-------

Batch Number	B08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1062

Folder: Product Use

Form: Product administration-THS menthol (40)

Data signed: (hfarmer1) 26 Mar 2015 14:19:42

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Product Use

Form: Product administration-THS menthol (41)

Data signed: (hfarmer1) 26 Mar 2015 14:19:42

Generated On: 20 Jul 2016 12:09:14

Date of product use DD/MMM/YYYY	23 JAN 2014
------------------------------------	-------------

Visit	Day 4 <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 _____

Time of distribution	08:33
----------------------	-------

Time of product return	08:43
------------------------	-------

SODIM device number	159
---------------------	-----

SODIM sample holder number	1125
----------------------------	------

Tobacco plug kit number	T1834
-------------------------	-------

Tobacco plug vial number	03
--------------------------	----

SODIM file number	08DY0159COHB11125013
-------------------	----------------------

Comment	_____
---------	-------

Batch Number	B08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1062

Folder: Product Use

Form: Product administration-THS menthol (41)

Data signed: (hfarmer1) 26 Mar 2015 14:19:42

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Product Use

Form: Product administration-THS menthol (42)

Data signed: (hfarmer1) 26 Mar 2015 14:19:42

Generated On: 20 Jul 2016 12:09:14

Date of product use DD/MMM/YYYY	23 JAN 2014
------------------------------------	-------------

Visit	Day 4 <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 _____

Time of distribution	10:33
----------------------	-------

Time of product return	10:42
------------------------	-------

SODIM device number	159
---------------------	-----

SODIM sample holder number	1125
----------------------------	------

Tobacco plug kit number	T1834
-------------------------	-------

Tobacco plug vial number	04
--------------------------	----

SODIM file number	08DY0159COHB11125014
-------------------	----------------------

Comment	_____
---------	-------

Batch Number	B08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1062

Folder: Product Use

Form: Product administration-THS menthol (42)

Data signed: (hfarmer1) 26 Mar 2015 14:19:42

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Product Use

Form: Product administration-THS menthol (43)

Data signed: (hfarmer1) 26 Mar 2015 14:19:42

Generated On: 20 Jul 2016 12:09:14

Date of product use DD/MMM/YYYY	23 JAN 2014
------------------------------------	-------------

Visit	Day 4 <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 _____

Time of distribution	11:49
----------------------	-------

Time of product return	11:54
------------------------	-------

SODIM device number	159
---------------------	-----

SODIM sample holder number	1125
----------------------------	------

Tobacco plug kit number	T1834
-------------------------	-------

Tobacco plug vial number	05
--------------------------	----

SODIM file number	08DY0159COHB11125015
-------------------	----------------------

Comment	_____
---------	-------

Batch Number	B08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1062

Folder: Product Use

Form: Product administration-THS menthol (43)

Data signed: (hfarmer1) 26 Mar 2015 14:19:42

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Product Use

Form: Product administration-THS menthol (44)

Data signed: (hfarmer1) 26 Mar 2015 14:19:42

Generated On: 20 Jul 2016 12:09:14

Date of product use DD/MMM/YYYY	23 JAN 2014
------------------------------------	-------------

Visit	Day 4 <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 _____

Time of distribution	13:50
----------------------	-------

Time of product return	13:58
------------------------	-------

SODIM device number	159
---------------------	-----

SODIM sample holder number	1125
----------------------------	------

Tobacco plug kit number	T1834
-------------------------	-------

Tobacco plug vial number	06
--------------------------	----

SODIM file number	08DY0159COHB11125016
-------------------	----------------------

Comment	_____
---------	-------

Batch Number	B08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1062

Folder: Product Use

Form: Product administration-THS menthol (44)

Data signed: (hfarmer1) 26 Mar 2015 14:19:42

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Product Use

Form: Product administration-THS menthol (45)

Data signed: (hfarmer1) 26 Mar 2015 14:19:42

Generated On: 20 Jul 2016 12:09:14

Date of product use DD/MMM/YYYY	23 JAN 2014
------------------------------------	-------------

Visit	Day 4 <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 _____

Time of distribution	14:37
----------------------	-------

Time of product return	14:46
------------------------	-------

SODIM device number	159
---------------------	-----

SODIM sample holder number	1125
----------------------------	------

Tobacco plug kit number	T1834
-------------------------	-------

Tobacco plug vial number	07
--------------------------	----

SODIM file number	08DY0159COHB11125017
-------------------	----------------------

Comment	_____
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Batch Number	B08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1062

Folder: Product Use

Form: Product administration-THS menthol (45)

Data signed: (hfarmer1) 26 Mar 2015 14:19:42

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Product Use

Form: Product administration-THS menthol (46)

Data signed: (hfarmer1) 26 Mar 2015 14:19:42

Generated On: 20 Jul 2016 12:09:14

Date of product use DD/MMM/YYYY	23 JAN 2014
------------------------------------	-------------

Visit	Day 4 <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 _____

Time of distribution	16:15
----------------------	-------

Time of product return	16:19
------------------------	-------

SODIM device number	159
---------------------	-----

SODIM sample holder number	1125
----------------------------	------

Tobacco plug kit number	T1834
-------------------------	-------

Tobacco plug vial number	08
--------------------------	----

SODIM file number	08DY0159COHB11125018
-------------------	----------------------

Comment	_____
---------	-------

Batch Number	B08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1062

Folder: Product Use

Form: Product administration-THS menthol (46)

Data signed: (hfarmer1) 26 Mar 2015 14:19:42

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Product Use

Form: Product administration-THS menthol (47)

Data signed: (hfarmer1) 26 Mar 2015 14:19:42

Generated On: 20 Jul 2016 12:09:14

Date of product use DD/MMM/YYYY	23 JAN 2014
------------------------------------	-------------

Visit	Day 4 <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 _____

Time of distribution	17:25
----------------------	-------

Time of product return	17:36
------------------------	-------

SODIM device number	159
---------------------	-----

SODIM sample holder number	1125
----------------------------	------

Tobacco plug kit number	T1834
-------------------------	-------

Tobacco plug vial number	09
--------------------------	----

SODIM file number	08DY0159COHB11125019
-------------------	----------------------

Comment	_____
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Batch Number	B08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1062

Folder: Product Use

Form: Product administration-THS menthol (47)

Data signed: (hfarmer1) 26 Mar 2015 14:19:42

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Product Use

Form: Product administration-THS menthol (48)

Data signed: (hfarmer1) 26 Mar 2015 14:19:42

Generated On: 20 Jul 2016 12:09:14

Date of product use DD/MMM/YYYY	23 JAN 2014
------------------------------------	-------------

Visit	Day 4 <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 _____

Time of distribution	17:38
----------------------	-------

Time of product return	17:48
------------------------	-------

SODIM device number	159
---------------------	-----

SODIM sample holder number	1125
----------------------------	------

Tobacco plug kit number	T1834
-------------------------	-------

Tobacco plug vial number	10
--------------------------	----

SODIM file number	08DY0159COHB11125020
-------------------	----------------------

Comment	_____
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Batch Number	B08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1062

Folder: Product Use

Form: Product administration-THS menthol (48)

Data signed: (hfarmer1) 26 Mar 2015 14:19:42

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Product Use

Form: Product administration-THS menthol (49)

Data signed: (hfarmer1) 26 Mar 2015 14:19:42

Generated On: 20 Jul 2016 12:09:14

Date of product use DD/MMM/YYYY	23 JAN 2014
------------------------------------	-------------

Visit	Day 4 <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 _____

Time of distribution	19:20
----------------------	-------

Time of product return	19:31
------------------------	-------

SODIM device number	159
---------------------	-----

SODIM sample holder number	1125
----------------------------	------

Tobacco plug kit number	T1834
-------------------------	-------

Tobacco plug vial number	11
--------------------------	----

SODIM file number	08DY0159COHB11125021
-------------------	----------------------

Comment	_____
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Batch Number	B08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1062

Folder: Product Use

Form: Product administration-THS menthol (49)

Data signed: (hfarmer1) 26 Mar 2015 14:19:42

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Product Use

Form: Product administration-THS menthol (50)

Data signed: (hfarmer1) 26 Mar 2015 14:19:42

Generated On: 20 Jul 2016 12:09:14

Date of product use DD/MMM/YYYY	23 JAN 2014
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Visit	Day 4 <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 _____

Time of distribution	20:25
----------------------	-------

Time of product return	20:36
------------------------	-------

SODIM device number	159
---------------------	-----

SODIM sample holder number	1125
----------------------------	------

Tobacco plug kit number	T1834
-------------------------	-------

Tobacco plug vial number	12
--------------------------	----

SODIM file number	08DY0159COHB11125022
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Comment	_____
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Batch Number	B08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1062

Folder: Product Use

Form: Product administration-THS menthol (50)

Data signed: (hfarmer1) 26 Mar 2015 14:19:42

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Product Use

Form: Product administration-THS menthol (51)

Data signed: (hfarmer1) 26 Mar 2015 14:19:42

Generated On: 20 Jul 2016 12:09:14

Date of product use DD/MMM/YYYY	23 JAN 2014
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Visit	Day 4 <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 _____

Time of distribution	20:58
----------------------	-------

Time of product return	21:08
------------------------	-------

SODIM device number	159
---------------------	-----

SODIM sample holder number	1125
----------------------------	------

Tobacco plug kit number	T1834
-------------------------	-------

Tobacco plug vial number	13
--------------------------	----

SODIM file number	08DY0159COHB11125022
-------------------	----------------------

Comment	_____
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Batch Number	B08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1062

Folder: Product Use

Form: Product administration-THS menthol (51)

Data signed: (hfarmer1) 26 Mar 2015 14:19:42

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Product Use

Form: Product administration-THS menthol (52)

Data signed: (hfarmer1) 26 Mar 2015 14:19:42

Generated On: 20 Jul 2016 12:09:14

Date of product use DD/MMM/YYYY	23 JAN 2014
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Visit	Day 4 <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 _____

Time of distribution	21:54
----------------------	-------

Time of product return	22:02
------------------------	-------

SODIM device number	159
---------------------	-----

SODIM sample holder number	1125
----------------------------	------

Tobacco plug kit number	T1834
-------------------------	-------

Tobacco plug vial number	14
--------------------------	----

SODIM file number	08DY0159COHB11125023
-------------------	----------------------

Comment	_____
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Batch Number	B08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1062

Folder: Product Use

Form: Product administration-THS menthol (52)

Data signed: (hfarmer1) 26 Mar 2015 14:19:42

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Product Use

Form: Product administration-THS menthol (53)

Data signed: (hfarmer1) 26 Mar 2015 14:19:42

Generated On: 20 Jul 2016 12:09:14

Date of product use DD/MMM/YYYY	24 JAN 2014
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Visit	Day 5 <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 _____

Time of distribution	06:32
----------------------	-------

Time of product return	06:44
------------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

Tobacco plug kit number	T1838
-------------------------	-------

Tobacco plug vial number	01
--------------------------	----

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

Batch Number	B08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1062

Folder: Product Use

Form: Product administration-THS menthol (53)

Data signed: (hfarmer1) 26 Mar 2015 14:19:42

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Product Use

Form: Product administration-THS menthol (54)

Data signed: (hfarmer1) 26 Mar 2015 14:19:42

Generated On: 20 Jul 2016 12:09:14

Date of product use DD/MMM/YYYY	24 JAN 2014
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Visit	Day 5 <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 _____

Time of distribution	07:09
----------------------	-------

Time of product return	07:17
------------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

Tobacco plug kit number	T1838
-------------------------	-------

Tobacco plug vial number	02
--------------------------	----

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

Batch Number	B08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1062

Folder: Product Use

Form: Product administration-THS menthol (54)

Data signed: (hfarmer1) 26 Mar 2015 14:19:42

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Product Use

Form: Product administration-THS menthol (55)

Data signed: (hfarmer1) 26 Mar 2015 14:19:42

Generated On: 20 Jul 2016 12:09:14

Date of product use DD/MMM/YYYY	24 JAN 2014
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Visit	Day 5 <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

Time of distribution	10:27
----------------------	-------

Time of product return	10:36
------------------------	-------

SODIM device number	<hr/>
---------------------	-------

SODIM sample holder number	<hr/>
----------------------------	-------

Tobacco plug kit number	T1838
-------------------------	-------

Tobacco plug vial number	03
--------------------------	----

SODIM file number	<hr/>
-------------------	-------

Comment	<hr/>
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Batch Number	B08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1062

Folder: Product Use

Form: Product administration-THS menthol (55)

Data signed: (hfarmer1) 26 Mar 2015 14:19:42

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Product Use

Form: Product administration-THS menthol (56)

Data signed: (hfarmer1) 26 Mar 2015 14:19:42

Generated On: 20 Jul 2016 12:09:14

Date of product use DD/MMM/YYYY	24 JAN 2014
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Visit	Day 5 <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

Time of distribution	11:14
----------------------	-------

Time of product return	11:22
------------------------	-------

SODIM device number	
---------------------	--

SODIM sample holder number	
----------------------------	--

Tobacco plug kit number	T1838
-------------------------	-------

Tobacco plug vial number	04
--------------------------	----

SODIM file number	
-------------------	--

Comment	
---------	--

Batch Number	B08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1062

Folder: Product Use

Form: Product administration-THS menthol (56)

Data signed: (hfarmer1) 26 Mar 2015 14:19:42

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Product Use

Form: Product administration-THS menthol (57)

Data signed: (hfarmer1) 26 Mar 2015 14:19:42

Generated On: 20 Jul 2016 12:09:14

Date of product use DD/MMM/YYYY	24 JAN 2014
------------------------------------	-------------

Visit	Day 5 <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 _____

Time of distribution	12:29
----------------------	-------

Time of product return	12:37
------------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

Tobacco plug kit number	T1838
-------------------------	-------

Tobacco plug vial number	05
--------------------------	----

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

Batch Number	B08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1062

Folder: Product Use

Form: Product administration-THS menthol (57)

Data signed: (hfarmer1) 26 Mar 2015 14:19:42

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Product Use

Form: Product administration-THS menthol (58)

Data signed: (hfarmer1) 26 Mar 2015 14:19:42

Generated On: 20 Jul 2016 12:09:14

Date of product use DD/MMM/YYYY	24 JAN 2014
------------------------------------	-------------

Visit	Day 5 <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

Time of distribution	13:41
----------------------	-------

Time of product return	13:50
------------------------	-------

SODIM device number	<hr/>
---------------------	-------

SODIM sample holder number	<hr/>
----------------------------	-------

Tobacco plug kit number	T1838
-------------------------	-------

Tobacco plug vial number	06
--------------------------	----

SODIM file number	<hr/>
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Comment	<hr/>
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Batch Number	B08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1062

Folder: Product Use

Form: Product administration-THS menthol (58)

Data signed: (hfarmer1) 26 Mar 2015 14:19:42

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Product Use

Form: Product administration-THS menthol (59)

Data signed: (hfarmer1) 26 Mar 2015 14:19:42

Generated On: 20 Jul 2016 12:09:14

Date of product use DD/MMM/YYYY	24 JAN 2014
------------------------------------	-------------

Visit	Day 5 <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

Time of distribution	15:15
----------------------	-------

Time of product return	15:24
------------------------	-------

SODIM device number	<hr/>
---------------------	-------

SODIM sample holder number	<hr/>
----------------------------	-------

Tobacco plug kit number	T1838
-------------------------	-------

Tobacco plug vial number	07
--------------------------	----

SODIM file number	<hr/>
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Comment	<hr/>
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Batch Number	B08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1062

Folder: Product Use

Form: Product administration-THS menthol (59)

Data signed: (hfarmer1) 26 Mar 2015 14:19:42

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Product Use

Form: Product administration-THS menthol (60)

Data signed: (hfarmer1) 26 Mar 2015 14:19:42

Generated On: 20 Jul 2016 12:09:14

Date of product use DD/MMM/YYYY	24 JAN 2014
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Visit	Day 5 <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

Time of distribution	16:22
----------------------	-------

Time of product return	16:31
------------------------	-------

SODIM device number	<hr/>
---------------------	-------

SODIM sample holder number	<hr/>
----------------------------	-------

Tobacco plug kit number	T1838
-------------------------	-------

Tobacco plug vial number	08
--------------------------	----

SODIM file number	<hr/>
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Comment	<hr/>
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Batch Number	B08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1062

Folder: Product Use

Form: Product administration-THS menthol (60)

Data signed: (hfarmer1) 26 Mar 2015 14:19:42

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Product Use

Form: Product administration-THS menthol (61)

Data signed: (hfarmer1) 26 Mar 2015 14:19:42

Generated On: 20 Jul 2016 12:09:14

Date of product use DD/MMM/YYYY	24 JAN 2014
------------------------------------	-------------

Visit	Day 5 <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 _____

Time of distribution	18:58
----------------------	-------

Time of product return	19:06
------------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

Tobacco plug kit number	T1838
-------------------------	-------

Tobacco plug vial number	09
--------------------------	----

SODIM file number	_____
-------------------	-------

Comment	_____
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Batch Number	B08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1062

Folder: Product Use

Form: Product administration-THS menthol (61)

Data signed: (hfarmer1) 26 Mar 2015 14:19:42

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Product Use

Form: Product administration-THS menthol (62)

Data signed: (hfarmer1) 26 Mar 2015 14:19:42

Generated On: 20 Jul 2016 12:09:14

Date of product use DD/MMM/YYYY	24 JAN 2014
------------------------------------	-------------

Visit	Day 5 <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 _____

Time of distribution	19:53
----------------------	-------

Time of product return	20:00
------------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

Tobacco plug kit number	T1838
-------------------------	-------

Tobacco plug vial number	10
--------------------------	----

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

Batch Number	B08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1062

Folder: Product Use

Form: Product administration-THS menthol (62)

Data signed: (hfarmer1) 26 Mar 2015 14:19:42

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Product Use

Form: Product administration-THS menthol (63)

Data signed: (hfarmer1) 26 Mar 2015 14:19:42

Generated On: 20 Jul 2016 12:09:14

Date of product use DD/MMM/YYYY	24 JAN 2014
------------------------------------	-------------

Visit	Day 5 <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 _____

Time of distribution	20:50
----------------------	-------

Time of product return	21:05
------------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

Tobacco plug kit number	T1838
-------------------------	-------

Tobacco plug vial number	11
--------------------------	----

SODIM file number	_____
-------------------	-------

Comment	_____
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Batch Number	B08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1062

Folder: Product Use

Form: Product administration-THS menthol (63)

Data signed: (hfarmer1) 26 Mar 2015 14:19:42

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Product Use

Form: Product administration-THS menthol (64)

Data signed: (hfarmer1) 26 Mar 2015 14:19:42

Generated On: 20 Jul 2016 12:09:14

Date of product use DD/MMM/YYYY	24 JAN 2014
------------------------------------	-------------

Visit	Day 5 <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 _____

Time of distribution	21:46
----------------------	-------

Time of product return	21:53
------------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

Tobacco plug kit number	T1838
-------------------------	-------

Tobacco plug vial number	12
--------------------------	----

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

Batch Number	B08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1062

Folder: Product Use

Form: Product administration-THS menthol (64)

Data signed: (hfarmer1) 26 Mar 2015 14:19:42

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Product Use

Form: Product administration-THS menthol (65)

Data signed: (hfarmer1) 26 Mar 2015 14:19:42

Generated On: 20 Jul 2016 12:09:14

Date of product use DD/MMM/YYYY	24 JAN 2014
------------------------------------	-------------

Visit	Day 5 <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 _____

Time of distribution	22:21
----------------------	-------

Time of product return	22:29
------------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

Tobacco plug kit number	T1838
-------------------------	-------

Tobacco plug vial number	13
--------------------------	----

SODIM file number	_____
-------------------	-------

Comment	_____
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Batch Number	B08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1062

Folder: Product Use

Form: Product administration-THS menthol (65)

Data signed: (hfarmer1) 26 Mar 2015 14:19:42

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Product Use

Form: Product administration-THS menthol (66)

Data signed: (hfarmer1) 26 Mar 2015 14:19:42

Generated On: 20 Jul 2016 12:09:14

Date of product use DD/MMM/YYYY	25 JAN 2014
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Visit	Day 6 <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

Time of distribution	08:45
----------------------	-------

Time of product return	08:53
------------------------	-------

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
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1062

Folder: Product Use

Form: Product administration-THS menthol (66)

Data signed: (hfarmer1) 26 Mar 2015 14:19:42

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Product Use

Form: Product administration-THS menthol (67)

Data signed: (hfarmer1) 26 Mar 2015 14:19:42

Generated On: 20 Jul 2016 12:09:14

Date of product use DD/MMM/YYYY	25 JAN 2014
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Visit	Day 6 <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

Time of distribution	09:10
----------------------	-------

Time of product return	09:18
------------------------	-------

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
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1062

Folder: Product Use

Form: Product administration-THS menthol (67)

Data signed: (hfarmer1) 26 Mar 2015 14:19:42

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Product Use

Form: Product administration-THS menthol (68)

Data signed: (hfarmer1) 26 Mar 2015 14:19:42

Generated On: 20 Jul 2016 12:09:14

Date of product use DD/MMM/YYYY	25 JAN 2014
------------------------------------	-------------

Visit	Day 6 <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

Time of distribution	09:59
----------------------	-------

Time of product return	10:15
------------------------	-------

SODIM device number	<hr/>
---------------------	-------

SODIM sample holder number	<hr/>
----------------------------	-------

Tobacco plug kit number	<hr/>
-------------------------	-------

Tobacco plug vial number	<hr/>
--------------------------	-------

SODIM file number	<hr/>
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Comment	<hr/>
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Batch Number	B08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1062

Folder: Product Use

Form: Product administration-THS menthol (68)

Data signed: (hfarmer1) 26 Mar 2015 14:19:42

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Product Use

Form: Product administration-THS menthol (69)

Data signed: (hfarmer1) 26 Mar 2015 14:19:42

Generated On: 20 Jul 2016 12:09:14

Date of product use DD/MMM/YYYY	17 JAN 2014
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Visit	Day -2 <input type="radio"/>
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Type of Product Use	THS 2.2 Menthol <input type="radio"/>
---------------------	---------------------------------------

If type of Product Use different from the randomization please explain	PRODUCT TEST
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Time of distribution	16:01
----------------------	-------

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/>
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Comment	<hr/>
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Batch Number	B08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1062

Folder: Product Use

Form: Product administration-THS menthol (69)

Data signed: (hfarmer1) 26 Mar 2015 14:19:42

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Product Use

Form: Product administration-THS menthol (70)

Data signed: (hfarmer1) 26 Mar 2015 14:19:42

Generated On: 20 Jul 2016 12:09:14

Date of product use DD/MMM/YYYY	21 JAN 2014
------------------------------------	-------------

Visit	Day 2 <input checked="" type="radio"/>
-------	--

Type of Product Use	THS 2.2 Menthol <input checked="" type="radio"/>
---------------------	--

If type of Product Use different from the randomization
please explain _____

Time of distribution	22:30
----------------------	-------

Time of product return	22:39
------------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

Tobacco plug kit number	T1821
-------------------------	-------

Tobacco plug vial number	16
--------------------------	----

SODIM file number	_____
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Comment	_____
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Batch Number	B08545
--------------	--------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1062

Folder: Product Use

Form: Product administration-THS menthol (70)

Data signed: (hfarmer1) 26 Mar 2015 14:19:42

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Product Use

Form: HST 4 hours (1)

Data signed: (hfarmer1) 26 Mar 2015 14:19:50

Generated On: 20 Jul 2016 12:09:14

Visit

Day 30 ☒

Not Done

True

If Not Done, please specify

EARLY TERMINATION

Date
DD/MMM/YYYY

SODIM device distribution time
hour:min 24-hour clock

SODIM device collection time

hour:min 24-hour clock

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Product Use

Form: HST 4 hours (2)

Data signed: (hfarmer1) 26 Mar 2015 14:19:50

Generated On: 20 Jul 2016 12:09:14

Visit	Day 60 <input checked="" type="radio"/>
-------	---

Not Done	True
----------	------

If Not Done, please specify	EARLY TERMINATION
-----------------------------	-------------------

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: 1062**

Folder: Product Use

Form: HST 4 hours (3)

Data signed: (hfarmer1) 26 Mar 2015 14:19:50

Generated On: 20 Jul 2016 12:09:14

Visit	Day 90 <input checked="" type="radio"/>
-------	---

Not Done	True
----------	------

If Not Done, please specify	EARLY TERMINATION
-----------------------------	-------------------

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/>
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Product Use

Form: Topography files status for mCC (1)

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Product Use

Form: Topography files status for mCC (2)

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Product Use

Form: Topography files status for mCC (3)

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Product Use

Form: Topography files status for mCC (4)

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Product Use

Form: Topography files status for mCC (5)

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Product Use

Form: Topography files status for mCC (6)

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Product Use

Form: Topography files status for mCC (7)

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Product Use

Form: Topography files status for mCC (8)

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Product Use

Form: Topography files status for mCC (9)

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Product Use

Form: Topography files status for mCC (10)

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Product Use

Form: Topography files status for mCC (11)

Generated On: 20 Jul 2016 12:09:14

SODIM file number	08DY0159COHB10540001
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File Status	Accepted <input checked="" type="radio"/>
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Rejection / Error reason	<hr/>
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Date of analysis DD/MMM/YYYY	19 AUG 2014
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Operator	Thierry Bachmann <input checked="" type="radio"/>
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Comment	<hr/>
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Modified File Number	<hr/>
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Product Use

Form: Topography files status for mCC (12)

Generated On: 20 Jul 2016 12:09:14

SODIM file number	08DY0159COHB10540002
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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	19 AUG 2014
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Operator	Thierry Bachmann <input checked="" type="radio"/>
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Comment	<hr/>
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Modified File Number	<hr/>
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Product Use

Form: Topography files status for mCC (13)

Generated On: 20 Jul 2016 12:09:14

SODIM file number	08DY0159COHB10540003
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File Status	Accepted <input checked="" type="radio"/>
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Rejection / Error reason	<hr/>
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Date of analysis DD/MMM/YYYY	19 AUG 2014
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Operator	Thierry Bachmann <input checked="" type="radio"/>
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Comment	<hr/>
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Modified File Number	<hr/>
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Product Use

Form: Topography files status for mCC (14)

Generated On: 20 Jul 2016 12:09:14

SODIM file number	08DY0159COHB10540004
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File Status	Accepted <input checked="" type="radio"/>
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Rejection / Error reason	<hr/>
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Date of analysis DD/MMM/YYYY	19 AUG 2014
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Operator	Thierry Bachmann <input checked="" type="radio"/>
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Comment	<hr/>
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Modified File Number	<hr/>
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Product Use

Form: Topography files status for mCC (15)

Generated On: 20 Jul 2016 12:09:14

SODIM file number	08DY0159COHB10540005
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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	19 AUG 2014
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Operator	Thierry Bachmann 
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Comment	<hr/>
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Modified File Number	<hr/>
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Product Use

Form: Topography files status for mCC (16)

Generated On: 20 Jul 2016 12:09:14

SODIM file number	08DY0159COHB10540006
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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	19 AUG 2014
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Operator	Thierry Bachmann 
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Comment	<hr/>
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Modified File Number	<hr/>
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Product Use

Form: Topography files status for mCC (17)

Generated On: 20 Jul 2016 12:09:14

SODIM file number	08DY0159COHB10540007
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File Status	Accepted <input checked="" type="radio"/>
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Rejection / Error reason	<hr/>
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Date of analysis DD/MMM/YYYY	19 AUG 2014
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Operator	Thierry Bachmann <input checked="" type="radio"/>
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Comment	<hr/>
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Modified File Number	<hr/>
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Product Use

Form: Topography files status for mCC (18)

Generated On: 20 Jul 2016 12:09:14

SODIM file number	08DY0159COHB10540008
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File Status	Accepted <input checked="" type="radio"/>
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Rejection / Error reason	<hr/>
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Date of analysis DD/MMM/YYYY	19 AUG 2014
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Operator	Thierry Bachmann <input checked="" type="radio"/>
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Comment	<hr/>
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Modified File Number	<hr/>
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Product Use

Form: Topography files status for mCC (19)

Generated On: 20 Jul 2016 12:09:14

SODIM file number	08DY0159COHB10540009
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File Status	Accepted <input checked="" type="radio"/>
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Rejection / Error reason	<hr/>
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Date of analysis DD/MMM/YYYY	19 AUG 2014
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Operator	Thierry Bachmann <input checked="" type="radio"/>
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Comment	<hr/>
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Modified File Number	<hr/>
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Product Use

Form: Topography files status for mCC (20)

Generated On: 20 Jul 2016 12:09:14

SODIM file number	08DY0159COHB10540010
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File Status	Accepted <input checked="" type="radio"/>
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Rejection / Error reason	<hr/>
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Date of analysis DD/MMM/YYYY	19 AUG 2014
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Operator	Thierry Bachmann <input checked="" type="radio"/>
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Comment	<hr/>
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Modified File Number	<hr/>
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Product Use

Form: Topography files status for THS menthol (1)

Generated On: 20 Jul 2016 12:09:14

SODIM file number	08DY0159COHB11125001
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File Status	Accepted <input checked="" type="radio"/>
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Rejection / Error reason	<hr/>
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Date of analysis DD/MMM/YYYY	19 AUG 2014
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Operator	Thierry Bachmann <input checked="" type="radio"/>
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Comment	<hr/>
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Modified File Number	<hr/>
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Product Use

Form: Topography files status for THS menthol (2)

Generated On: 20 Jul 2016 12:09:14

SODIM file number	08DY0159COHB11125002
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File Status	Accepted <input checked="" type="radio"/>
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Rejection / Error reason	<hr/>
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Date of analysis DD/MMM/YYYY	19 AUG 2014
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Operator	Thierry Bachmann <input checked="" type="radio"/>
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Comment	<hr/>
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Modified File Number	<hr/>
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Product Use

Form: Topography files status for THS menthol (3)

Generated On: 20 Jul 2016 12:09:14

SODIM file number	08DY0159COHB11125003
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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	19 AUG 2014
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Operator	Thierry Bachmann 
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Comment	<hr/>
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Modified File Number	<hr/>
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Product Use

Form: Topography files status for THS menthol (4)

Generated On: 20 Jul 2016 12:09:14

SODIM file number	08DY0159COHB11125004
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File Status	Accepted <input checked="" type="radio"/>
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Rejection / Error reason	<hr/>
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Date of analysis DD/MMM/YYYY	19 AUG 2014
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Operator	Thierry Bachmann <input checked="" type="radio"/>
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Comment	<hr/>
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Modified File Number	<hr/>
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Product Use

Form: Topography files status for THS menthol (5)

Generated On: 20 Jul 2016 12:09:14

SODIM file number	08DY0159COHB11125005
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File Status	Accepted <input checked="" type="radio"/>
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Rejection / Error reason	<hr/>
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Date of analysis DD/MMM/YYYY	19 AUG 2014
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Operator	Thierry Bachmann <input checked="" type="radio"/>
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Comment	<hr/>
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Modified File Number	<hr/>
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Product Use

Form: Topography files status for THS menthol (6)

Generated On: 20 Jul 2016 12:09:14

SODIM file number	08DY0159COHB11125006
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File Status	Accepted <input checked="" type="radio"/>
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Rejection / Error reason	<hr/>
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Date of analysis DD/MMM/YYYY	19 AUG 2014
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Operator	Thierry Bachmann <input checked="" type="radio"/>
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Comment	<hr/>
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Modified File Number	<hr/>
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Product Use

Form: Topography files status for THS menthol (7)

Generated On: 20 Jul 2016 12:09:14

SODIM file number	08DY0159COHB11125007
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File Status	Accepted <input checked="" type="radio"/>
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Rejection / Error reason	<hr/>
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Date of analysis DD/MMM/YYYY	19 AUG 2014
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Operator	Thierry Bachmann <input checked="" type="radio"/>
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Comment	<hr/>
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Modified File Number	<hr/>
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Product Use

Form: Topography files status for THS menthol (8)

Generated On: 20 Jul 2016 12:09:14

SODIM file number	08DY0159COHB11125008
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File Status	Accepted <input checked="" type="radio"/>
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Rejection / Error reason	<hr/>
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Date of analysis DD/MMM/YYYY	19 AUG 2014
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Operator	Thierry Bachmann <input checked="" type="radio"/>
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Comment	<hr/>
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Modified File Number	<hr/>
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Product Use

Form: Topography files status for THS menthol (9)

Generated On: 20 Jul 2016 12:09:14

SODIM file number	08DY0159COHB11125009
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File Status	Accepted <input checked="" type="radio"/>
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Rejection / Error reason	<hr/>
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Date of analysis DD/MMM/YYYY	19 AUG 2014
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Operator	Thierry Bachmann <input checked="" type="radio"/>
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Comment	<hr/>
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Modified File Number	<hr/>
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Product Use

Form: Topography files status for THS menthol (10)

Generated On: 20 Jul 2016 12:09:14

SODIM file number	08DY0159COHB11125010
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File Status	Accepted <input checked="" type="radio"/>
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Rejection / Error reason	<hr/>
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Date of analysis DD/MMM/YYYY	19 AUG 2014
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Operator	Thierry Bachmann <input checked="" type="radio"/>
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Comment	<hr/>
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Modified File Number	<hr/>
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Product Use

Form: Topography files status for THS menthol (11)

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Product Use

Form: Topography files status for THS menthol (12)

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Product Use

Form: Topography files status for THS menthol (13)

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Product Use

Form: Topography files status for THS menthol (14)

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Product Use

Form: Topography files status for THS menthol (15)

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Product Use

Form: Topography files status for THS menthol (16)

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Product Use

Form: Topography files status for THS menthol (17)

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Product Use

Form: Topography files status for THS menthol (18)

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Product Use

Form: Topography files status for THS menthol (19)

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Product Use

Form: Topography files status for THS menthol (20)

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Product Use

Form: Topography files status for THS menthol (21)

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Product Use

Form: Topography files status for THS menthol (22)

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Product Use

Form: Topography files status for THS menthol (23)

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Product Use

Form: Topography files status for THS menthol (24)

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Product Use

Form: Topography files status for THS menthol (25)

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Product Use

Form: Topography files status for THS menthol (26)

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Product Use

Form: Topography files status for THS menthol (27)

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Product Use

Form: Topography files status for THS menthol (28)

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Product Use

Form: Topography files status for THS menthol (29)

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Product Use

Form: Topography files status for THS menthol (30)

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Product Use

Form: Topography files status for THS menthol (31)

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Product Use

Form: Topography files status for THS menthol (32)

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Product Use

Form: Topography files status for THS menthol (33)

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Product Use

Form: Topography files status for THS menthol (34)

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Product Use

Form: Topography files status for THS menthol (35)

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Product Use

Form: Topography files status for THS menthol (36)

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Product Use

Form: Topography files status for THS menthol (37)

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Product Use

Form: Topography files status for THS menthol (38)

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Product Use

Form: Topography files status for THS menthol (39)

Generated On: 20 Jul 2016 12:09:14

SODIM file number	08DY0159COHB11125011
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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	19 AUG 2014
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Operator	Thierry Bachmann 
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Comment	<hr/>
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Modified File Number	<hr/>
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Product Use

Form: Topography files status for THS menthol (40)

Generated On: 20 Jul 2016 12:09:14

SODIM file number	08DY0159COHB11125012
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File Status	Accepted <input checked="" type="radio"/>
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Rejection / Error reason	<hr/>
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Date of analysis DD/MMM/YYYY	19 AUG 2014
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Operator	Thierry Bachmann <input checked="" type="radio"/>
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Comment	<hr/>
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Modified File Number	<hr/>
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Product Use

Form: Topography files status for THS menthol (41)

Generated On: 20 Jul 2016 12:09:14

SODIM file number	08DY0159COHB11125013
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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	19 AUG 2014
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Operator	Thierry Bachmann 
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Comment	<hr/>
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Modified File Number	<hr/>
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Product Use

Form: Topography files status for THS menthol (42)

Generated On: 20 Jul 2016 12:09:14

SODIM file number	08DY0159COHB11125014
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File Status	Accepted <input checked="" type="radio"/>
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Rejection / Error reason	<hr/>
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Date of analysis DD/MMM/YYYY	19 AUG 2014
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Operator	Thierry Bachmann <input checked="" type="radio"/>
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Comment	<hr/>
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Modified File Number	<hr/>
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Product Use

Form: Topography files status for THS menthol (43)

Generated On: 20 Jul 2016 12:09:14

SODIM file number	08DY0159COHB11125015
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File Status	Accepted <input checked="" type="radio"/>
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Rejection / Error reason	<hr/>
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Date of analysis DD/MMM/YYYY	19 AUG 2014
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Operator	Thierry Bachmann <input checked="" type="radio"/>
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Comment	<hr/>
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Modified File Number	<hr/>
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Product Use

Form: Topography files status for THS menthol (44)

Generated On: 20 Jul 2016 12:09:14

SODIM file number	08DY0159COHB11125016
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File Status	Accepted <input checked="" type="radio"/>
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Rejection / Error reason	<hr/>
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Date of analysis DD/MMM/YYYY	19 AUG 2014
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Operator	Thierry Bachmann <input checked="" type="radio"/>
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Comment	<hr/>
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Modified File Number	<hr/>
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Product Use

Form: Topography files status for THS menthol (45)

Generated On: 20 Jul 2016 12:09:14

SODIM file number	08DY0159COHB11125017
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File Status	Accepted <input checked="" type="radio"/>
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Rejection / Error reason	<hr/>
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Date of analysis DD/MMM/YYYY	19 AUG 2014
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Operator	Thierry Bachmann <input checked="" type="radio"/>
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Comment	<hr/>
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Modified File Number	<hr/>
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Product Use

Form: Topography files status for THS menthol (46)

Generated On: 20 Jul 2016 12:09:14

SODIM file number	08DY0159COHB11125018
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File Status	Accepted <input checked="" type="radio"/>
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Rejection / Error reason	<hr/>
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Date of analysis DD/MMM/YYYY	19 AUG 2014
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Operator	Thierry Bachmann <input checked="" type="radio"/>
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Comment	<hr/>
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Modified File Number	<hr/>
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Product Use

Form: Topography files status for THS menthol (47)

Generated On: 20 Jul 2016 12:09:14

SODIM file number	08DY0159COHB11125019
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File Status	Accepted <input checked="" type="radio"/>
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Rejection / Error reason	<hr/>
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Date of analysis DD/MMM/YYYY	19 AUG 2014
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Operator	Thierry Bachmann <input checked="" type="radio"/>
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Comment	<hr/>
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Modified File Number	<hr/>
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Product Use

Form: Topography files status for THS menthol (48)

Generated On: 20 Jul 2016 12:09:14

SODIM file number	08DY0159COHB11125020
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File Status	Accepted <input checked="" type="radio"/>
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Rejection / Error reason	<hr/>
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Date of analysis DD/MMM/YYYY	19 AUG 2014
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Operator	Thierry Bachmann <input checked="" type="radio"/>
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Comment	<hr/>
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Modified File Number	<hr/>
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Product Use

Form: Topography files status for THS menthol (49)

Generated On: 20 Jul 2016 12:09:14

SODIM file number	08DY0159COHB11125021
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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 AUG 2014
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Operator	Thierry Bachmann 
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Comment	<hr/>
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Modified File Number	<hr/>
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Product Use

Form: Topography files status for THS menthol (52)

Generated On: 20 Jul 2016 12:09:14

SODIM file number	08DY0159COHB11125023
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File Status	Accepted <input checked="" type="radio"/>
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Rejection / Error reason	<hr/>
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Date of analysis DD/MMM/YYYY	19 AUG 2014
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Operator	Thierry Bachmann <input checked="" type="radio"/>
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Comment	<hr/>
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Modified File Number	<hr/>
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Product Use

Form: Topography files status for THS menthol (53)

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Product Use

Form: Topography files status for THS menthol (54)

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Product Use

Form: Topography files status for THS menthol (55)

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Product Use

Form: Topography files status for THS menthol (56)

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Product Use

Form: Topography files status for THS menthol (57)

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Product Use

Form: Topography files status for THS menthol (58)

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Product Use

Form: Topography files status for THS menthol (59)

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Product Use

Form: Topography files status for THS menthol (60)

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Product Use

Form: Topography files status for THS menthol (61)

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Product Use

Form: Topography files status for THS menthol (62)

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Product Use

Form: Topography files status for THS menthol (63)

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Product Use

Form: Topography files status for THS menthol (64)

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Product Use

Form: Topography files status for THS menthol (65)

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Product Use

Form: Topography files status for THS menthol (66)

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Product Use

Form: Topography files status for THS menthol (67)

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Product Use

Form: Topography files status for THS menthol (68)

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Product Use

Form: Topography files status for THS menthol (69)

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Product Use

Form: Topography files status for THS menthol (70)

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (1)

Generated On: 20 Jul 2016 12:09:14

Tobacco plug kit number	T1809
-------------------------	-------

Tobacco plug vial number	01
--------------------------	----

Level	0 
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Observation	
-------------	--

Picture File Name	T1809_01_F91Z.JPG
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Date of analysis DD/MMM/YYYY	03 JUN 2014
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (2)

Generated On: 20 Jul 2016 12:09:14

Tobacco plug kit number	T1809
-------------------------	-------

Tobacco plug vial number	02
--------------------------	----

Level	0 
-------	---

Observation	<hr/>
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Picture File Name	T1809_02_G0F6.JPG
-------------------	-------------------

Date of analysis DD/MMM/YYYY	03 JUN 2014
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (3)

Generated On: 20 Jul 2016 12:09:14

Tobacco plug kit number	T1809
-------------------------	-------

Tobacco plug vial number	03
--------------------------	----

Level	0 <input checked="" type="radio"/>
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Observation	
-------------	--

Picture File Name	T1809_03_8QAN.JPG
-------------------	-------------------

Date of analysis DD/MMM/YYYY	03 JUN 2014
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (4)

Generated On: 20 Jul 2016 12:09:14

Tobacco plug kit number	T1809
-------------------------	-------

Tobacco plug vial number	04
--------------------------	----

Level	0 <input checked="" type="radio"/>
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Observation	
-------------	--

Picture File Name	T1809_04_3IMF.JPG
-------------------	-------------------

Date of analysis DD/MMM/YYYY	03 JUN 2014
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (5)

Generated On: 20 Jul 2016 12:09:14

Tobacco plug kit number	T1809
-------------------------	-------

Tobacco plug vial number	05
--------------------------	----

Level	0 
-------	---

Observation	<hr/>
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Picture File Name	T1809_05_9VB8.JPG
-------------------	-------------------

Date of analysis DD/MMM/YYYY	03 JUN 2014
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (6)

Generated On: 20 Jul 2016 12:09:14

Tobacco plug kit number	T1809
-------------------------	-------

Tobacco plug vial number	06
--------------------------	----

Level	0 
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Observation	<hr/>
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Picture File Name	T1809_06_INJ0.JPG
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Date of analysis DD/MMM/YYYY	03 JUN 2014
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (7)

Generated On: 20 Jul 2016 12:09:14

Tobacco plug kit number	T1809
-------------------------	-------

Tobacco plug vial number	07
--------------------------	----

Level	0 
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Observation	<hr/>
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Picture File Name	T1809_07_5A42.JPG
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Date of analysis DD/MMM/YYYY	03 JUN 2014
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (8)

Generated On: 20 Jul 2016 12:09:14

Tobacco plug kit number	T1809
-------------------------	-------

Tobacco plug vial number	08
--------------------------	----

Level	0 
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Observation	<hr/>
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Picture File Name	T1809_08_93OT.JPG
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Date of analysis DD/MMM/YYYY	03 JUN 2014
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (9)

Generated On: 20 Jul 2016 12:09:14

Tobacco plug kit number	T1809
-------------------------	-------

Tobacco plug vial number	09
--------------------------	----

Level	0 
-------	---

Observation	<hr/>
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Picture File Name	T1809_09_AQV1.JPG
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Date of analysis DD/MMM/YYYY	03 JUN 2014
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (10)

Generated On: 20 Jul 2016 12:09:14

Tobacco plug kit number	T1809
-------------------------	-------

Tobacco plug vial number	10
--------------------------	----

Level	0 
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Observation	<hr/>
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Picture File Name	T1809_10_OCWP.JPG
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Date of analysis DD/MMM/YYYY	03 JUN 2014
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (1)

Generated On: 20 Jul 2016 12:09:14

Tobacco plug kit number	T1821
-------------------------	-------

Tobacco plug vial number	01
--------------------------	----

Level	0 
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Observation	<hr/>
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Picture File Name	T1821_01_OU85.JPG
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Date of analysis DD/MMM/YYYY	03 JUN 2014
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (2)

Generated On: 20 Jul 2016 12:09:14

Tobacco plug kit number	T1821
-------------------------	-------

Tobacco plug vial number	02
--------------------------	----

Level	0 
-------	---

Observation	<hr/>
-------------	-------

Picture File Name	T1821_02_6H03.JPG
-------------------	-------------------

Date of analysis DD/MMM/YYYY	03 JUN 2014
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (3)

Generated On: 20 Jul 2016 12:09:14

Tobacco plug kit number	T1821
-------------------------	-------

Tobacco plug vial number	03
--------------------------	----

Level	0 <input checked="" type="radio"/>
-------	------------------------------------

Observation	
-------------	--

Picture File Name	T1821_03_HSPD.JPG
-------------------	-------------------

Date of analysis DD/MMM/YYYY	03 JUN 2014
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (4)

Generated On: 20 Jul 2016 12:09:14

Tobacco plug kit number	T1821
-------------------------	-------

Tobacco plug vial number	04
--------------------------	----

Level	0 <input checked="" type="radio"/>
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Observation	
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Picture File Name	T1821_04_JKS7.JPG
-------------------	-------------------

Date of analysis DD/MMM/YYYY	03 JUN 2014
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (5)

Generated On: 20 Jul 2016 12:09:14

Tobacco plug kit number	T1821
-------------------------	-------

Tobacco plug vial number	05
--------------------------	----

Level	0 <input checked="" type="radio"/>
-------	------------------------------------

Observation	
-------------	--

Picture File Name	T1821_05_FJBN.JPG
-------------------	-------------------

Date of analysis DD/MMM/YYYY	03 JUN 2014
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (6)

Generated On: 20 Jul 2016 12:09:14

Tobacco plug kit number	T1821
-------------------------	-------

Tobacco plug vial number	06
--------------------------	----

Level	0 
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Observation	<hr/>
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Picture File Name	T1821_06_I55F.JPG
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Date of analysis DD/MMM/YYYY	03 JUN 2014
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (7)

Generated On: 20 Jul 2016 12:09:14

Tobacco plug kit number	T1821
-------------------------	-------

Tobacco plug vial number	07
--------------------------	----

Level	0 
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Observation	<hr/>
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Picture File Name	T1821_07_BT4R.JPG
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Date of analysis DD/MMM/YYYY	03 JUN 2014
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (8)

Generated On: 20 Jul 2016 12:09:14

Tobacco plug kit number	T1821
-------------------------	-------

Tobacco plug vial number	08
--------------------------	----

Level	0 <input checked="" type="radio"/>
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Observation	
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Picture File Name	T1821_08_UJAK.JPG
-------------------	-------------------

Date of analysis DD/MMM/YYYY	03 JUN 2014
---------------------------------	-------------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (9)

Generated On: 20 Jul 2016 12:09:14

Tobacco plug kit number	T1821
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Tobacco plug vial number	09
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Level	0 <input checked="" type="radio"/>
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Observation	
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Picture File Name	T1821_09_DB9Y.JPG
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Date of analysis DD/MMM/YYYY	03 JUN 2014
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (10)

Generated On: 20 Jul 2016 12:09:14

Tobacco plug kit number	T1821
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Tobacco plug vial number	10
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Level	0 <input checked="" type="radio"/>
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Observation	
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Picture File Name	T1821_10_XAKI.JPG
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Date of analysis DD/MMM/YYYY	03 JUN 2014
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (11)

Generated On: 20 Jul 2016 12:09:14

Tobacco plug kit number	T1821
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Tobacco plug vial number	11
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Level	0 <input type="radio"/>
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Observation	
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Picture File Name	T1821_11_A6FU.JPG
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Date of analysis DD/MMM/YYYY	03 JUN 2014
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (12)

Generated On: 20 Jul 2016 12:09:14

Tobacco plug kit number	T1821
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Tobacco plug vial number	12
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Level	0 <input type="radio"/>
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Observation	
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Picture File Name	T1821_12_PA1A.JPG
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Date of analysis DD/MMM/YYYY	03 JUN 2014
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (13)

Generated On: 20 Jul 2016 12:09:14

Tobacco plug kit number	T1821
-------------------------	-------

Tobacco plug vial number	13
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Level	NA <input type="radio"/>
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Observation	No tobacco plug in the vial <input type="radio"/>
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Picture File Name	T1821_13_IX66.JPG
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Date of analysis DD/MMM/YYYY	03 JUN 2014
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (14)

Generated On: 20 Jul 2016 12:09:14

Tobacco plug kit number	T1821
-------------------------	-------

Tobacco plug vial number	14
--------------------------	----

Level	0 
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Observation	<hr/>
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Picture File Name	T1821_14_9W42.JPG
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Date of analysis DD/MMM/YYYY	03 JUN 2014
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (15)

Generated On: 20 Jul 2016 12:09:14

Tobacco plug kit number	T1821
-------------------------	-------

Tobacco plug vial number	15
--------------------------	----

Level	0 <input type="radio"/>
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Observation	
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Picture File Name	T1821_15_GV0E.JPG
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Date of analysis DD/MMM/YYYY	03 JUN 2014
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (16)

Generated On: 20 Jul 2016 12:09:14

Tobacco plug kit number	T1821
-------------------------	-------

Tobacco plug vial number	16
--------------------------	----

Level	0 <input checked="" type="radio"/>
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Observation	
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Picture File Name	T1821_16_IEIR.JPG
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Date of analysis DD/MMM/YYYY	03 JUN 2014
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (1)

Generated On: 20 Jul 2016 12:09:14

Tobacco plug kit number	T1825
-------------------------	-------

Tobacco plug vial number	01
--------------------------	----

Level	0 
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Observation	<hr/>
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Picture File Name	T1825_01_ASS7.JPG
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Date of analysis DD/MMM/YYYY	03 JUN 2014
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (2)

Generated On: 20 Jul 2016 12:09:14

Tobacco plug kit number	T1825
-------------------------	-------

Tobacco plug vial number	02
--------------------------	----

Level	0 
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Observation	<hr/>
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Picture File Name	T1825_02_EOJW.JPG
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Date of analysis DD/MMM/YYYY	03 JUN 2014
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (3)

Generated On: 20 Jul 2016 12:09:14

Tobacco plug kit number	T1825
-------------------------	-------

Tobacco plug vial number	03
--------------------------	----

Level	0 
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Observation	<hr/>
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Picture File Name	T1825_03_05MJ.JPG
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Date of analysis DD/MMM/YYYY	03 JUN 2014
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (4)

Generated On: 20 Jul 2016 12:09:14

Tobacco plug kit number	T1825
-------------------------	-------

Tobacco plug vial number	04
--------------------------	----

Level	0 
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Observation	<hr/>
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Picture File Name	T1825_04_HE3O.JPG
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Date of analysis DD/MMM/YYYY	03 JUN 2014
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (5)

Generated On: 20 Jul 2016 12:09:14

Tobacco plug kit number	T1825
-------------------------	-------

Tobacco plug vial number	05
--------------------------	----

Level	0 
-------	---

Observation	
-------------	--

Picture File Name	T1825_05_5CM3.JPG
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Date of analysis DD/MMM/YYYY	03 JUN 2014
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (6)

Generated On: 20 Jul 2016 12:09:14

Tobacco plug kit number	T1825
-------------------------	-------

Tobacco plug vial number	06
--------------------------	----

Level	0 
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Observation	<hr/>
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Picture File Name	T1825_06_U0RI.JPG
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Date of analysis DD/MMM/YYYY	03 JUN 2014
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (7)

Generated On: 20 Jul 2016 12:09:14

Tobacco plug kit number	T1825
-------------------------	-------

Tobacco plug vial number	07
--------------------------	----

Level	0 
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Observation	<hr/>
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Picture File Name	T1825_07_S76J.JPG
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Date of analysis DD/MMM/YYYY	03 JUN 2014
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (8)

Generated On: 20 Jul 2016 12:09:14

Tobacco plug kit number	T1825
-------------------------	-------

Tobacco plug vial number	08
--------------------------	----

Level	0 
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Observation	<hr/>
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Picture File Name	T1825_08_V2NE.JPG
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Date of analysis DD/MMM/YYYY	03 JUN 2014
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (9)

Generated On: 20 Jul 2016 12:09:14

Tobacco plug kit number	T1825
-------------------------	-------

Tobacco plug vial number	09
--------------------------	----

Level	0 
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Observation	<hr/>
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Picture File Name	T1825_09_VSQP.JPG
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Date of analysis DD/MMM/YYYY	03 JUN 2014
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (10)

Generated On: 20 Jul 2016 12:09:14

Tobacco plug kit number	T1825
-------------------------	-------

Tobacco plug vial number	10
--------------------------	----

Level	0 
-------	---

Observation	
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Picture File Name	T1825_10_5WQX.JPG
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Date of analysis DD/MMM/YYYY	03 JUN 2014
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (11)

Generated On: 20 Jul 2016 12:09:14

Tobacco plug kit number	T1825
-------------------------	-------

Tobacco plug vial number	11
--------------------------	----

Level	0 
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Observation	<hr/>
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Picture File Name	T1825_11_V97Z.JPG
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Date of analysis DD/MMM/YYYY	03 JUN 2014
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (12)

Generated On: 20 Jul 2016 12:09:14

Tobacco plug kit number	T1825
-------------------------	-------

Tobacco plug vial number	12
--------------------------	----

Level	0 <input checked="" type="radio"/>
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Observation	
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Picture File Name	T1825_12_V6YL.JPG
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Date of analysis DD/MMM/YYYY	03 JUN 2014
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (13)

Generated On: 20 Jul 2016 12:09:14

Tobacco plug kit number	T1825
-------------------------	-------

Tobacco plug vial number	13
--------------------------	----

Level	0 
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Observation	<hr/>
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Picture File Name	T1825_13_G5ZQ.JPG
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Date of analysis DD/MMM/YYYY	03 JUN 2014
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**


Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (1)

Generated On: 20 Jul 2016 12:09:14

Tobacco plug kit number	T1834
-------------------------	-------

Tobacco plug vial number	01
--------------------------	----

Level	0 
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Observation	
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Picture File Name	T1834_01_ZTOQ.JPG
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Date of analysis DD/MMM/YYYY	03 JUN 2014
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (2)

Generated On: 20 Jul 2016 12:09:14

Tobacco plug kit number	T1834
-------------------------	-------

Tobacco plug vial number	02
--------------------------	----

Level	0 
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Observation	<hr/>
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Picture File Name	T1834_02_DRXZ.JPG
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Date of analysis DD/MMM/YYYY	03 JUN 2014
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (3)

Generated On: 20 Jul 2016 12:09:14

Tobacco plug kit number	T1834
-------------------------	-------

Tobacco plug vial number	03
--------------------------	----

Level	0 
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Observation	
-------------	--

Picture File Name	T1834_03_RZ6O.JPG
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Date of analysis DD/MMM/YYYY	03 JUN 2014
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (4)

Generated On: 20 Jul 2016 12:09:14

Tobacco plug kit number	T1834
-------------------------	-------

Tobacco plug vial number	04
--------------------------	----

Level	0 
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Observation	
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Picture File Name	T1834_04_OO9F.JPG
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Date of analysis DD/MMM/YYYY	03 JUN 2014
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (5)

Generated On: 20 Jul 2016 12:09:14

Tobacco plug kit number	T1834
-------------------------	-------

Tobacco plug vial number	05
--------------------------	----

Level	0 
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Observation	
-------------	--

Picture File Name	T1834_05_TLUX.JPG
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Date of analysis DD/MMM/YYYY	03 JUN 2014
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (6)

Generated On: 20 Jul 2016 12:09:14

Tobacco plug kit number	T1834
-------------------------	-------

Tobacco plug vial number	06
--------------------------	----

Level	0 
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Observation	
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Picture File Name	T1834_06_VYB2.JPG
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Date of analysis DD/MMM/YYYY	03 JUN 2014
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (7)

Generated On: 20 Jul 2016 12:09:14

Tobacco plug kit number	T1834
-------------------------	-------

Tobacco plug vial number	07
--------------------------	----

Level	0 
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Observation	
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Picture File Name	T1834_07_B8XB.JPG
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Date of analysis DD/MMM/YYYY	03 JUN 2014
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (8)

Generated On: 20 Jul 2016 12:09:14

Tobacco plug kit number	T1834
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Tobacco plug vial number	08
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Level	0 
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Observation	<hr/>
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Picture File Name	T1834_08_W3QV.JPG
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Date of analysis DD/MMM/YYYY	03 JUN 2014
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (9)

Generated On: 20 Jul 2016 12:09:14

Tobacco plug kit number	T1834
-------------------------	-------

Tobacco plug vial number	09
--------------------------	----

Level	0 
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Observation	
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Picture File Name	T1834_09_CF22.JPG
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Date of analysis DD/MMM/YYYY	03 JUN 2014
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (10)

Generated On: 20 Jul 2016 12:09:14

Tobacco plug kit number	T1834
-------------------------	-------

Tobacco plug vial number	10
--------------------------	----

Level	0 <input checked="" type="radio"/>
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Observation	
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Picture File Name	T1834_10_SB0R.JPG
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Date of analysis DD/MMM/YYYY	03 JUN 2014
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (11)

Generated On: 20 Jul 2016 12:09:14

Tobacco plug kit number	T1834
-------------------------	-------

Tobacco plug vial number	11
--------------------------	----

Level	0 <input type="radio"/>
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Observation	
-------------	--

Picture File Name	T1834_11_50TZ.JPG
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Date of analysis DD/MMM/YYYY	03 JUN 2014
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (12)

Generated On: 20 Jul 2016 12:09:14

Tobacco plug kit number	T1834
-------------------------	-------

Tobacco plug vial number	12
--------------------------	----

Level	0 
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Observation	<hr/>
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Picture File Name	T1834_12_MPPK.JPG
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Date of analysis DD/MMM/YYYY	03 JUN 2014
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (13)

Generated On: 20 Jul 2016 12:09:14

Tobacco plug kit number	T1834
-------------------------	-------

Tobacco plug vial number	13
--------------------------	----

Level	0 
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Observation	<hr/>
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Picture File Name	T1834_13_8TPX.JPG
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Date of analysis DD/MMM/YYYY	03 JUN 2014
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (14)

Generated On: 20 Jul 2016 12:09:14

Tobacco plug kit number	T1834
-------------------------	-------

Tobacco plug vial number	14
--------------------------	----

Level	0 
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Observation	
-------------	--

Picture File Name	T1834_14_L8BR.JPG
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Date of analysis DD/MMM/YYYY	03 JUN 2014
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (1)

Generated On: 20 Jul 2016 12:09:14

Tobacco plug kit number	T1838
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Tobacco plug vial number	01
--------------------------	----

Level	0 
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Observation	<hr/>
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Picture File Name	T1838_01_E17O.JPG
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Date of analysis DD/MMM/YYYY	03 JUN 2014
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (2)

Generated On: 20 Jul 2016 12:09:14

Tobacco plug kit number	T1838
-------------------------	-------

Tobacco plug vial number	02
--------------------------	----

Level	0 
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Observation	
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Picture File Name	T1838_02_OI8M.JPG
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Date of analysis DD/MMM/YYYY	03 JUN 2014
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (3)

Generated On: 20 Jul 2016 12:09:14

Tobacco plug kit number	T1838
-------------------------	-------

Tobacco plug vial number	03
--------------------------	----

Level	0 <input checked="" type="radio"/>
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Observation	
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Picture File Name	T1838_03_69FV.JPG
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Date of analysis DD/MMM/YYYY	03 JUN 2014
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (4)

Generated On: 20 Jul 2016 12:09:14

Tobacco plug kit number	T1838
-------------------------	-------

Tobacco plug vial number	04
--------------------------	----

Level	0 
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Observation	
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Picture File Name	T1838_04_B6V6.JPG
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Date of analysis DD/MMM/YYYY	03 JUN 2014
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (5)

Generated On: 20 Jul 2016 12:09:14

Tobacco plug kit number	T1838
-------------------------	-------

Tobacco plug vial number	05
--------------------------	----

Level	0 
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Observation	<hr/>
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Picture File Name	T1838_05_DF82.JPG
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Date of analysis DD/MMM/YYYY	03 JUN 2014
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (6)

Generated On: 20 Jul 2016 12:09:14

Tobacco plug kit number	T1838
-------------------------	-------

Tobacco plug vial number	06
--------------------------	----

Level	0 <input checked="" type="radio"/>
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Observation	
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Picture File Name	T1838_06_ZVF5.JPG
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Date of analysis DD/MMM/YYYY	03 JUN 2014
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (7)

Generated On: 20 Jul 2016 12:09:14

Tobacco plug kit number	T1838
-------------------------	-------

Tobacco plug vial number	07
--------------------------	----

Level	0 
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Observation	<hr/>
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Picture File Name	T1838_07_B2C6.JPG
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Date of analysis DD/MMM/YYYY	03 JUN 2014
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (8)

Generated On: 20 Jul 2016 12:09:14

Tobacco plug kit number	T1838
-------------------------	-------

Tobacco plug vial number	08
--------------------------	----

Level	0 
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Observation	<hr/>
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Picture File Name	T1838_08_RT7L.JPG
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Date of analysis DD/MMM/YYYY	03 JUN 2014
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (9)

Generated On: 20 Jul 2016 12:09:14

Tobacco plug kit number	T1838
-------------------------	-------

Tobacco plug vial number	09
--------------------------	----

Level	0 <input checked="" type="radio"/>
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Observation	
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Picture File Name	T1838_09_OOU4.JPG
-------------------	-------------------

Date of analysis DD/MMM/YYYY	03 JUN 2014
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (10)

Generated On: 20 Jul 2016 12:09:14

Tobacco plug kit number	T1838
-------------------------	-------

Tobacco plug vial number	10
--------------------------	----

Level	0 
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Observation	<hr/>
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Picture File Name	T1838_10_SP1Y.JPG
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Date of analysis DD/MMM/YYYY	03 JUN 2014
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (11)

Generated On: 20 Jul 2016 12:09:14

Tobacco plug kit number	T1838
-------------------------	-------

Tobacco plug vial number	11
--------------------------	----

Level	0 <input checked="" type="radio"/>
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Observation	
-------------	--

Picture File Name	T1838_11_0AT7.JPG
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Date of analysis DD/MMM/YYYY	03 JUN 2014
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (12)

Generated On: 20 Jul 2016 12:09:14

Tobacco plug kit number	T1838
-------------------------	-------

Tobacco plug vial number	12
--------------------------	----

Level	0 
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Observation	<hr/>
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Picture File Name	T1838_12_JY5H.JPG
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Date of analysis DD/MMM/YYYY	03 JUN 2014
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (13)

Generated On: 20 Jul 2016 12:09:14

Tobacco plug kit number	T1838
-------------------------	-------

Tobacco plug vial number	13
--------------------------	----

Level	0 
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Observation	
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Picture File Name	T1838_13_ON9Z.JPG
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Date of analysis DD/MMM/YYYY	03 JUN 2014
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Product Use

Form: Product use diary(Paper)

Data signed: (hcoleman1) 18 Jun 2015 19:58:08

Generated On: 20 Jul 2016 12:09:14

Was paper questionnaire used?

No ☒

Reason not done

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Product Use

Form: Product use diary(Paper) (1)

Data signed: (hcoleman1) 18 Jun 2015 19:58:08

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Product Use

Form: Product use diary(Paper) (1)

Data signed: (hcoleman1) 18 Jun 2015 19:58:08

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Folder: Adverse Events

Form: Adverse Events Y/N

Data signed: (hfarmer1) 26 Mar 2015 14:19:50

Generated On: 20 Jul 2016 12:09:14

Was there any Adverse Event for this subject?

No ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Previous and Concomitant Medication

Form: Previous and Concomitant Medication Y/N

Data signed: (hfarmer1) 26 Mar 2015 14:19:50

Generated On: 20 Jul 2016 12:09:14

Has the subject taken previous or concomitant
medication?

No ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Device Events

Form: Device report - THS 2.2 menthol Cigarette Holder

Data signed: (hfarmer1) 26 Mar 2015 14:19:50

Generated On: 20 Jul 2016 12:09:14

Were there any events with the device?

No ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Device Events

Form: Device report - THS 2.2 menthol Cigarette Holder (1)

Data signed: (hfarmer1) 26 Mar 2015 14:19:50

Generated On: 20 Jul 2016 12:09:14

Were there any events with the device?

No ☒

Event Log Number

Date of Device Event
DD/MMM/YYYY

Time of
Device Event
hour:min 24-hour clock

Event Relates to Device Type:

THS 2.2 CIGARETTE HOLDER

Unique Device Identifier Serial Number

Event Description

Other Describe

Severity of Event

Adverse Event
Relationship

If Related to AE, AE Number

Solution Proposed:

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Device Events

Form: Device report - THS 2.2 menthol Cigarette Holder (1)

Data signed: (hfarmer1) 26 Mar 2015 14:19:50

Generated On: 20 Jul 2016 12:09:14

If the device was replaced, New Device Serial Number: _____

Date of Device Event Closure
DD/MMM/YYYY _____

Time of Device Event Closure
hour:min 24-hour clock _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Device Events

Form: Device report - THS 2.2 menthol Charging Unit

Data signed: (hfarmer1) 26 Mar 2015 14:19:50

Generated On: 20 Jul 2016 12:09:14

Were there any events with the device?

No ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Device Events

Form: Device report - THS 2.2 menthol Charging Unit (1)

Data signed: (hfarmer1) 26 Mar 2015 14:19:50

Generated On: 20 Jul 2016 12:09:14

Were there any events with the device?

No ☒

Event Log Number

Date of Device Event
DD/MMM/YYYY

Time of
Device Event
hour:min 24-hour clock

Event Relates to
Device Type:

THS 2.2 CHARGING UNIT

Unique Device Identifier Serial Number

Event Description

Other Describe

Severity of Event

Adverse Event
Relationship

Solution Proposed:

If the device was replaced, New Device Serial Number:

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Device Events

Form: Device report - THS 2.2 menthol Charging Unit (1)

Data signed: (hfarmer1) 26 Mar 2015 14:19:50

Generated On: 20 Jul 2016 12:09:14

Date of Device Event Closure
DD/MMM/YYYY

Time of Device Event Closure
hour:min 24-hour clock

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Device Inventory

Form: Device Inventory - THS 2.2 menthol Cigarette Holder (1)

Data signed: (hfarmer1) 26 Mar 2015 14:19:51

Generated On: 20 Jul 2016 12:09:14

Device Inventory	1
Log Number	

Date of Device Distribution	20 JAN 2014
DD/MMM/YYYY	

Time of	07:14
Device Distribution	
hour:min 24-hour clock	

Device Type	THS 2.2 CIGARETTE HOLDER
-------------	--------------------------

Device Serial Number	1249421
----------------------	---------

Date of Device Collection	25 JAN 2014
DD/MMM/YYYY	

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Device Inventory

Form: Device Inventory - THS 2.2 menthol Cigarette Holder (2)

Data signed: (hfarmer1) 26 Mar 2015 14:19:51

Generated On: 20 Jul 2016 12:09:14

Device Inventory	2
Log Number	

Date of Device Distribution	20 JAN 2014
DD/MMM/YYYY	

Time of	07:14
Device Distribution	
hour:min 24-hour clock	

Device Type	THS 2.2 CIGARETTE HOLDER
-------------	--------------------------

Device Serial Number	1245018
----------------------	---------

Date of Device Collection	25 JAN 2014
DD/MMM/YYYY	

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Folder: Device Inventory

Form: Device Inventory - THS 2.2 menthol Charging Unit (1)

Data signed: (hfarmer1) 26 Mar 2015 14:19:51

Generated On: 20 Jul 2016 12:09:14

Device Inventory	1
Log Number	

Date of Device Distribution	20 JAN 2014
DD/MMM/YYYY	

Time of	07:14
Device Distribution	
hour:min 24-hour clock	

Device Type	THS 2.2 CHARGING UNIT
-------------	-----------------------

Device Serial Number	1318235
----------------------	---------

Date of Device Collection	25 JAN 2014
DD/MMM/YYYY	

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

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1062

Form: Product use diary (1)

Data signed: (hfarmer1) 26 Mar 2015 14:17:54

Generated On: 20 Jul 2016 12:09:14

Date of Birth	(b) (6)
Date of completion DD/MMM/YYYY	2014 JAN 25
Time of completion hh:mm	20:01
Date the questionnaire was completed for DD/MMM/YYYY	2014 JAN 25
Assessment Status	Completed <input checked="" type="radio"/>
What tobacco/nicotine product did you use today?	THS 2.2 <input checked="" type="radio"/>
How many THS 2.2 tobacco sticks did you use today?	3
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: 1062

Form: Product use diary (1)

Data signed: (hfarmer1) 26 Mar 2015 14:17:54

Generated On: 20 Jul 2016 12:09:14

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: 1062

Form: Product use diary (2)

Data signed: (hfarmer1) 26 Mar 2015 14:17:54

Generated On: 20 Jul 2016 12:09:14

Date of Birth

(b) (6)

Date of completion
DD/MMM/YYYY

2014 JAN 26

Time of completion
hh:mm

20:00

Date the questionnaire was completed for
DD/MMM/YYYY

2014 JAN 26

Assessment Status

Completed ☒

What tobacco/nicotine product did you use today?

THS 2.2 ☒

How many THS 2.2 tobacco sticks did you use today?

7

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: 1062

Form: Product use diary (2)

Data signed: (hfarmer1) 26 Mar 2015 14:17:54

Generated On: 20 Jul 2016 12:09:14

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: 1062

Form: Product use diary (3)

Data signed: (hfarmer1) 26 Mar 2015 14:17:54

Generated On: 20 Jul 2016 12:09:14

Date of Birth

(b) (6)

Date of completion
DD/MMM/YYYY

2014 JAN 27

Time of completion
hh:mm

20:01

Date the questionnaire was completed for
DD/MMM/YYYY

2014 JAN 27

Assessment Status

Completed ☒

What tobacco/nicotine product did you use today?

THS 2.2 ☒

How many THS 2.2 tobacco sticks did you use today?

7

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: 1062

Form: Product use diary (3)

Data signed: (hfarmer1) 26 Mar 2015 14:17:54

Generated On: 20 Jul 2016 12:09:14

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: 1062

Form: Product use diary (4)

Data signed: (hfarmer1) 26 Mar 2015 14:17:54

Generated On: 20 Jul 2016 12:09:14

Date of Birth	(b) (6)
Date of completion DD/MMM/YYYY	2014 JAN 28
Time of completion hh:mm	22:00
Date the questionnaire was completed for DD/MMM/YYYY	2014 JAN 28
Assessment Status	Completed
What tobacco/nicotine product did you use today?	THS 2.2
How many THS 2.2 tobacco sticks did you use today?	6
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: 1062

Form: Product use diary (4)

Data signed: (hfarmer1) 26 Mar 2015 14:17:54

Generated On: 20 Jul 2016 12:09:14

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: 1062**

Form: End of study

Data signed: (hfarmer1) 26 Mar 2015 14:17:53

Generated On: 20 Jul 2016 12:09:14

End of study date

28 FEB 2014
DD/MMM/YYYY

Has the subject completed the study ?

No ☒

If No, please specify the reason:

Other ☐

Details:

UNABLE TO RETURN LIVES
OUT OF STATE.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1062**

Form: Consent Withdrawal

Data signed: (hfarmer1) 26 Mar 2015 14:17:54

Generated On: 20 Jul 2016 12:09:14

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
