

Subject Case Report Forms

1252 (Prod: Covance Clinical Development Services, Daytona Beach, Florida)

Generated On: 20 Jul 2016 22:28:45

All time stamps listed in this document are displayed in GMT

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Form: Subject

Data signed: (hfarmer1) 30 Mar 2015 13:32:59

Generated On: 20 Jul 2016 22:28:45

Screening number	1252
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Site number	DAY
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Subject Status

Form: Subject Status

Data signed: (hfarmer1) 30 Mar 2015 13:33:10

Generated On: 20 Jul 2016 22:28:45

Date of 'Screen Failed' Event

Date of 'Discontinued From
Enrollment' Event

Randomization Date

04 APR 2014
DD/MMM/YYYY

Randomization Time

12:18
hour:min 24-hour clock

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Screening

Form: Date of Visit

Data signed: (hfarmer1) 30 Mar 2015 13:33:14

Generated On: 20 Jul 2016 22:28:45

Date of Visit

25 MAR 2014
DD/MMM/YYYY

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Screening

Form: Additional Informed Consent

Data signed: (hfarmer1) 30 Mar 2015 13:33:11

Generated On: 20 Jul 2016 22:28:45

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

Yes ☒

Consent Date

25 MAR 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

25 MAR 2014
DD/MMM/YYYY

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Screening

Form: Inclusion Criteria

Data signed: (hfarmer1) 30 Mar 2015 13:33:11

Generated On: 20 Jul 2016 22:28:45

*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: 1252**

Folder: Screening

Form: Inclusion Criteria (1)

Data signed: (hfarmer1) 30 Mar 2015 13:33:11

Generated On: 20 Jul 2016 22:28:45

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Screening

Form: Inclusion Criteria (2)

Data signed: (hfarmer1) 30 Mar 2015 13:33:11

Generated On: 20 Jul 2016 22:28:45

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: 1252

Folder: Screening

Form: Inclusion Criteria (3)

Data signed: (hfarmer1) 30 Mar 2015 13:33:11

Generated On: 20 Jul 2016 22:28:45

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: 1252

Folder: Screening

Form: Inclusion Criteria (4)

Data signed: (hfarmer1) 30 Mar 2015 13:33:11

Generated On: 20 Jul 2016 22:28:45

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Screening

Form: Inclusion Criteria (5)

Data signed: (hfarmer1) 30 Mar 2015 13:33:11

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Screening

Form: Inclusion Criteria (6)

Data signed: (hfarmer1) 30 Mar 2015 13:33:11

Generated On: 20 Jul 2016 22:28:45

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Screening

Form: Exclusion Criteria

Data signed: (hfarmer1) 30 Mar 2015 13:33:11

Generated On: 20 Jul 2016 22:28:45

*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: 1252**

Folder: Screening

Form: Exclusion Criteria (1)

Data signed: (hfarmer1) 30 Mar 2015 13:33:11

Generated On: 20 Jul 2016 22:28:45

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: 1252

Folder: Screening

Form: Exclusion Criteria (2)

Data signed: (hfarmer1) 30 Mar 2015 13:33:11

Generated On: 20 Jul 2016 22:28:45

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: 1252

Folder: Screening

Form: Exclusion Criteria (3)

Data signed: (hfarmer1) 30 Mar 2015 13:33:11

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Screening

Form: Exclusion Criteria (4)

Data signed: (hfarmer1) 30 Mar 2015 13:33:11

Generated On: 20 Jul 2016 22:28:45

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Screening

Form: Exclusion Criteria (5)

Data signed: (hfarmer1) 30 Mar 2015 13:33:11

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Screening

Form: Exclusion Criteria (6)

Data signed: (hfarmer1) 30 Mar 2015 13:33:11

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Screening

Form: Exclusion Criteria (7)

Data signed: (hfarmer1) 30 Mar 2015 13:33:11

Generated On: 20 Jul 2016 22:28:45

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Screening

Form: Exclusion Criteria (8)

Data signed: (hfarmer1) 30 Mar 2015 13:33:11

Generated On: 20 Jul 2016 22:28:45

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: 1252

Folder: Screening

Form: Exclusion Criteria (9)

Data signed: (hfarmer1) 30 Mar 2015 13:33:11

Generated On: 20 Jul 2016 22:28:45

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

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Screening

Form: Exclusion Criteria (10)

Data signed: (hfarmer1) 30 Mar 2015 13:33:11

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Screening

Form: Exclusion Criteria (11)

Data signed: (hfarmer1) 30 Mar 2015 13:33:11

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Screening

Form: Exclusion Criteria (12)

Data signed: (hfarmer1) 30 Mar 2015 13:33:11

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Screening

Form: Exclusion Criteria (13)

Data signed: (hfarmer1) 30 Mar 2015 13:33:11

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Screening

Form: Exclusion Criteria (14)

Data signed: (hfarmer1) 30 Mar 2015 13:33:11

Generated On: 20 Jul 2016 22:28:45

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

Exclusion Criterion	The subject has a positive urine drug test. <input checked="" type="radio"/>
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Result	No <input type="radio"/>
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*If any has been answered Yes, subject must not be included in the study.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Screening

Form: Exclusion Criteria (15)

Data signed: (hfarmer1) 30 Mar 2015 13:33:11

Generated On: 20 Jul 2016 22:28:45

Exclusion Criterion Number	16
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Exclusion Criterion	Positive serology test for human immunodeficiency virus (HIV)1/2, hepatitis B or hepatitis C.
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Result	No <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: 1252**

Folder: Screening

Form: Exclusion Criteria (16)

Data signed: (hfarmer1) 30 Mar 2015 13:33:11

Generated On: 20 Jul 2016 22:28:45

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Screening

Form: Exclusion Criteria (17)

Data signed: (hfarmer1) 30 Mar 2015 13:33:11

Generated On: 20 Jul 2016 22:28:45

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).
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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: 1252**

Folder: Screening

Form: Exclusion Criteria (18)

Data signed: (hfarmer1) 30 Mar 2015 13:33:11

Generated On: 20 Jul 2016 22:28:45

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
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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: 1252

Folder: Screening

Form: Exclusion Criteria (19)

Data signed: (hfarmer1) 30 Mar 2015 13:33:11

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Screening

Form: Exclusion Criteria (20)

Data signed: (hfarmer1) 30 Mar 2015 13:33:11

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Screening

Form: Exclusion Criteria (21)

Data signed: (hfarmer1) 30 Mar 2015 13:33:11

Generated On: 20 Jul 2016 22:28:45

Exclusion Criterion Number	22
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Exclusion Criterion	For women only : Subject does not agree to use an acceptable method of effective contraception
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Result	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: 1252**

Folder: Screening

Form: Demographics

Data signed: (hfarmer1) 30 Mar 2015 13:33:10

Generated On: 20 Jul 2016 22:28:45

Date of Birth	(b) (6)
Sex	Male <input checked="" type="radio"/>
Race	White <input checked="" type="radio"/>
Other, specify	
Ethnicity	Not Hispanic <input checked="" type="radio"/>
Date the Subject signed the Informed Consent	25 MAR 2014 DD/MMM/YYYY
Time the Subject signed the Informed Consent	09:42 hour:min 24-hour clock
Age(Derived)	48

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Screening

Form: Medical History/Concomitant Disease

Data signed: (hfarmer1) 30 Mar 2015 13:33:11

Generated On: 20 Jul 2016 22:28:45

Date of collection

25 MAR 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: 1252**

Folder: Screening

Form: Medical History/Concomitant Disease (1)

Data signed: (hfarmer1) 30 Mar 2015 13:33:11

Generated On: 20 Jul 2016 22:28:45

Date of collection	25 MAR 2014 DD/MMM/YYYY
--------------------	----------------------------

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

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

Diagnosis Description	WISDOM TEETH EXTRACTIONS TIMES FOUR
-----------------------	--

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

Ongoing?	False
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Screening

Form: Medical History/Concomitant Disease (2)

Data signed: (hfarmer1) 30 Mar 2015 13:33:11

Generated On: 20 Jul 2016 22:28:45

Date of collection	25 MAR 2014 DD/MMM/YYYY
--------------------	----------------------------

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

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

Diagnosis Description	FREQUENT HEARTBURN
-----------------------	--------------------

Onset Date DD/MMM/YYYY	UN UNK 2012
---------------------------	-------------

Stop Date DD/MMM/YYYY	
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Ongoing?	True
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Screening

Form: Medical History/Concomitant Disease (3)

Data signed: (hfarmer1) 30 Mar 2015 13:33:11

Generated On: 20 Jul 2016 22:28:45

Date of collection	25 MAR 2014 DD/MMM/YYYY
--------------------	----------------------------

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

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

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

Onset Date DD/MMM/YYYY	UN UNK 2004
---------------------------	-------------

Stop Date DD/MMM/YYYY	
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Ongoing?	True
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Screening

Form: Medical History/Concomitant Disease (4)

Data signed: (hfarmer1) 30 Mar 2015 13:33:11

Generated On: 20 Jul 2016 22:28:45

Date of collection	25 MAR 2014 DD/MMM/YYYY
--------------------	----------------------------

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

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

Diagnosis Description	FREQUENT INDIGESTION
-----------------------	----------------------

Onset Date DD/MMM/YYYY	UN UNK 2012
---------------------------	-------------

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

Ongoing?	True
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Screening

Form: Vital Signs<Screening/<

Data signed: (hfarmer1) 30 Mar 2015 13:33:14

Generated On: 20 Jul 2016 22:28:45

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 25 MAR 2014
DD/MMM/YYYY

Time of assessment 10:41
hour:min 24-hour clock

Pulse rate 50
beats per minute

Respiratory rate 16
breaths per minute

Blood Pressure (systolic) 123
mmHg

Blood Pressure (diastolic) 79
mmHg

Vital Signs Position of Subject Supine ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Screening

Form: Physical Examination

Data signed: (hfarmer1) 30 Mar 2015 13:33:12

Generated On: 20 Jul 2016 22:28:45

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

25 MAR 2014
DD/MMM/YYYY

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Screening

Form: Physical Examination (1)

Data signed: (hfarmer1) 30 Mar 2015 13:33:12

Generated On: 20 Jul 2016 22:28:45

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of assessment 25 MAR 2014
DD/MMM/YYYY

System General Appearance ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Screening

Form: Physical Examination (2)

Data signed: (hfarmer1) 30 Mar 2015 13:33:12

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Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

25 MAR 2014
DD/MMM/YYYY

System

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

Outcome

Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done

False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Screening

Form: Physical Examination (3)

Data signed: (hfarmer1) 30 Mar 2015 13:33:12

Generated On: 20 Jul 2016 22:28:45

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of assessment 25 MAR 2014
DD/MMM/YYYY

System Thyroid Gland ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Screening

Form: Physical Examination (4)

Data signed: (hfarmer1) 30 Mar 2015 13:33:12

Generated On: 20 Jul 2016 22:28:45

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of assessment 25 MAR 2014
DD/MMM/YYYY

System Heart ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Screening

Form: Physical Examination (5)

Data signed: (hfarmer1) 30 Mar 2015 13:33:12

Generated On: 20 Jul 2016 22:28:45

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of assessment 25 MAR 2014
DD/MMM/YYYY

System Chest ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Screening

Form: Physical Examination (6)

Data signed: (hfarmer1) 30 Mar 2015 13:33:12

Generated On: 20 Jul 2016 22:28:45

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of assessment 25 MAR 2014
DD/MMM/YYYY

System Lungs ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Screening

Form: Physical Examination (7)

Data signed: (hfarmer1) 30 Mar 2015 13:33:12

Generated On: 20 Jul 2016 22:28:45

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of assessment 25 MAR 2014
DD/MMM/YYYY

System Gastrointestinal ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Screening

Form: Physical Examination (8)

Data signed: (hfarmer1) 30 Mar 2015 13:33:12

Generated On: 20 Jul 2016 22:28:45

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of assessment 25 MAR 2014
DD/MMM/YYYY

System Cardiovascular System ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Screening

Form: Physical Examination (9)

Data signed: (hfarmer1) 30 Mar 2015 13:33:12

Generated On: 20 Jul 2016 22:28:45

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of assessment 25 MAR 2014
DD/MMM/YYYY

System Neurologic ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Screening

Form: Physical Examination (10)

Data signed: (hfarmer1) 30 Mar 2015 13:33:12

Generated On: 20 Jul 2016 22:28:45

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of assessment 25 MAR 2014
DD/MMM/YYYY

System Skin ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Screening

Form: Physical Examination (11)

Data signed: (hfarmer1) 30 Mar 2015 13:33:12

Generated On: 20 Jul 2016 22:28:45

Was the physical examination performed? Yes ☐

If No, please specify the reason: _____

Date of assessment 25 MAR 2014
DD/MMM/YYYY

System Back ☐

Outcome Normal ☐

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Screening

Form: Physical Examination (12)

Data signed: (hfarmer1) 30 Mar 2015 13:33:12

Generated On: 20 Jul 2016 22:28:45

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of assessment 25 MAR 2014
DD/MMM/YYYY

System Musculoskeletal ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Screening

Form: Physical Examination (13)

Data signed: (hfarmer1) 30 Mar 2015 13:33:12

Generated On: 20 Jul 2016 22:28:45

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of assessment 25 MAR 2014
DD/MMM/YYYY

System Abdomen ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Screening

Form: Physical Examination (14)

Data signed: (hfarmer1) 30 Mar 2015 13:33:12

Generated On: 20 Jul 2016 22:28:45

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of assessment 25 MAR 2014
DD/MMM/YYYY

System Dentition ☒

Outcome Abnormal ☒

Abnormal, please specify MISSING AND DECAYED
TEETH

Clinically significant No ☒

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Screening

Form: Physical Examination (15)

Data signed: (hfarmer1) 30 Mar 2015 13:33:12

Generated On: 20 Jul 2016 22:28:45

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

25 MAR 2014
DD/MMM/YYYY

System

Other ☒

Other, Specify _____

Outcome _____

Abnormal, please specify _____

Clinically significant _____

Not Done

True

Not Done; please specify the reason: _____

NOT EXAMINED

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Screening

Form: Physical Examination (16)

Data signed: (hfarmer1) 30 Mar 2015 13:33:12

Generated On: 20 Jul 2016 22:28:45

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

25 MAR 2014
DD/MMM/YYYY

System

Other ☒

Other, Specify _____

Outcome _____

Abnormal, please specify _____

Clinically significant _____

Not Done

True

Not Done; please specify the reason: _____

NOT EXAMINED

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Screening

Form: Physical Examination (17)

Data signed: (hfarmer1) 30 Mar 2015 13:33:12

Generated On: 20 Jul 2016 22:28:45

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

25 MAR 2014
DD/MMM/YYYY

System

Other ☒

Other, Specify _____

Outcome _____

Abnormal, please specify _____

Clinically significant _____

Not Done

True

Not Done; please specify the reason: _____

NOT EXAMINED

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Screening

Form: Physical Examination (18)

Data signed: (hfarmer1) 30 Mar 2015 13:33:12

Generated On: 20 Jul 2016 22:28:45

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

25 MAR 2014
DD/MMM/YYYY

System

Other ☒

Other, Specify _____

Outcome _____

Abnormal, please specify _____

Clinically significant _____

Not Done

True

Not Done; please specify the reason: _____

NOT EXAMINED

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Screening

Form: Physical Examination (19)

Data signed: (hfarmer1) 30 Mar 2015 13:33:12

Generated On: 20 Jul 2016 22:28:45

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

25 MAR 2014
DD/MMM/YYYY

System

Other ☒

Other, Specify _____

Outcome _____

Abnormal, please specify _____

Clinically significant _____

Not Done

True

Not Done; please specify the reason: _____

NOT EXAMINED

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Screening

Form: Advice on the risk of smoking and debriefing

Data signed: (hfarmer1) 30 Mar 2015 13:33:14

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Screening

Form: Identification of Current Cigarette Brand

Data signed: (hfarmer1) 30 Mar 2015 13:33:13

Generated On: 20 Jul 2016 22:28:45

Date

25 MAR 2014
DD/MMM/YYYY

Brand name

305'S MENTHOL

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Screening

Form: THS 2.2 menthol product demonstration

Data signed: (hfarmer1) 30 Mar 2015 13:33:14

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Screening

Form: Smoking History

Data signed: (hfarmer1) 30 Mar 2015 13:33:14

Generated On: 20 Jul 2016 22:28:45

Date of Assessment

25 MAR 2014
DD/MMM/YYYY

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

No ☐

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

Yes ☐

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

>19 ☐

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

Yes ☐

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

No ☐

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Screening

Form: Weight and Height

Data signed: (hfarmer1) 30 Mar 2015 13:33:14

Generated On: 20 Jul 2016 22:28:45

Measurement(s) assessed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

25 MAR 2014
DD/MMM/YYYY

Weight

86.0
kg

Height

176.5
cm

BMI (Derived)

27.6
kg/m2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Screening

Form: ECG (12-Lead Standard)

Data signed: (hfarmer1) 30 Mar 2015 13:33:10

Generated On: 20 Jul 2016 22:28:45

Was the ECG performed? Yes ☒

If No, please specify the reason: _____

Date of assessment: 25 MAR 2014
DD/MMM/YYYY

Position Supine ☒

Heart Rate 49
beats per minute

QRS Interval 94
msec

QT Interval 461
msec

QTcB Interval 417
msec

QTcF Interval 431
msec

PR Interval 162
msec

Interpretation Abnormal ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Screening

Form: ECG (12-Lead Standard)

Data signed: (hfarmer1) 30 Mar 2015 13:33:10

Generated On: 20 Jul 2016 22:28:45

If Abnormal, Clinical Significance

Not clinically significant ☒

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Screening

Form: Spirometry (1)

Data signed: (hfarmer1) 30 Mar 2015 13:33:13

Generated On: 20 Jul 2016 22:28:45

Was the spirometry performed? Yes ☒

If No, please specify the reason: _____

Category Without short-acting ☒
bronchodilator

Position SITTING

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

Date of assessment DD/MMM/YYYY 25 MAR 2014

Time of assessment 11:37

Predicted FVC value 5.08
L

Best measured FVC value 6.39
L

Percent of predicted FVC value 126
%

Best measured FEV1 value 3.64
L

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Screening

Form: Spirometry (1)

Data signed: (hfarmer1) 30 Mar 2015 13:33:13

Generated On: 20 Jul 2016 22:28:45

Predicted FEV1 value	3.98 L
----------------------	-----------

Percent of predicted FEV1 value	92 %
---------------------------------	---------

Calculated ratio between FEV1/FVC	0.57
-----------------------------------	------

MEF 25/75 value	1.20 L/s
-----------------	-------------

Interpretation	Normal <input checked="" type="radio"/>
----------------	---

If Abnormal, Clinical Significance	<hr/>
------------------------------------	-------

If Not Clinically Significant or Clinically Significant, Please specify the finding(s)	<hr/>
---	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Screening

Form: Spirometry (2)

Data signed: (hfarmer1) 30 Mar 2015 13:33:13

Generated On: 20 Jul 2016 22:28:45

Was the spirometry performed? Yes ☒

If No, please specify the reason: _____

Category With short-acting bronchodilator ☒

Position SITTING

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

Date of assessment DD/MMM/YYYY 25 MAR 2014

Time of assessment 12:24

Name of bronchodilator ALBUTEROL SULFATE

Dose 180 MCG

Predicted FVC value 5.08 L

Best measured FVC value 4.38 L

Percent of predicted FVC value 95 %

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Screening

Form: Spirometry (2)

Data signed: (hfarmer1) 30 Mar 2015 13:33:13

Generated On: 20 Jul 2016 22:28:45

Best measured FEV1 value	3.56 L
--------------------------	-----------

Predicted FEV1 value	3.98 L
----------------------	-----------

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

Calculated ratio between FEV1/FVC	0.81
-----------------------------------	------

MEF 25/75 value	2.60 L/s
-----------------	-------------

Interpretation	Normal <input checked="" type="radio"/>
----------------	---

If Abnormal, Clinical Significance	<hr/>
------------------------------------	-------

If Not Clinically Significant or Clinically Significant, Please specify the finding(s)	<hr/>
---	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Screening

Form: Chest X-Ray

Data signed: (hfarmer1) 30 Mar 2015 13:33:14

Generated On: 20 Jul 2016 22:28:45

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

Yes ☒

If No, please specify the reason: _____

Date of assessment

31 MAR 2014
DD/MMM/YYYY

System

Chest ☒

Interpretation

Normal ☒

Clinically significant _____

Abnormal, please specify: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Screening

Form: Haematology

Data signed: (hfarmer1) 30 Mar 2015 13:33:11

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Screening

Form: Clinical Chemistry

Data signed: (hfarmer1) 30 Mar 2015 13:33:11

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Screening

Form: Urine analysis

Data signed: (hfarmer1) 30 Mar 2015 13:33:11

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Screening

Form: Serology for HIV and Hepatitis B and C

Data signed: (hfarmer1) 30 Mar 2015 13:33:11

Generated On: 20 Jul 2016 22:28:45

Category

Serology ☒

Not Done

False

If Not Done, please specify the reason:

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Screening

Form: Urine Drug Screen

Data signed: (hfarmer1) 30 Mar 2015 13:33:11

Generated On: 20 Jul 2016 22:28:45

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

If Not Done, please specify the reason: _____

Date of sample collection	25 MAR 2014 DD/MMM/YYYY
---------------------------	----------------------------

Time of sample collection	10:26 hour:min 24-hour clock
---------------------------	---------------------------------

Drug type	Result
Amphetamines	Negative
Barbiturates	Negative
Benzodiazepines	Negative

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Screening

Form: Urine Drug Screen (4)

Data signed: (hfarmer1) 30 Mar 2015 13:33:11

Generated On: 20 Jul 2016 22:28:45

Drug type	Result
Cannabinoids	Negative
Cocaine	Negative
Opiates	Negative

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Screening

Form: Alcohol Test

Data signed: (hfarmer1) 30 Mar 2015 13:33:11

Generated On: 20 Jul 2016 22:28:45

Was the alcohol test performed? Yes ☒

If No, please specify the reason: _____

Method used Breath test ☒

Date of assessment 25 MAR 2014
DD/MMM/YYYY

Time of assessment 10:33
hour:min 24-hour clock

Result Negative ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Screening

Form: Urine Cotinine Test

Data signed: (hfarmer1) 30 Mar 2015 13:33:11

Generated On: 20 Jul 2016 22:28:45

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

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

If Not Done, please specify the reason: _____

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

Time of Sample Collection	10:26 hour:min 24-hour clock
---------------------------	---------------------------------

Result	Positive >=200 ng/ml <input checked="" type="radio"/>
--------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Screening

Form: Lab-BU-LabCorp CHEMISTRY(25 MAR 2014)

Data signed: (hfarmer1) 30 Mar 2015 13:33:14

Generated On: 20 Jul 2016 22:28:45

Experiment Type

CHEMISTRY

Date of Sample Collection
YYYY/MM/DD

25 MAR 2014

Please document clinically relevant abnormalities in the AE form

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Screening

Form: Lab-BU-LabCorp CHEMISTRY(25 MAR 2014)

Data signed: (hfarmer1) 30 Mar 2015 13:33:14

Generated On: 20 Jul 2016 22:28:45

Experiment Type

CHEMISTRY

Date of Sample Collection
YYYY/MM/DD

25 MAR 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male ☒

Time of Sample Collection

11:30

Analyte Name

GLUCOSE, SERUM

Code

001032

Result

94

Unit

MG/DL

Lower limit

65

Upper limit

99

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Screening

Form: Lab-BU-LabCorp CHEMISTRY(25 MAR 2014)

Data signed: (hfarmer1) 30 Mar 2015 13:33:14

Generated On: 20 Jul 2016 22:28:45

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

08457100020

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Screening

Form: Lab-BU-LabCorp (2)

Data signed: (hfarmer1) 30 Mar 2015 13:33:14

Generated On: 20 Jul 2016 22:28:45

Experiment Type	CHEMISTRY
Date of Sample Collection YYYY/MM/DD	25 MAR 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Male <input checked="" type="radio"/>
Time of Sample Collection	11:30
Analyte Name	BUN
Code	001040
Result	10
Unit	MG/DL
Lower limit	6
Upper limit	24
Flag	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Screening

Form: Lab-BU-LabCorp (2)

Data signed: (hfarmer1) 30 Mar 2015 13:33:14

Generated On: 20 Jul 2016 22:28:45

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

08457100020

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Screening

Form: Lab-BU-LabCorp (3)

Data signed: (hfarmer1) 30 Mar 2015 13:33:14

Generated On: 20 Jul 2016 22:28:45

Experiment Type	CHEMISTRY
Date of Sample Collection YYYY/MM/DD	25 MAR 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Male <input checked="" type="radio"/>
Time of Sample Collection	11:30
Analyte Name	CHOLESTEROL, TOTAL
Code	001065
Result	227
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: 1252**

Folder: Screening

Form: Lab-BU-LabCorp (3)

Data signed: (hfarmer1) 30 Mar 2015 13:33:14

Generated On: 20 Jul 2016 22:28:45

Clinically Significant?

No ☒

Comment

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

08457100020

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Screening

Form: Lab-BU-LabCorp (4)

Data signed: (hfarmer1) 30 Mar 2015 13:33:14

Generated On: 20 Jul 2016 22:28:45

Experiment Type	CHEMISTRY
Date of Sample Collection YYYY/MM/DD	25 MAR 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Male <input checked="" type="radio"/>
Time of Sample Collection	11:30
Analyte Name	PROTEIN, TOTAL, SERUM
Code	001073
Result	7.2
Unit	G/DL
Lower limit	6.0
Upper limit	8.5
Flag	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Screening

Form: Lab-BU-LabCorp (4)

Data signed: (hfarmer1) 30 Mar 2015 13:33:14

Generated On: 20 Jul 2016 22:28:45

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

08457100020

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Screening

Form: Lab-BU-LabCorp (5)

Data signed: (hfarmer1) 30 Mar 2015 13:33:14

Generated On: 20 Jul 2016 22:28:45

Experiment Type

CHEMISTRY

Date of Sample Collection
YYYY/MM/DD

25 MAR 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male ☒

Time of Sample Collection

11:30

Analyte Name

ALBUMIN, SERUM

Code

001081

Result

4.7

Unit

G/DL

Lower limit

3.5

Upper limit

5.5

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Screening

Form: Lab-BU-LabCorp (5)

Data signed: (hfarmer1) 30 Mar 2015 13:33:14

Generated On: 20 Jul 2016 22:28:45

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

08457100020

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Screening

Form: Lab-BU-LabCorp (6)

Data signed: (hfarmer1) 30 Mar 2015 13:33:14

Generated On: 20 Jul 2016 22:28:45

Experiment Type

CHEMISTRY

Date of Sample Collection
YYYY/MM/DD

25 MAR 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male ☒

Time of Sample Collection

11:30

Analyte Name

BILIRUBIN, TOTAL

Code

001099

Result

0.3

Unit

MG/DL

Lower limit

0.0

Upper limit

1.2

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Screening

Form: Lab-BU-LabCorp (6)

Data signed: (hfarmer1) 30 Mar 2015 13:33:14

Generated On: 20 Jul 2016 22:28:45

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

08457100020

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Screening

Form: Lab-BU-LabCorp (7)

Data signed: (hfarmer1) 30 Mar 2015 13:33:14

Generated On: 20 Jul 2016 22:28:45

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

Date of Sample Collection YYYY/MM/DD	25 MAR 2014
---	-------------

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

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

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

Time of Sample Collection	11:30
---------------------------	-------

Analyte Name	ALKALINE PHOSPHATASE, S
--------------	-------------------------

Code	001107
------	--------

Result	58
--------	----

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

Lower limit	39
-------------	----

Upper limit	117
-------------	-----

Flag	
------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Screening

Form: Lab-BU-LabCorp (7)

Data signed: (hfarmer1) 30 Mar 2015 13:33:14

Generated On: 20 Jul 2016 22:28:45

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

08457100020

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Screening

Form: Lab-BU-LabCorp (8)

Data signed: (hfarmer1) 30 Mar 2015 13:33:14

Generated On: 20 Jul 2016 22:28:45

Experiment Type	CHEMISTRY
Date of Sample Collection YYYY/MM/DD	25 MAR 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Male <input checked="" type="radio"/>
Time of Sample Collection	11:30
Analyte Name	LDH
Code	001115
Result	190
Unit	IU/L
Lower limit	0
Upper limit	225
Flag	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Screening

Form: Lab-BU-LabCorp (8)

Data signed: (hfarmer1) 30 Mar 2015 13:33:14

Generated On: 20 Jul 2016 22:28:45

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

08457100020

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Screening

Form: Lab-BU-LabCorp (9)

Data signed: (hfarmer1) 30 Mar 2015 13:33:14

Generated On: 20 Jul 2016 22:28:45

Experiment Type	CHEMISTRY
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Date of Sample Collection YYYY/MM/DD	25 MAR 2014
---	-------------

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

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

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

Time of Sample Collection	11:30
---------------------------	-------

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

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

Result	18
--------	----

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

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

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

Flag	
------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Screening

Form: Lab-BU-LabCorp (9)

Data signed: (hfarmer1) 30 Mar 2015 13:33:14

Generated On: 20 Jul 2016 22:28:45

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

08457100020

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Screening

Form: Lab-BU-LabCorp (10)

Data signed: (hfarmer1) 30 Mar 2015 13:33:14

Generated On: 20 Jul 2016 22:28:45

Experiment Type	CHEMISTRY
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Date of Sample Collection YYYY/MM/DD	25 MAR 2014
---	-------------

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

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

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

Time of Sample Collection	11:30
---------------------------	-------

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

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

Result	150
--------	-----

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

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

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

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Screening

Form: Lab-BU-LabCorp (10)

Data signed: (hfarmer1) 30 Mar 2015 13:33:14

Generated On: 20 Jul 2016 22:28:45

Clinically Significant?

No ☒

Comment

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

08457100020

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Screening

Form: Lab-BU-LabCorp (11)

Data signed: (hfarmer1) 30 Mar 2015 13:33:14

Generated On: 20 Jul 2016 22:28:45

Experiment Type	CHEMISTRY
Date of Sample Collection YYYY/MM/DD	25 MAR 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Male <input checked="" type="radio"/>
Time of Sample Collection	11:30
Analyte Name	POTASSIUM, SERUM
Code	001180
Result	4.9
Unit	MMOL/L
Lower limit	3.5
Upper limit	5.2
Flag	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Screening

Form: Lab-BU-LabCorp (11)

Data signed: (hfarmer1) 30 Mar 2015 13:33:14

Generated On: 20 Jul 2016 22:28:45

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

08457100020

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Screening

Form: Lab-BU-LabCorp (12)

Data signed: (hfarmer1) 30 Mar 2015 13:33:14

Generated On: 20 Jul 2016 22:28:45

Experiment Type	CHEMISTRY
Date of Sample Collection YYYY/MM/DD	25 MAR 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Male <input checked="" type="radio"/>
Time of Sample Collection	11:30
Analyte Name	SODIUM, SERUM
Code	001198
Result	138
Unit	MMOL/L
Lower limit	134
Upper limit	144
Flag	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Screening

Form: Lab-BU-LabCorp (12)

Data signed: (hfarmer1) 30 Mar 2015 13:33:14

Generated On: 20 Jul 2016 22:28:45

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

08457100020

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Screening

Form: Lab-BU-LabCorp (13)

Data signed: (hfarmer1) 30 Mar 2015 13:33:14

Generated On: 20 Jul 2016 22:28:45

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

Date of Sample Collection YYYY/MM/DD	25 MAR 2014
---	-------------

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

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

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

Time of Sample Collection	11:30
---------------------------	-------

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: 1252**

Folder: Screening

Form: Lab-BU-LabCorp (13)

Data signed: (hfarmer1) 30 Mar 2015 13:33:14

Generated On: 20 Jul 2016 22:28:45

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

08457100020

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Screening

Form: Lab-BU-LabCorp (14)

Data signed: (hfarmer1) 30 Mar 2015 13:33:14

Generated On: 20 Jul 2016 22:28:45

Experiment Type

CHEMISTRY

Date of Sample Collection
YYYY/MM/DD

25 MAR 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male ☒

Time of Sample Collection

11:30

Analyte Name

CREATININE, SERUM

Code

001370

Result

0.79

Unit

MG/DL

Lower limit

0.76

Upper limit

1.27

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Screening

Form: Lab-BU-LabCorp (14)

Data signed: (hfarmer1) 30 Mar 2015 13:33:14

Generated On: 20 Jul 2016 22:28:45

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

08457100020

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Screening

Form: Lab-BU-LabCorp (15)

Data signed: (hfarmer1) 30 Mar 2015 13:33:14

Generated On: 20 Jul 2016 22:28:45

Experiment Type

CHEMISTRY

Date of Sample Collection
YYYY/MM/DD

25 MAR 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male ☒

Time of Sample Collection

11:30

Analyte Name

ALT (SGPT)

Code

001545

Result

20

Unit

IU/L

Lower limit

0

Upper limit

44

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Screening

Form: Lab-BU-LabCorp (15)

Data signed: (hfarmer1) 30 Mar 2015 13:33:14

Generated On: 20 Jul 2016 22:28:45

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

08457100020

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Screening

Form: Lab-BU-LabCorp (16)

Data signed: (hfarmer1) 30 Mar 2015 13:33:14

Generated On: 20 Jul 2016 22:28:45

Experiment Type	CHEMISTRY
Date of Sample Collection YYYY/MM/DD	25 MAR 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Male <input checked="" type="radio"/>
Time of Sample Collection	11:30
Analyte Name	GGT
Code	001958
Result	26
Unit	IU/L
Lower limit	0
Upper limit	65
Flag	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Screening

Form: Lab-BU-LabCorp (16)

Data signed: (hfarmer1) 30 Mar 2015 13:33:14

Generated On: 20 Jul 2016 22:28:45

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

08457100020

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Screening

Form: Lab-BU-LabCorp (17)

Data signed: (hfarmer1) 30 Mar 2015 13:33:14

Generated On: 20 Jul 2016 22:28:45

Experiment Type

CHEMISTRY

Date of Sample Collection
YYYY/MM/DD

25 MAR 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male ☒

Time of Sample Collection

11:30

Analyte Name

HEP C VIRUS AB

Code

140683

Result

0.2

Unit

S/CO RATIO

Lower limit

0.0

Upper limit

0.9

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Screening

Form: Lab-BU-LabCorp (17)

Data signed: (hfarmer1) 30 Mar 2015 13:33:14

Generated On: 20 Jul 2016 22:28:45

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

08457100020

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Screening

Form: Lab-BU-LabCorp SEROLOGY(25 MAR 2014)

Data signed: (hfarmer1) 30 Mar 2015 13:33:15

Generated On: 20 Jul 2016 22:28:45

Experiment Type

SEROLOGY

Date of Sample Collection
YYYY/MM/DD

25 MAR 2014

Please document clinically relevant abnormalities in the AE form

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Screening

Form: Lab-BU-LabCorp SEROLOGY(25 MAR 2014)

Data signed: (hfarmer1) 30 Mar 2015 13:33:15

Generated On: 20 Jul 2016 22:28:45

Experiment Type

SEROLOGY

Date of Sample Collection
YYYY/MM/DD

25 MAR 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male ☒

Time of Sample Collection

11:30

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: 1252**

Folder: Screening

Form: Lab-BU-LabCorp SEROLOGY(25 MAR 2014)

Data signed: (hfarmer1) 30 Mar 2015 13:33:15

Generated On: 20 Jul 2016 22:28:45

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

08457100020

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Screening

Form: Lab-BU-LabCorp (2)

Data signed: (hfarmer1) 30 Mar 2015 13:33:15

Generated On: 20 Jul 2016 22:28:45

Experiment Type

SEROLOGY

Date of Sample Collection
YYYY/MM/DD

25 MAR 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male ☒

Time of Sample Collection

11:30

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: 1252**

Folder: Screening

Form: Lab-BU-LabCorp (2)

Data signed: (hfarmer1) 30 Mar 2015 13:33:15

Generated On: 20 Jul 2016 22:28:45

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

08457100020

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Screening

Form: Lab-BU-LabCorp (3)

Data signed: (hfarmer1) 30 Mar 2015 13:33:15

Generated On: 20 Jul 2016 22:28:45

Experiment Type

SEROLOGY

Date of Sample Collection
YYYY/MM/DD

25 MAR 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male

Time of Sample Collection

11:30

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: 1252**

Folder: Screening

Form: Lab-BU-LabCorp (3)

Data signed: (hfarmer1) 30 Mar 2015 13:33:15

Generated On: 20 Jul 2016 22:28:45

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

08457100020

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Screening

Form: Lab-BU-LabCorp HEMATOLOGY(25 MAR 2014)

Data signed: (hfarmer1) 30 Mar 2015 13:33:16

Generated On: 20 Jul 2016 22:28:45

Experiment Type

HEMATOLOGY

Date of Sample Collection
YYYY/MM/DD

25 MAR 2014

Please document clinically relevant abnormalities in the AE form

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Screening

Form: Lab-BU-LabCorp HEMATOLOGY(25 MAR 2014)

Data signed: (hfarmer1) 30 Mar 2015 13:33:16

Generated On: 20 Jul 2016 22:28:45

Experiment Type	HEMATOLOGY
Date of Sample Collection YYYY/MM/DD	25 MAR 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Male <input checked="" type="radio"/>
Time of Sample Collection	11:30
Analyte Name	WBC
Code	005025
Result	7.2
Unit	X10E3/UL
Lower limit	3.4
Upper limit	10.8
Flag	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Screening

Form: Lab-BU-LabCorp HEMATOLOGY(25 MAR 2014)

Data signed: (hfarmer1) 30 Mar 2015 13:33:16

Generated On: 20 Jul 2016 22:28:45

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

08457100020

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Screening

Form: Lab-BU-LabCorp (2)

Data signed: (hfarmer1) 30 Mar 2015 13:33:16

Generated On: 20 Jul 2016 22:28:45

Experiment Type	HEMATOLOGY
Date of Sample Collection YYYY/MM/DD	25 MAR 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Male <input checked="" type="radio"/>
Time of Sample Collection	11:30
Analyte Name	RBC
Code	005033
Result	4.34
Unit	X10E6/UL
Lower limit	4.14
Upper limit	5.80
Flag	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Screening

Form: Lab-BU-LabCorp (2)

Data signed: (hfarmer1) 30 Mar 2015 13:33:16

Generated On: 20 Jul 2016 22:28:45

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

08457100020

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Screening

Form: Lab-BU-LabCorp (3)

Data signed: (hfarmer1) 30 Mar 2015 13:33:16

Generated On: 20 Jul 2016 22:28:45

Experiment Type	HEMATOLOGY
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Date of Sample Collection YYYY/MM/DD	25 MAR 2014
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Subject Number	
----------------	--

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

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

Time of Sample Collection	11:30
---------------------------	-------

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

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

Result	15.0
--------	------

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

Lower limit	12.6
-------------	------

Upper limit	17.7
-------------	------

Flag	
------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Screening

Form: Lab-BU-LabCorp (3)

Data signed: (hfarmer1) 30 Mar 2015 13:33:16

Generated On: 20 Jul 2016 22:28:45

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

08457100020

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Screening

Form: Lab-BU-LabCorp (4)

Data signed: (hfarmer1) 30 Mar 2015 13:33:16

Generated On: 20 Jul 2016 22:28:45

Experiment Type

HEMATOLOGY

Date of Sample Collection
YYYY/MM/DD

25 MAR 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male

Time of Sample Collection

11:30

Analyte Name

HEMATOCRIT

Code

005058

Result

43.0

Unit

%

Lower limit

37.5

Upper limit

51.0

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Screening

Form: Lab-BU-LabCorp (4)

Data signed: (hfarmer1) 30 Mar 2015 13:33:16

Generated On: 20 Jul 2016 22:28:45

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

08457100020

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Screening

Form: Lab-BU-LabCorp (5)

Data signed: (hfarmer1) 30 Mar 2015 13:33:16

Generated On: 20 Jul 2016 22:28:45

Experiment Type	HEMATOLOGY
Date of Sample Collection YYYY/MM/DD	25 MAR 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Male <input checked="" type="radio"/>
Time of Sample Collection	11:30
Analyte Name	MCV
Code	015065
Result	99
Unit	FL
Lower limit	79
Upper limit	97
Flag	High <input checked="" type="radio"/>

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Screening

Form: Lab-BU-LabCorp (5)

Data signed: (hfarmer1) 30 Mar 2015 13:33:16

Generated On: 20 Jul 2016 22:28:45

Clinically Significant?

No ☒

Comment

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

08457100020

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Screening

Form: Lab-BU-LabCorp (6)

Data signed: (hfarmer1) 30 Mar 2015 13:33:16

Generated On: 20 Jul 2016 22:28:45

Experiment Type	HEMATOLOGY
Date of Sample Collection YYYY/MM/DD	25 MAR 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Male <input checked="" type="radio"/>
Time of Sample Collection	11:30
Analyte Name	MCH
Code	015073
Result	34.6
Unit	PG
Lower limit	26.6
Upper limit	33.0
Flag	High <input checked="" type="radio"/>

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Screening

Form: Lab-BU-LabCorp (6)

Data signed: (hfarmer1) 30 Mar 2015 13:33:16

Generated On: 20 Jul 2016 22:28:45

Clinically Significant?

No ☒

Comment

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

08457100020

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Screening

Form: Lab-BU-LabCorp (7)

Data signed: (hfarmer1) 30 Mar 2015 13:33:16

Generated On: 20 Jul 2016 22:28:45

Experiment Type

HEMATOLOGY

Date of Sample Collection
YYYY/MM/DD

25 MAR 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male ☒

Time of Sample Collection

11:30

Analyte Name

MCHC

Code

015081

Result

34.9

Unit

G/DL

Lower limit

31.5

Upper limit

35.7

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Screening

Form: Lab-BU-LabCorp (7)

Data signed: (hfarmer1) 30 Mar 2015 13:33:16

Generated On: 20 Jul 2016 22:28:45

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

08457100020

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Screening

Form: Lab-BU-LabCorp (8)

Data signed: (hfarmer1) 30 Mar 2015 13:33:16

Generated On: 20 Jul 2016 22:28:45

Experiment Type

HEMATOLOGY

Date of Sample Collection
YYYY/MM/DD

25 MAR 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male ☒

Time of Sample Collection

11:30

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: 1252**

Folder: Screening

Form: Lab-BU-LabCorp (8)

Data signed: (hfarmer1) 30 Mar 2015 13:33:16

Generated On: 20 Jul 2016 22:28:45

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

08457100020

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Screening

Form: Lab-BU-LabCorp (9)

Data signed: (hfarmer1) 30 Mar 2015 13:33:16

Generated On: 20 Jul 2016 22:28:45

Experiment Type

HEMATOLOGY

Date of Sample Collection
YYYY/MM/DD

25 MAR 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male ☒

Time of Sample Collection

11:30

Analyte Name

LYMPHS

Code

015123

Result

19

Unit

%

Lower limit

14

Upper limit

46

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Screening

Form: Lab-BU-LabCorp (9)

Data signed: (hfarmer1) 30 Mar 2015 13:33:16

Generated On: 20 Jul 2016 22:28:45

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

08457100020

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Screening

Form: Lab-BU-LabCorp (10)

Data signed: (hfarmer1) 30 Mar 2015 13:33:16

Generated On: 20 Jul 2016 22:28:45

Experiment Type

HEMATOLOGY

Date of Sample Collection
YYYY/MM/DD

25 MAR 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male

Time of Sample Collection

11:30

Analyte Name

MONOCYTES

Code

015131

Result

9

Unit

%

Lower limit

4

Upper limit

12

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Screening

Form: Lab-BU-LabCorp (10)

Data signed: (hfarmer1) 30 Mar 2015 13:33:16

Generated On: 20 Jul 2016 22:28:45

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

08457100020

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Screening

Form: Lab-BU-LabCorp (11)

Data signed: (hfarmer1) 30 Mar 2015 13:33:16

Generated On: 20 Jul 2016 22:28:45

Experiment Type

HEMATOLOGY

Date of Sample Collection
YYYY/MM/DD

25 MAR 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male ☒

Time of Sample Collection

11:30

Analyte Name

EOS

Code

015149

Result

2

Unit

%

Lower limit

0

Upper limit

5

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Screening

Form: Lab-BU-LabCorp (11)

Data signed: (hfarmer1) 30 Mar 2015 13:33:16

Generated On: 20 Jul 2016 22:28:45

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

08457100020

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Screening

Form: Lab-BU-LabCorp (12)

Data signed: (hfarmer1) 30 Mar 2015 13:33:16

Generated On: 20 Jul 2016 22:28:45

Experiment Type

HEMATOLOGY

Date of Sample Collection
YYYY/MM/DD

25 MAR 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male

Time of Sample Collection

11:30

Analyte Name

BASOS

Code

015156

Result

0

Unit

%

Lower limit

0

Upper limit

3

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Screening

Form: Lab-BU-LabCorp (12)

Data signed: (hfarmer1) 30 Mar 2015 13:33:16

Generated On: 20 Jul 2016 22:28:45

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

08457100020

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Screening

Form: Lab-BU-LabCorp (13)

Data signed: (hfarmer1) 30 Mar 2015 13:33:16

Generated On: 20 Jul 2016 22:28:45

Experiment Type

HEMATOLOGY

Date of Sample Collection
YYYY/MM/DD

25 MAR 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male ☒

Time of Sample Collection

11:30

Analyte Name

PLATELETS

Code

015172

Result

313

Unit

X10E3/UL

Lower limit

155

Upper limit

379

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Screening

Form: Lab-BU-LabCorp (13)

Data signed: (hfarmer1) 30 Mar 2015 13:33:16

Generated On: 20 Jul 2016 22:28:45

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

08457100020

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Screening

Form: Lab-BU-LabCorp (14)

Data signed: (hfarmer1) 30 Mar 2015 13:33:16

Generated On: 20 Jul 2016 22:28:45

Experiment Type	HEMATOLOGY
Date of Sample Collection YYYY/MM/DD	25 MAR 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Male <input checked="" type="radio"/>
Time of Sample Collection	11:30
Analyte Name	NEUTROPHILS (ABSOLUTE)
Code	015909
Result	5.0
Unit	X10E3/UL
Lower limit	1.4
Upper limit	7.0
Flag	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Screening

Form: Lab-BU-LabCorp (14)

Data signed: (hfarmer1) 30 Mar 2015 13:33:16

Generated On: 20 Jul 2016 22:28:45

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

08457100020

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Screening

Form: Lab-BU-LabCorp (15)

Data signed: (hfarmer1) 30 Mar 2015 13:33:16

Generated On: 20 Jul 2016 22:28:45

Experiment Type	HEMATOLOGY
Date of Sample Collection YYYY/MM/DD	25 MAR 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Male <input checked="" type="radio"/>
Time of Sample Collection	11:30
Analyte Name	LYMPHS (ABSOLUTE)
Code	015917
Result	1.4
Unit	X10E3/UL
Lower limit	0.7
Upper limit	3.1
Flag	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Screening

Form: Lab-BU-LabCorp (15)

Data signed: (hfarmer1) 30 Mar 2015 13:33:16

Generated On: 20 Jul 2016 22:28:45

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

08457100020

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Screening

Form: Lab-BU-LabCorp (16)

Data signed: (hfarmer1) 30 Mar 2015 13:33:16

Generated On: 20 Jul 2016 22:28:45

Experiment Type

HEMATOLOGY

Date of Sample Collection
YYYY/MM/DD

25 MAR 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male ☒

Time of Sample Collection

11:30

Analyte Name

MONOCYTES(ABSOLUTE)

Code

015925

Result

0.7

Unit

X10E3/UL

Lower limit

0.1

Upper limit

0.9

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Screening

Form: Lab-BU-LabCorp (16)

Data signed: (hfarmer1) 30 Mar 2015 13:33:16

Generated On: 20 Jul 2016 22:28:45

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

08457100020

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Screening

Form: Lab-BU-LabCorp (17)

Data signed: (hfarmer1) 30 Mar 2015 13:33:16

Generated On: 20 Jul 2016 22:28:45

Experiment Type	HEMATOLOGY
Date of Sample Collection YYYY/MM/DD	25 MAR 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Male <input checked="" type="radio"/>
Time of Sample Collection	11:30
Analyte Name	EOS (ABSOLUTE)
Code	015933
Result	0.2
Unit	X10E3/UL
Lower limit	0.0
Upper limit	0.4
Flag	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Screening

Form: Lab-BU-LabCorp (17)

Data signed: (hfarmer1) 30 Mar 2015 13:33:16

Generated On: 20 Jul 2016 22:28:45

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

08457100020

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Screening

Form: Lab-BU-LabCorp (18)

Data signed: (hfarmer1) 30 Mar 2015 13:33:16

Generated On: 20 Jul 2016 22:28:45

Experiment Type	HEMATOLOGY
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Date of Sample Collection YYYY/MM/DD	25 MAR 2014
---	-------------

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

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

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

Time of Sample Collection	11:30
---------------------------	-------

Analyte Name	BASO (ABSOLUTE)
--------------	-----------------

Code	015941
------	--------

Result	0.0
--------	-----

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

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

Upper limit	0.2
-------------	-----

Flag	
------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Screening

Form: Lab-BU-LabCorp (18)

Data signed: (hfarmer1) 30 Mar 2015 13:33:16

Generated On: 20 Jul 2016 22:28:45

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

08457100020

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Screening

Form: Lab-BU-LabCorp URINALYSIS(25 MAR 2014)

Data signed: (hfarmer1) 30 Mar 2015 13:33:18

Generated On: 20 Jul 2016 22:28:45

Experiment Type

URINALYSIS

Date of Sample Collection
YYYY/MM/DD

25 MAR 2014

Please document clinically relevant abnormalities in the AE form

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Screening

Form: Lab-BU-LabCorp URINALYSIS(25 MAR 2014)

Data signed: (hfarmer1) 30 Mar 2015 13:33:18

Generated On: 20 Jul 2016 22:28:45

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

Date of Sample Collection YYYY/MM/DD	25 MAR 2014
---	-------------

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

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

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

Time of Sample Collection	10:42
---------------------------	-------

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

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

Result	1
--------	---

Unit	
------	--

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

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

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Screening

Form: Lab-BU-LabCorp URINALYSIS(25 MAR 2014)

Data signed: (hfarmer1) 30 Mar 2015 13:33:18

Generated On: 20 Jul 2016 22:28:45

Clinically Significant?

No ☒

Comment

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Screening

Form: Lab-BU-LabCorp (2)

Data signed: (hfarmer1) 30 Mar 2015 13:33:18

Generated On: 20 Jul 2016 22:28:45

Experiment Type

URINALYSIS

Date of Sample Collection
YYYY/MM/DD

25 MAR 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male



Time of Sample Collection

10:42

Analyte Name

PH

Code

13078

Result

8

Unit

Lower limit

5

Upper limit

8

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Screening

Form: Lab-BU-LabCorp (2)

Data signed: (hfarmer1) 30 Mar 2015 13:33:18

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Screening

Form: Lab-BU-LabCorp (3)

Data signed: (hfarmer1) 30 Mar 2015 13:33:18

Generated On: 20 Jul 2016 22:28:45

Experiment Type

URINALYSIS

Date of Sample Collection
YYYY/MM/DD

25 MAR 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male ☒

Time of Sample Collection

10:42

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: 1252**

Folder: Screening

Form: Lab-BU-LabCorp (3)

Data signed: (hfarmer1) 30 Mar 2015 13:33:18

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Screening

Form: Lab-BU-LabCorp (4)

Data signed: (hfarmer1) 30 Mar 2015 13:33:18

Generated On: 20 Jul 2016 22:28:45

Experiment Type

URINALYSIS

Date of Sample Collection
YYYY/MM/DD

25 MAR 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male

Time of Sample Collection

10:42

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: 1252**

Folder: Screening

Form: Lab-BU-LabCorp (4)

Data signed: (hfarmer1) 30 Mar 2015 13:33:18

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Screening

Form: Lab-BU-LabCorp (5)

Data signed: (hfarmer1) 30 Mar 2015 13:33:18

Generated On: 20 Jul 2016 22:28:45

Experiment Type

URINALYSIS

Date of Sample Collection
YYYY/MM/DD

25 MAR 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male ☒

Time of Sample Collection

10:42

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: 1252**

Folder: Screening

Form: Lab-BU-LabCorp (5)

Data signed: (hfarmer1) 30 Mar 2015 13:33:18

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Screening

Form: Lab-BU-LabCorp (6)

Data signed: (hfarmer1) 30 Mar 2015 13:33:18

Generated On: 20 Jul 2016 22:28:45

Experiment Type

URINALYSIS

Date of Sample Collection
YYYY/MM/DD

25 MAR 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male ☒

Time of Sample Collection

10:42

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: 1252**

Folder: Screening

Form: Lab-BU-LabCorp (6)

Data signed: (hfarmer1) 30 Mar 2015 13:33:18

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Screening

Form: Lab-BU-LabCorp (7)

Data signed: (hfarmer1) 30 Mar 2015 13:33:18

Generated On: 20 Jul 2016 22:28:45

Experiment Type

URINALYSIS

Date of Sample Collection
YYYY/MM/DD

25 MAR 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male ☒

Time of Sample Collection

10:42

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: 1252**

Folder: Screening

Form: Lab-BU-LabCorp (7)

Data signed: (hfarmer1) 30 Mar 2015 13:33:18

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Screening

Form: FTND Questionnaire

Generated On: 20 Jul 2016 22:28:45

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

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

Date of assessment	2014 MAR 25
DD/MMM/YYYY	DD/MMM/YYYY

Time of assessment	12:32
	hour:min 24-hour clock

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

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

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

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

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

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

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Screening

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

Data signed: (hfarmer1) 30 Mar 2015 13:33:13

Generated On: 20 Jul 2016 22:28:45

Was paper questionnaire used? Yes ☒

Reason not done _____

Type PROCHASKA STAGE OF
CHANGE QUESTIONNAIRE:
INTENTION TO QUIT
SMOKING

Date of assessment 25 MAR 2014
DD/MMM/YYYY

Time of assessment 09:55
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? 1

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Admission (Day -2)

Form: Date of Visit

Data signed: (hfarmer1) 30 Mar 2015 13:33:23

Generated On: 20 Jul 2016 22:28:45

Date of Visit

02 APR 2014
DD/MMM/YYYY

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Admission (Day -2)

Form: Inclusion Criteria

Data signed: (hfarmer1) 30 Mar 2015 13:33:20

Generated On: 20 Jul 2016 22:28:45

*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: 1252

Folder: Admission (Day -2)

Form: Inclusion Criteria (1)

Data signed: (hfarmer1) 30 Mar 2015 13:33:20

Generated On: 20 Jul 2016 22:28:45

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: 1252

Folder: Admission (Day -2)

Form: Inclusion Criteria (2)

Data signed: (hfarmer1) 30 Mar 2015 13:33:20

Generated On: 20 Jul 2016 22:28:45

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: 1252

Folder: Admission (Day -2)

Form: Inclusion Criteria (3)

Data signed: (hfarmer1) 30 Mar 2015 13:33:20

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Admission (Day -2)

Form: Inclusion Criteria (4)

Data signed: (hfarmer1) 30 Mar 2015 13:33:20

Generated On: 20 Jul 2016 22:28:45

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

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

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

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Admission (Day -2)

Form: Exclusion Criteria

Data signed: (hfarmer1) 30 Mar 2015 13:33:19

Generated On: 20 Jul 2016 22:28:45

*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: 1252**

Folder: Admission (Day -2)

Form: Exclusion Criteria (1)

Data signed: (hfarmer1) 30 Mar 2015 13:33:19

Generated On: 20 Jul 2016 22:28:45

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: 1252

Folder: Admission (Day -2)

Form: Exclusion Criteria (2)

Data signed: (hfarmer1) 30 Mar 2015 13:33:19

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Admission (Day -2)

Form: Exclusion Criteria (3)

Data signed: (hfarmer1) 30 Mar 2015 13:33:19

Generated On: 20 Jul 2016 22:28:45

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: 1252

Folder: Admission (Day -2)

Form: Exclusion Criteria (4)

Data signed: (hfarmer1) 30 Mar 2015 13:33:19

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Admission (Day -2)

Form: Exclusion Criteria (5)

Data signed: (hfarmer1) 30 Mar 2015 13:33:19

Generated On: 20 Jul 2016 22:28:45

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: 1252

Folder: Admission (Day -2)

Form: Exclusion Criteria (6)

Data signed: (hfarmer1) 30 Mar 2015 13:33:19

Generated On: 20 Jul 2016 22:28:45

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: 1252

Folder: Admission (Day -2)

Form: Exclusion Criteria (7)

Data signed: (hfarmer1) 30 Mar 2015 13:33:19

Generated On: 20 Jul 2016 22:28:45

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: 1252

Folder: Admission (Day -2)

Form: Exclusion Criteria (8)

Data signed: (hfarmer1) 30 Mar 2015 13:33:19

Generated On: 20 Jul 2016 22:28:45

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

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

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

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Admission (Day -2)

Form: Exclusion Criteria (9)

Data signed: (hfarmer1) 30 Mar 2015 13:33:19

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Admission (Day -2)

Form: Exclusion Criteria (10)

Data signed: (hfarmer1) 30 Mar 2015 13:33:19

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Admission (Day -2)

Form: Exclusion Criteria (11)

Data signed: (hfarmer1) 30 Mar 2015 13:33:19

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Admission (Day -2)

Form: Exclusion Criteria (12)

Data signed: (hfarmer1) 30 Mar 2015 13:33:19

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Admission (Day -2)

Form: Exclusion Criteria (13)

Data signed: (hfarmer1) 30 Mar 2015 13:33:19

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Admission (Day -2)

Form: Exclusion Criteria (14)

Data signed: (hfarmer1) 30 Mar 2015 13:33:19

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Admission (Day -2)

Form: Vital Signs

Data signed: (hfarmer1) 30 Mar 2015 13:33:23

Generated On: 20 Jul 2016 22:28:45

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 13:04
hour:min 24-hour clock

Pulse rate 59
beats per minute

Respiratory rate 16
breaths per minute

Blood Pressure (systolic) 126
mmHg

Blood Pressure (diastolic) 78
mmHg

Vital Signs Position of Subject Supine ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Admission (Day -2)

Form: Product preference

Data signed: (hfarmer1) 30 Mar 2015 13:33:23

Generated On: 20 Jul 2016 22:28:45

Which Product Arm would you prefer to be randomized
to:

No preference ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Admission (Day -2)

Form: Advice on the risk of smoking and debriefing

Data signed: (hfarmer1) 30 Mar 2015 13:33:23

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Admission (Day -2)

Form: Physical Examination

Data signed: (hfarmer1) 30 Mar 2015 13:33:21

Generated On: 20 Jul 2016 22:28:45

Was the physical examination performed?

Yes ☒

If No, please specify the reason:

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Admission (Day -2)

Form: Physical Examination (1)

Data signed: (hfarmer1) 30 Mar 2015 13:33:21

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Admission (Day -2)

Form: Physical Examination (2)

Data signed: (hfarmer1) 30 Mar 2015 13:33:21

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Admission (Day -2)

Form: Physical Examination (3)

Data signed: (hfarmer1) 30 Mar 2015 13:33:21

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Admission (Day -2)

Form: Physical Examination (4)

Data signed: (hfarmer1) 30 Mar 2015 13:33:21

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Admission (Day -2)

Form: Physical Examination (5)

Data signed: (hfarmer1) 30 Mar 2015 13:33:21

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Admission (Day -2)

Form: Physical Examination (6)

Data signed: (hfarmer1) 30 Mar 2015 13:33:21

Generated On: 20 Jul 2016 22:28:45

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: 1252

Folder: Admission (Day -2)

Form: Physical Examination (7)

Data signed: (hfarmer1) 30 Mar 2015 13:33:21

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Admission (Day -2)

Form: Physical Examination (8)

Data signed: (hfarmer1) 30 Mar 2015 13:33:21

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Admission (Day -2)

Form: Physical Examination (9)

Data signed: (hfarmer1) 30 Mar 2015 13:33:21

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Admission (Day -2)

Form: Physical Examination (10)

Data signed: (hfarmer1) 30 Mar 2015 13:33:21

Generated On: 20 Jul 2016 22:28:45

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: 1252

Folder: Admission (Day -2)

Form: Physical Examination (11)

Data signed: (hfarmer1) 30 Mar 2015 13:33:21

Generated On: 20 Jul 2016 22:28:45

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: 1252

Folder: Admission (Day -2)

Form: Physical Examination (12)

Data signed: (hfarmer1) 30 Mar 2015 13:33:21

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Admission (Day -2)

Form: Physical Examination (13)

Data signed: (hfarmer1) 30 Mar 2015 13:33:21

Generated On: 20 Jul 2016 22:28:45

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: 1252

Folder: Admission (Day -2)

Form: Physical Examination (14)

Data signed: (hfarmer1) 30 Mar 2015 13:33:21

Generated On: 20 Jul 2016 22:28:45

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

System Dentition ☒

Outcome Abnormal ☒

Abnormal, please specify MISSING AND DECAYED
TEETH

Clinically significant No ☒

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Admission (Day -2)

Form: Physical Examination (15)

Data signed: (hfarmer1) 30 Mar 2015 13:33:21

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Admission (Day -2)

Form: Physical Examination (16)

Data signed: (hfarmer1) 30 Mar 2015 13:33:21

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Admission (Day -2)

Form: Physical Examination (17)

Data signed: (hfarmer1) 30 Mar 2015 13:33:21

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Admission (Day -2)

Form: Physical Examination (18)

Data signed: (hfarmer1) 30 Mar 2015 13:33:21

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Admission (Day -2)

Form: Physical Examination (19)

Data signed: (hfarmer1) 30 Mar 2015 13:33:21

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Admission (Day -2)

Form: Identification of Current Cigarette Brand

Data signed: (hfarmer1) 30 Mar 2015 13:33:23

Generated On: 20 Jul 2016 22:28:45

Brand name

305'S MENTHOL

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Admission (Day -2)

Form: THS 2.2 menthol product test

Data signed: (hfarmer1) 30 Mar 2015 13:33:23

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Admission (Day -2)

Form: Smoking History

Data signed: (hfarmer1) 30 Mar 2015 13:33:23

Generated On: 20 Jul 2016 22:28:45

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

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

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

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Admission (Day -2)

Form: Weight

Data signed: (hfarmer1) 30 Mar 2015 13:33:23

Generated On: 20 Jul 2016 22:28:45

Measurement(s) assessed?

Yes ☒

If No, please specify the reason: _____

Time of assessment

12:27
hour:min 24-hour clock

Weight

86.7
kg

Waist circumference

95
cm

BMI

27.8

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Admission (Day -2)

Form: Urine Drug Screen

Data signed: (hfarmer1) 30 Mar 2015 13:33:20

Generated On: 20 Jul 2016 22:28:45

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

If Not Done, please specify the reason: _____

Time of sample collection	12:12 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: 1252

Folder: Admission (Day -2)

Form: Urine Drug Screen (6)

Data signed: (hfarmer1) 30 Mar 2015 13:33:20

Generated On: 20 Jul 2016 22:28:45

Drug type	Result
Opiates	Negative

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Admission (Day -2)

Form: Alcohol Test

Data signed: (hfarmer1) 30 Mar 2015 13:33:20

Generated On: 20 Jul 2016 22:28:45

Was the alcohol test performed? Yes ☒

If No, please specify the reason: _____

Method used Breath test ☒

Time of assessment 12:46
hour:min 24-hour clock

Result Negative ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Admission (Day -2)

Form: CO Breath Test

Data signed: (hfarmer1) 30 Mar 2015 13:33:19

Generated On: 20 Jul 2016 22:28:45

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

If Not Done, please specify the reason: _____

Actual Time of Assessment	12:48
	hour:min 24-hour clock

Result	7
	ppm

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Admission (Day -2)

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

Data signed: (hfarmer1) 30 Mar 2015 13:33:23

Generated On: 20 Jul 2016 22:28:45

Was paper questionnaire used? Yes ☒

Reason not done _____

Type PROCHASKA STAGE OF
CHANGE QUESTIONNAIRE:
INTENTION TO QUIT
SMOKING

Date of assessment 02 APR 2014
DD/MMM/YYYY

Time of assessment 12:53
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? 1

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day -1)

Form: Date of Visit

Data signed: (hfarmer1) 30 Mar 2015 13:33:28

Generated On: 20 Jul 2016 22:28:45

Date of Visit

03 APR 2014
DD/MMM/YYYY

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day -1)

Form: Vital Signs

Data signed: (hfarmer1) 30 Mar 2015 13:33:28

Generated On: 20 Jul 2016 22:28:45

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 10:32
hour:min 24-hour clock

Pulse rate 59
beats per minute

Respiratory rate 20
breaths per minute

Blood Pressure (systolic) 130
mmHg

Blood Pressure (diastolic) 80
mmHg

Vital Signs Position of Subject Supine ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day -1)

Form: CoHb Blood Sample

Data signed: (hfarmer1) 30 Mar 2015 13:33:24

Generated On: 20 Jul 2016 22:28:45

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	03 APR 2014
---------------------	-------------

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

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day -1)

Form: CO Breath Test (1)

Data signed: (hfarmer1) 30 Mar 2015 13:33:23

Generated On: 20 Jul 2016 22:28:45

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

If Not Done, please specify the reason: _____

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

Actual Time of Assessment hour:min 24-hour clock	06:28
---	-------

Result(ppm)	10
-------------	----

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day -1)

Form: CO Breath Test (2)

Data signed: (hfarmer1) 30 Mar 2015 13:33:23

Generated On: 20 Jul 2016 22:28:45

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

If Not Done, please specify the reason: _____

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

Actual Time of Assessment hour:min 24-hour clock	12:06
---	-------

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day -1)

Form: CO Breath Test (3)

Data signed: (hfarmer1) 30 Mar 2015 13:33:23

Generated On: 20 Jul 2016 22:28:45

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

If Not Done, please specify the reason: _____

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

Actual Time of Assessment hour:min 24-hour clock	16:08
---	-------

Result(ppm)	20
-------------	----

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day -1)

Form: CO Breath Test (4)

Data signed: (hfarmer1) 30 Mar 2015 13:33:23

Generated On: 20 Jul 2016 22:28:45

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

If Not Done, please specify the reason: _____

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

Actual Time of Assessment hour:min 24-hour clock	20:16
---	-------

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day -1)

Form: 4 hour urine collection

Data signed: (hfarmer1) 30 Mar 2015 13:33:27

Generated On: 20 Jul 2016 22:28:45

Start Time	10:11
	hour:min 24-hour clock

End Time	14:06
	hour:min 24-hour clock

Volume	545
	mL

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day -1)

Form: Sample Urine Collection (4 Hour collection)

Data signed: (hfarmer1) 30 Mar 2015 13:33:27

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Baseline (Day -1)

Form: Lab_BU_COHB (1)

Data signed: (hfarmer1) 30 Mar 2015 13:33:30

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05115150004497
Analyte	CARBOXYHEMOGLOBIN
Sample type	BLOOD
Result	8.20
Result Unit	%
Lab Status	OK
Sample comment	.
Detection method	SPECTROPHOTOMETRIC
Lower limit of quantification	0.500
Planned time point (Hour)	20
Day of Visit	-1
Celerion Study Number	AA99128-16
Date of Collection	2014-APR-03
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day -1)

Form: Lab_BU_COHB (1)

Data signed: (hfarmer1) 30 Mar 2015 13:33:30

Generated On: 20 Jul 2016 22:28:45

Start Day (24 hour urine only) _____

End Day (24 hour Urine Only) _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day -1)

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)

Data signed: (hfarmer1) 30 Mar 2015 13:33:28

Generated On: 20 Jul 2016 22:28:45

Date of Birth	(b) (6)
Date of assessment DD/MMM/YYYY	2014 APR 03 DD/MMM/YYYY
Time of assessment	20:17 hour:min 24-hour clock
Assessment Status	Completed <input type="radio"/>
1. Was smoking satisfying?	Moderately <input type="radio"/>
2. Did cigarettes taste good?	Moderately <input type="radio"/>
3. Did you enjoy the sensation in your throat and chest?	Moderately <input type="radio"/>
4. Did smoking calm you down?	Moderately <input type="radio"/>
5. Did smoking make you feel more awake?	Moderately <input type="radio"/>
6. Did smoking make you feel less irritable?	Not at all <input type="radio"/>
7. Did smoking help you concentrate?	Very little <input type="radio"/>
8. Did smoking reduce your hunger for food?	Moderately <input type="radio"/>

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day -1)

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)

Data signed: (hfarmer1) 30 Mar 2015 13:33:28

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Baseline (Day -1)

Form: Behavioral Risk Factor Surveillance System Questionnaire

Data signed: (hfarmer1) 30 Mar 2015 13:33:24

Generated On: 20 Jul 2016 22:28:45

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

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

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

Date of assessment	03 APR 2014 DD/MMM/YYYY
--------------------	----------------------------

Time of assessment	21:26 hour:min 24-hour clock
--------------------	---------------------------------

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

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

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

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day -1)

Form: Behavioral Risk Factor Surveillance System Questionnaire

Data signed: (hfarmer1) 30 Mar 2015 13:33:24

Generated On: 20 Jul 2016 22:28:45

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: 1252

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ)

Data signed: (hfarmer1) 30 Mar 2015 13:33:25

Generated On: 20 Jul 2016 22:28:45

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

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

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

Date of assessment	03 APR 2014 DD/MMM/YYYY
--------------------	----------------------------

Time of assessment	21:31 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?	23 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: 1252**

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ)

Data signed: (hfarmer1) 30 Mar 2015 13:33:25

Generated On: 20 Jul 2016 22:28:45

Months

Days

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

Years

00 Years

Months

00 Months

Days

00 Days

7. What brand of cigarettes/hand-rolled tobacco did you predominantly smoke in the last 12 months of smoking? 305'S MENTHOL

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (1)

Data signed: (hfarmer1) 30 Mar 2015 13:33:25

Generated On: 20 Jul 2016 22:28:45

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

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

Date of assessment	03 APR 2014 DD/MMM/YYYY
--------------------	----------------------------

Time of assessment	21:31 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?	23 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: 1252

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (1)

Data signed: (hfarmer1) 30 Mar 2015 13:33:25

Generated On: 20 Jul 2016 22:28:45

Months

Days

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

Years

00 Years

Months

00 Months

Days

00 Days

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

Time

Currently (last 3 months) ☒

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

Manufactured Cigarettes
per day

20

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

None ☒

Hand-rolled Cigarettes
per day

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (1)

Data signed: (hfarmer1) 30 Mar 2015 13:33:25

Generated On: 20 Jul 2016 22:28:45

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: 1252

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (2)

Data signed: (hfarmer1) 30 Mar 2015 13:33:25

Generated On: 20 Jul 2016 22:28:45

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

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

Reason not done	
-----------------	--

Date of assessment	03 APR 2014 DD/MMM/YYYY
--------------------	----------------------------

Time of assessment	21:31 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?	23 Years
---	----------

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

Years	
-------	--

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (2)

Data signed: (hfarmer1) 30 Mar 2015 13:33:25

Generated On: 20 Jul 2016 22:28:45

Months

Days

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

Years 00 Years

Months 00 Months

Days 00 Days

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

Time 1 year ago ☒

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

Manufactured Cigarettes per day 20

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

Hand-rolled Cigarettes per day

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (2)

Data signed: (hfarmer1) 30 Mar 2015 13:33:25

Generated On: 20 Jul 2016 22:28:45

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: 1252

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (3)

Data signed: (hfarmer1) 30 Mar 2015 13:33:25

Generated On: 20 Jul 2016 22:28:45

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

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

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

Date of assessment	03 APR 2014 DD/MMM/YYYY
--------------------	----------------------------

Time of assessment	21:31 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?	23 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: 1252

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (3)

Data signed: (hfarmer1) 30 Mar 2015 13:33:25

Generated On: 20 Jul 2016 22:28:45

Months

Days

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

Years

00 Years

Months

00 Months

Days

00 Days

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

Time

5 years ago ☒

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

Manufactured Cigarettes
per day

20

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

None ☒

Hand-rolled Cigarettes
per day

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (3)

Data signed: (hfarmer1) 30 Mar 2015 13:33:25

Generated On: 20 Jul 2016 22:28:45

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: 1252

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (4)

Data signed: (hfarmer1) 30 Mar 2015 13:33:25

Generated On: 20 Jul 2016 22:28:45

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

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

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

Date of assessment	03 APR 2014 DD/MMM/YYYY
--------------------	----------------------------

Time of assessment	21:31 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?	23 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: 1252

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (4)

Data signed: (hfarmer1) 30 Mar 2015 13:33:25

Generated On: 20 Jul 2016 22:28:45

Months

Days

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

Years

00 Years

Months

00 Months

Days

00 Days

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

Time

10 years ago ☒

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

Manufactured Cigarettes
per day

20

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

None ☒

Hand-rolled Cigarettes
per day

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (4)

Data signed: (hfarmer1) 30 Mar 2015 13:33:25

Generated On: 20 Jul 2016 22:28:45

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: 1252

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (5)

Data signed: (hfarmer1) 30 Mar 2015 13:33:25

Generated On: 20 Jul 2016 22:28:45

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

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

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

Date of assessment	03 APR 2014 DD/MMM/YYYY
--------------------	----------------------------

Time of assessment	21:31 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?	23 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: 1252

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (5)

Data signed: (hfarmer1) 30 Mar 2015 13:33:25

Generated On: 20 Jul 2016 22:28:45

Months

Days

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

Years 00 Years

Months 00 Months

Days 00 Days

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

Time 15 years ago ☒

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

Manufactured Cigarettes per day 20

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

Hand-rolled Cigarettes per day

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (5)

Data signed: (hfarmer1) 30 Mar 2015 13:33:25

Generated On: 20 Jul 2016 22:28:45

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: 1252

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (6)

Data signed: (hfarmer1) 30 Mar 2015 13:33:25

Generated On: 20 Jul 2016 22:28:45

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

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

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

Date of assessment	03 APR 2014 DD/MMM/YYYY
--------------------	----------------------------

Time of assessment	21:31 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?	23 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: 1252

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (6)

Data signed: (hfarmer1) 30 Mar 2015 13:33:25

Generated On: 20 Jul 2016 22:28:45

Months

Days

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

Years 00 Years

Months 00 Months

Days 00 Days

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

Time 20 years ago ☒

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

Manufactured Cigarettes per day 20

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

Hand-rolled Cigarettes per day

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (6)

Data signed: (hfarmer1) 30 Mar 2015 13:33:25

Generated On: 20 Jul 2016 22:28:45

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: 1252

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (7)

Data signed: (hfarmer1) 30 Mar 2015 13:33:25

Generated On: 20 Jul 2016 22:28:45

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

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

Date of assessment	03 APR 2014 DD/MMM/YYYY
--------------------	----------------------------

Time of assessment	21:31 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?	23 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: 1252

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (7)

Data signed: (hfarmer1) 30 Mar 2015 13:33:25

Generated On: 20 Jul 2016 22:28:45

Months

Days

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

Years

00 Years

Months

00 Months

Days

00 Days

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

Time

More than 20 years ago ☒

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

Manufactured Cigarettes
per day

20

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

None ☒

Hand-rolled Cigarettes
per day

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (7)

Data signed: (hfarmer1) 30 Mar 2015 13:33:25

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Baseline (Day -1)

Form: Supplemental Questions

Data signed: (hfarmer1) 30 Mar 2015 13:33:26

Generated On: 20 Jul 2016 22:28:45

Was paper questionnaire used?

Yes ☒

Reason not done

Date of Assessment

03 APR 2014
DD/MMM/YYYY

Time of assessment

21:32

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

04 minutes

Comments (open-end)

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day -1)

Form: Supplemental Questions (1)

Data signed: (hfarmer1) 30 Mar 2015 13:33:26

Generated On: 20 Jul 2016 22:28:45

Was paper questionnaire used? Yes ☐

Reason not done _____

Date of Assessment 03 APR 2014
DD/MMM/YYYY

Time of assessment 21:32

1. How long it takes for the subject to complete the SQ 04 minutes

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

Answer Yes ☐

Comments (open-end) _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day -1)

Form: Supplemental Questions (2)

Data signed: (hfarmer1) 30 Mar 2015 13:33:26

Generated On: 20 Jul 2016 22:28:45

Was paper questionnaire used? Yes ☐

Reason not done _____

Date of Assessment 03 APR 2014
DD/MMM/YYYY

Time of assessment 21:32

1. How long it takes for the subject to complete the SQ 04 minutes

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

Answer Yes ☐

Comments (open-end) _____

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Baseline (Day -1)

Form: Supplemental Questions (3)

Data signed: (hfarmer1) 30 Mar 2015 13:33:26

Generated On: 20 Jul 2016 22:28:45

Was paper questionnaire used? Yes ☐

Reason not done _____

Date of Assessment 03 APR 2014
DD/MMM/YYYY

Time of assessment 21:32

1. How long it takes for the subject to complete the SQ 04 minutes

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

Answer Yes ☐

Comments (open-end) _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day -1)

Form: Supplemental Questions (4)

Data signed: (hfarmer1) 30 Mar 2015 13:33:26

Generated On: 20 Jul 2016 22:28:45

Was paper questionnaire used? Yes ☐

Reason not done _____

Date of Assessment 03 APR 2014
DD/MMM/YYYY

Time of assessment 21:32

1. How long it takes for the subject to complete the SQ 04 minutes

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

Answer Yes ☐

Comments (open-end) _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day -1)

Form: Supplemental Questions (5)

Data signed: (hfarmer1) 30 Mar 2015 13:33:26

Generated On: 20 Jul 2016 22:28:45

Was paper questionnaire used? Yes ☐

Reason not done _____

Date of Assessment 03 APR 2014
DD/MMM/YYYY

Time of assessment 21:32

1. How long it takes for the subject to complete the SQ 04 minutes

Question 6. Was the SQ ☐
self-explaining?

Answer Yes ☐

Comments (open-end) _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day -1)

Form: Supplemental Questions (6)

Data signed: (hfarmer1) 30 Mar 2015 13:33:26

Generated On: 20 Jul 2016 22:28:45

Was paper questionnaire used? Yes ☐

Reason not done _____

Date of Assessment 03 APR 2014
DD/MMM/YYYY

Time of assessment 21:32

1. How long it takes for the subject to complete the SQ 04 minutes

Question 7. Was the SQ easy to use? ☐

Answer Yes ☐

Comments (open-end) _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day -1)

Form: Questionnaire on smoking urges (QSU)

Data signed: (hfarmer1) 30 Mar 2015 13:33:29

Generated On: 20 Jul 2016 22:28:45

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

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

Date of assessment	2014 APR 03
--------------------	-------------

DD/MMM/YYYY

Time of assessment	20:14
--------------------	-------

hour:min 24-hour clock

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

1. I have a desire for a cigarette right now	Do not agree or disagree <input type="radio"/>
--	--

2. Nothing would be better than smoking a cigarette right now	Do not agree or disagree <input type="radio"/>
---	--

3. If it were possible I would probably smoke now	Do not agree or disagree <input type="radio"/>
---	--

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

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

6. I have an urge for a cigarette	Do not agree or disagree <input type="radio"/>
-----------------------------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day -1)

Form: Questionnaire on smoking urges (QSU)

Data signed: (hfarmer1) 30 Mar 2015 13:33:29

Generated On: 20 Jul 2016 22:28:45

7. A cigarette would taste good now Strongly disagree ☐

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

9. Smoking would make me less depressed Strongly disagree ☐

10. I am going to smoke as soon as possible Do not agree or disagree ☐

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day -1)

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

Data signed: (hfarmer1) 30 Mar 2015 13:33:32

Generated On: 20 Jul 2016 22:28:45

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day -1)

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

Data signed: (hfarmer1) 30 Mar 2015 13:33:32

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112450002842
----------------	----------------

Analyte	HPMA
---------	------

Sample type	URINE
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Result	938
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Result Unit	NG/ML
-------------	-------

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

Sample comment	ANALYZED IN ERROR
----------------	-------------------

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

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

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

Date of Collection	2014-APR-03
--------------------	-------------

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

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day -1)

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

Data signed: (hfarmer1) 30 Mar 2015 13:33:32

Generated On: 20 Jul 2016 22:28:45

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day -1)

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

Data signed: (hfarmer1) 30 Mar 2015 13:33:32

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112450002842
Analyte	CEMA
Sample type	URINE
Result	192
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	-1
Celerion Study Number	AA99128-03
Date of Collection	2014-APR-03
Timepoint-minutes	
Urine Start Day	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day -1)

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

Data signed: (hfarmer1) 30 Mar 2015 13:33:32

Generated On: 20 Jul 2016 22:28:45

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day -1)

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

Data signed: (hfarmer1) 30 Mar 2015 13:33:32

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112450002842
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Analyte	HBMA
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Sample type	URINE
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Result	549
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Result Unit	NG/ML
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Lab Status	OK
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Sample comment	ANALYZED IN ERROR
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Detection method	LC-MS/MS
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Planned time point (Hour)	0
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Day of Visit	-1
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Celerion Study Number	AA99128-03
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Date of Collection	2014-APR-03
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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: 1252**

Folder: Baseline (Day -1)

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

Data signed: (hfarmer1) 30 Mar 2015 13:33:32

Generated On: 20 Jul 2016 22:28:45

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (NNN, NNAL)

Data signed: (hfarmer1) 30 Mar 2015 13:33:30

Generated On: 20 Jul 2016 22:28:45

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day -1)

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

Data signed: (hfarmer1) 30 Mar 2015 13:33:30

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112460003395
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Analyte	NNAL
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Sample type	URINE
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Result	.
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Result Unit	PG/ML
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Lab Status	OK
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Sample comment	ANALYSIS NOT PERFORMED IN ERROR
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Detection method	LC-MS/MS
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Planned time point (Hour)	0
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Day of Visit	-1
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Celerion Study Number	AA99128-04
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Date of Collection	2014-APR-03
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Timepoint-minutes	
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day -1)

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

Data signed: (hfarmer1) 30 Mar 2015 13:33:30

Generated On: 20 Jul 2016 22:28:45

Urine Start Day

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day -1)

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

Data signed: (hfarmer1) 30 Mar 2015 13:33:30

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112460003395
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Analyte	NNN
---------	-----

Sample type	URINE
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Result	.
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Result Unit	PG/ML
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Lab Status	OK
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Sample comment	ANALYSIS NOT PERFORMED IN ERROR
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Detection method	LC-MS/MS
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Planned time point (Hour)	0
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Day of Visit	-1
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Celerion Study Number	AA99128-04
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Date of Collection	2014-APR-03
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Timepoint-minutes	
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day -1)

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

Data signed: (hfarmer1) 30 Mar 2015 13:33:30

Generated On: 20 Jul 2016 22:28:45

Urine Start Day

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (HEMA)

Data signed: (hfarmer1) 30 Mar 2015 13:33:30

Generated On: 20 Jul 2016 22:28:45

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (HEMA) (1)

Data signed: (hfarmer1) 30 Mar 2015 13:33:30

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112470001697
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Analyte	HEMA
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Sample type	URINE
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Result	1.64
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Result Unit	NG/ML
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Lab Status	OK
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Sample comment	ANALYZED IN ERROR
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Detection method	LC-MS/MS
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Planned time point (Hour)	0
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Day of Visit	-1
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Celerion Study Number	AA99128-05
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Date of Collection	2014-APR-03
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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: 1252**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (HEMA) (1)

Data signed: (hfarmer1) 30 Mar 2015 13:33:30

Generated On: 20 Jul 2016 22:28:45

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day -1)

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

Data signed: (hfarmer1) 30 Mar 2015 13:33:32

Generated On: 20 Jul 2016 22:28:45

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day -1)

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

Data signed: (hfarmer1) 30 Mar 2015 13:33:32

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112480000771
Analyte	COT
Sample type	URINE
Result	1050
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	-1
Celerion Study Number	AA99128-06
Date of Collection	2014-APR-03
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day -1)

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

Data signed: (hfarmer1) 30 Mar 2015 13:33:32

Generated On: 20 Jul 2016 22:28:45

Urine Start Day

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day -1)

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

Data signed: (hfarmer1) 30 Mar 2015 13:33:32

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112480000771
Analyte	COT-GLUC
Sample type	URINE
Result	3060
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	-1
Celerion Study Number	AA99128-06
Date of Collection	2014-APR-03
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day -1)

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

Data signed: (hfarmer1) 30 Mar 2015 13:33:32

Generated On: 20 Jul 2016 22:28:45

Urine Start Day

Urine End Day

-1

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Baseline (Day -1)

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

Data signed: (hfarmer1) 30 Mar 2015 13:33:32

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112480000771
Analyte	NIC
Sample type	URINE
Result	461
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	-1
Celerion Study Number	AA99128-06
Date of Collection	2014-APR-03
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day -1)

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

Data signed: (hfarmer1) 30 Mar 2015 13:33:32

Generated On: 20 Jul 2016 22:28:45

Urine Start Day

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day -1)

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

Data signed: (hfarmer1) 30 Mar 2015 13:33:32

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112480000771
Analyte	NIC-GLUC
Sample type	URINE
Result	357
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	-1
Celerion Study Number	AA99128-06
Date of Collection	2014-APR-03
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day -1)

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

Data signed: (hfarmer1) 30 Mar 2015 13:33:32

Generated On: 20 Jul 2016 22:28:45

Urine Start Day

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day -1)

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

Data signed: (hfarmer1) 30 Mar 2015 13:33:32

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112480000771
Analyte	THCOT
Sample type	URINE
Result	2920
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	-1
Celerion Study Number	AA99128-06
Date of Collection	2014-APR-03
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day -1)

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

Data signed: (hfarmer1) 30 Mar 2015 13:33:32

Generated On: 20 Jul 2016 22:28:45

Urine Start Day

Urine End Day

-1

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Baseline (Day -1)

Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc) (6)

Data signed: (hfarmer1) 30 Mar 2015 13:33:32

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112480000771
Analyte	THCOT-GLUC
Sample type	URINE
Result	1890
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	-1
Celerion Study Number	AA99128-06
Date of Collection	2014-APR-03
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day -1)

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(6)**

Data signed: (hfarmer1) 30 Mar 2015 13:33:32

Generated On: 20 Jul 2016 22:28:45

Urine Start Day

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (3-OH BaP)

Data signed: (hfarmer1) 30 Mar 2015 13:33:33

Generated On: 20 Jul 2016 22:28:45

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (3-OH BaP) (1)

Data signed: (hfarmer1) 30 Mar 2015 13:33:33

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112490001697
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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	OK
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Sample comment	ANALYSIS NOT PERFORMED IN ERROR
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Detection method	LC-MS/MS
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Planned time point (Hour)	0
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Day of Visit	-1
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Celerion Study Number	AA99128-07
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Date of Collection	2014-APR-03
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Timepoint-minutes	
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (3-OH BaP) (1)

Data signed: (hfarmer1) 30 Mar 2015 13:33:33

Generated On: 20 Jul 2016 22:28:45

Urine Start Day

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP)

Data signed: (hfarmer1) 30 Mar 2015 13:33:33

Generated On: 20 Jul 2016 22:28:45

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (1)

Data signed: (hfarmer1) 30 Mar 2015 13:33:33

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112510001719
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Analyte	1-NA
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Sample type	URINE
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Result	121
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Result Unit	PG/ML
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Lab Status	OK
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Sample comment	ANALYZED IN ERROR
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Detection method	LC-MS/MS
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Planned time point (Hour)	0
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Day of Visit	-1
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Celerion Study Number	AA99128-09
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Date of Collection	2014-APR-03
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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: 1252**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (1)

Data signed: (hfarmer1) 30 Mar 2015 13:33:33

Generated On: 20 Jul 2016 22:28:45

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (2)

Data signed: (hfarmer1) 30 Mar 2015 13:33:33

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112510001719
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Analyte	2-NA
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Sample type	URINE
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Result	38.3
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Result Unit	PG/ML
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Lab Status	OK
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Sample comment	ANALYZED IN ERROR
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Detection method	LC-MS/MS
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Planned time point (Hour)	0
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Day of Visit	-1
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Celerion Study Number	AA99128-09
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Date of Collection	2014-APR-03
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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: 1252**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (2)

Data signed: (hfarmer1) 30 Mar 2015 13:33:33

Generated On: 20 Jul 2016 22:28:45

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (3)

Data signed: (hfarmer1) 30 Mar 2015 13:33:33

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112510001719
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Analyte	4-ABP
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Sample type	URINE
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Result	43.1
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Result Unit	PG/ML
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Lab Status	OK
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Sample comment	ANALYZED IN ERROR
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Detection method	LC-MS/MS
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Planned time point (Hour)	0
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Day of Visit	-1
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Celerion Study Number	AA99128-09
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Date of Collection	2014-APR-03
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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: 1252**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (3)

Data signed: (hfarmer1) 30 Mar 2015 13:33:33

Generated On: 20 Jul 2016 22:28:45

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (4)

Data signed: (hfarmer1) 30 Mar 2015 13:33:33

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112510001719
Analyte	O-TOL
Sample type	URINE
Result	217
Result Unit	PG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	-1
Celerion Study Number	AA99128-09
Date of Collection	2014-APR-03
Timepoint-minutes	
Urine Start Day	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (4)

Data signed: (hfarmer1) 30 Mar 2015 13:33:33

Generated On: 20 Jul 2016 22:28:45

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (11-dTXb2)

Data signed: (hfarmer1) 30 Mar 2015 13:33:30

Generated On: 20 Jul 2016 22:28:45

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (11-dTXb2) (1)

Data signed: (hfarmer1) 30 Mar 2015 13:33:30

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112530000540
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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	OK
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Sample comment	ANALYSIS NOT PERFORMED IN ERROR
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Detection method	LC-MS/MS
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Planned time point (Hour)	0
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Day of Visit	-1
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Celerion Study Number	AA99128-11
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Date of Collection	2014-APR-03
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Timepoint-minutes	
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (11-dTXb2) (1)

Data signed: (hfarmer1) 30 Mar 2015 13:33:30

Generated On: 20 Jul 2016 22:28:45

Urine Start Day

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (iPF2a-III)

Data signed: (hfarmer1) 30 Mar 2015 13:33:31

Generated On: 20 Jul 2016 22:28:45

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (iPF2a-III) (1)

Data signed: (hfarmer1) 30 Mar 2015 13:33:31

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112540000533
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Analyte	IPF2A-III
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Sample type	URINE
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Result	344
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Result Unit	PG/ML
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Lab Status	OK
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Sample comment	ANALYZED IN ERROR
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Detection method	LC-MS/MS
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Planned time point (Hour)	0
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Day of Visit	-1
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Celerion Study Number	AA99128-12
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Date of Collection	2014-APR-03
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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: 1252**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (iPF2a-III) (1)

Data signed: (hfarmer1) 30 Mar 2015 13:33:31

Generated On: 20 Jul 2016 22:28:45

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (1-OHP)

Data signed: (hfarmer1) 30 Mar 2015 13:33:34

Generated On: 20 Jul 2016 22:28:45

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (1-OHP) (1)

Data signed: (hfarmer1) 30 Mar 2015 13:33:34

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05115190003721
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Analyte	1-OHP
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Sample type	URINE
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Result	.
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Result Unit	PG/ML
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Lab Status	OK
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Sample comment	NOT ANALYZED IN ERROR
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Detection method	LC-MS/MS
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Planned time point (Hour)	0
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Day of Visit	-1
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Celerion Study Number	AA99598-03
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Date of Collection	2014-APR-03
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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: 1252**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (1-OHP) (1)

Data signed: (hfarmer1) 30 Mar 2015 13:33:34

Generated On: 20 Jul 2016 22:28:45

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (SPMA, SBMA)

Data signed: (hfarmer1) 30 Mar 2015 13:33:31

Generated On: 20 Jul 2016 22:28:45

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (SPMA, SBMA) (1)

Data signed: (hfarmer1) 30 Mar 2015 13:33:31

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05115170003719
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Analyte	SBMA
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Sample type	URINE
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Result	.
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Result Unit	NG/ML
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Lab Status	OK
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Sample comment	NOT ANALYZED IN ERROR
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Detection method	LC-MS/MS
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Planned time point (Hour)	0
---------------------------	---

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

Celerion Study Number	AA99598-01
-----------------------	------------

Date of Collection	2014-APR-03
--------------------	-------------

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

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (SPMA, SBMA) (1)

Data signed: (hfarmer1) 30 Mar 2015 13:33:31

Generated On: 20 Jul 2016 22:28:45

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (SPMA, SBMA) (2)

Data signed: (hfarmer1) 30 Mar 2015 13:33:31

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05115170003719
----------------	----------------

Analyte	SPMA
---------	------

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

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

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

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

Sample comment	NOT ANALYZED IN ERROR
----------------	-----------------------

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

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

Celerion Study Number	AA99598-01
-----------------------	------------

Date of Collection	2014-APR-03
--------------------	-------------

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

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (SPMA, SBMA) (2)

Data signed: (hfarmer1) 30 Mar 2015 13:33:31

Generated On: 20 Jul 2016 22:28:45

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (MHBMA)

Data signed: (hfarmer1) 30 Mar 2015 13:33:31

Generated On: 20 Jul 2016 22:28:45

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (MHBMA) (1)

Data signed: (hfarmer1) 30 Mar 2015 13:33:31

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05115180003721
----------------	----------------

Analyte	MHBMA
---------	-------

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

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

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

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

Sample comment	NOT ANALYZED IN ERROR
----------------	-----------------------

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

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

Celerion Study Number	AA99598-02
-----------------------	------------

Date of Collection	2014-APR-03
--------------------	-------------

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

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (MHBMA) (1)

Data signed: (hfarmer1) 30 Mar 2015 13:33:31

Generated On: 20 Jul 2016 22:28:45

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (Creatinine)

Data signed: (hfarmer1) 30 Mar 2015 13:33:33

Generated On: 20 Jul 2016 22:28:45

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (Creatinine) (1)

Data signed: (hfarmer1) 30 Mar 2015 13:33:33

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05115160001697
----------------	----------------

Analyte	CREATININE
---------	------------

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

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

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

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

Sample comment	ANALYSIS NOT PERFORMED IN ERROR
----------------	------------------------------------

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

Planned time point (Hour)	0
---------------------------	---

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

Celerion Study Number	AA99128-14
-----------------------	------------

Date of Collection	2014-APR-03
--------------------	-------------

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (Creatinine) (1)

Data signed: (hfarmer1) 30 Mar 2015 13:33:33

Generated On: 20 Jul 2016 22:28:45

Urine Start Day

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day 0)

Form: Date of Visit

Data signed: (hfarmer1) 30 Mar 2015 13:33:37

Generated On: 20 Jul 2016 22:28:45

Date of Visit

04 APR 2014
DD/MMM/YYYY

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day 0)

Form: Randomization

Data signed: (hfarmer1) 30 Mar 2015 13:33:37

Generated On: 20 Jul 2016 22:28:45

Randomization number (4 digits)	2021
---------------------------------	------

Allocation Arm	THS 2.2 menthol <input checked="" type="radio"/>
----------------	--

Cigarette Consumption	Greater than 19 conventional menthol cigarettes per day <input checked="" type="radio"/>
-----------------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day 0)

Form: Vital Signs

Data signed: (hfarmer1) 30 Mar 2015 13:33:37

Generated On: 20 Jul 2016 22:28:45

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 10:32
hour:min 24-hour clock

Pulse rate 60
beats per minute

Respiratory rate 16
breaths per minute

Blood Pressure (systolic) 116
mmHg

Blood Pressure (diastolic) 69
mmHg

Vital Signs Position of Subject Supine ☒

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Baseline (Day 0)

Form: Gas Transfer

Data signed: (hfarmer1) 30 Mar 2015 13:33:36

Generated On: 20 Jul 2016 22:28:45

Was the Gas Transfer performed? Yes ☒

If No, please specify the reason: _____

Category _____

Position SITTING

Time of assessment 08:17

DLCO value 31.00
ml/min/mmHg

KCO value 1.23
mmol/min/kPa/L

DLCO/VA value 3.67
mL/min/mmHg/L

Interpretation Normal ☒

If Abnormal, Clinical Significance _____

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

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Baseline (Day 0)

Form: Lung Volume Measurements

Data signed: (hfarmer1) 30 Mar 2015 13:33:36

Generated On: 20 Jul 2016 22:28:45

Were the Lung Volume Measurements performed? Yes ☒

If No, please specify the reason: _____

Category _____

Position SITTING

Time of assessment 08:30

VC value 4.93
L

TLC value 7.49
L

IC value 4.05
L

FRC value 3.44
L

Interpretation Normal ☒

If Abnormal, Clinical Significance _____

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

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Baseline (Day 0)

Form: Spirometry with a short-acting bronchodilator

Data signed: (hfarmer1) 30 Mar 2015 13:33:37

Generated On: 20 Jul 2016 22:28:45

Was the Spirometry with a short-acting bronchodilator performed?

Yes ☒

If No, please specify the reason: _____

Category

With short-acting bronchodilator ☒

Position

SITTING

Time of assessment

09:05

Name of bronchodilator

ALBUTEROL SULFATE

Dose

180 MCG

Predicted FVC value

4.99
L

Best measured FVC value

4.93
L

Percent of predicted FVC value

98
%

Best measured FEV1 value

3.61
L

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day 0)

Form: Spirometry with a short-acting bronchodilator

Data signed: (hfarmer1) 30 Mar 2015 13:33:37

Generated On: 20 Jul 2016 22:28:45

Predicted FEV1 value	3.90 L
----------------------	-----------

Percent of predicted FEV1 value	92 %
---------------------------------	---------

Calculated ratio between FEV1/FVC	_____
-----------------------------------	-------

MEF 25/75 value	2.57 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: 1252**

Folder: Baseline (Day 0)

Form: Haematology

Data signed: (hfarmer1) 30 Mar 2015 13:33:34

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Baseline (Day 0)

Form: Clinical Chemistry

Data signed: (hfarmer1) 30 Mar 2015 13:33:34

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Baseline (Day 0)

Form: Urine analysis

Data signed: (hfarmer1) 30 Mar 2015 13:33:34

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Baseline (Day 0)

Form: Plasma Nicotine Sample

Data signed: (hfarmer1) 30 Mar 2015 13:33:36

Generated On: 20 Jul 2016 22:28:45

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	04 APR 2014
---------------------	-------------

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day 0)

Form: Plasma Cotinine Sample

Data signed: (hfarmer1) 30 Mar 2015 13:33:35

Generated On: 20 Jul 2016 22:28:45

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	04 APR 2014
---------------------	-------------

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day 0)

Form: CoHb Blood Sample <D0> (1)

Data signed: (hfarmer1) 30 Mar 2015 13:33:34

Generated On: 20 Jul 2016 22:28:45

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	04 APR 2014
---------------------	-------------

Timepoint	Prior to gas transfer assessment and prior to product use <input checked="" type="radio"/>
-----------	--

Time hour:min 24-hour clock	06:30
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day 0)

Form: CoHb Blood Sample <D0> (2)

Data signed: (hfarmer1) 30 Mar 2015 13:33:34

Generated On: 20 Jul 2016 22:28:45

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	04 APR 2014
---------------------	-------------

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

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day 0)

Form: Oxysterols

Data signed: (hfarmer1) 30 Mar 2015 13:33:36

Generated On: 20 Jul 2016 22:28:45

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	04 APR 2014
---------------------	-------------

Time hour:min 24-hour clock	06:30
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day 0)

Form: CO Breath Test (1)

Data signed: (hfarmer1) 30 Mar 2015 13:33:34

Generated On: 20 Jul 2016 22:28:45

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	09:20
---	-------

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day 0)

Form: CO Breath Test (2)

Data signed: (hfarmer1) 30 Mar 2015 13:33:34

Generated On: 20 Jul 2016 22:28:45

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

If Not Done, please specify the reason: _____

Scheduled Time	12:00 - 13:30 <input checked="" type="radio"/>
----------------	--

Actual Time of Assessment hour:min 24-hour clock	12:03
---	-------

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day 0)

Form: CO Breath Test (3)

Data signed: (hfarmer1) 30 Mar 2015 13:33:34

Generated On: 20 Jul 2016 22:28:45

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)	35
-------------	----

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day 0)

Form: CO Breath Test (4)

Data signed: (hfarmer1) 30 Mar 2015 13:33:34

Generated On: 20 Jul 2016 22:28:45

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)	30
-------------	----

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Baseline (Day 0)

Form: CYP2A6 activity Sample

Data signed: (hfarmer1) 30 Mar 2015 13:33:35

Generated On: 20 Jul 2016 22:28:45

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

04 APR 2014

06:30

trans-3'-hydroxyc
otinine

04 APR 2014

06:30

cotinine

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Baseline (Day 0)

Form: CYP1A2 activity Sample

Data signed: (hfarmer1) 30 Mar 2015 13:33:35

Generated On: 20 Jul 2016 22:28:45

Time of caffeine tablet intake	11:06
	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
04 APR 2014	17:01	Caffeine
04 APR 2014	17:01	Paraxanthine

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day 0)

**Form: Risk Marker: hs-CRP, fibrinogen, homocysteine, LDL, HDL,
sICAM-1, HbA1c, Apo A1, Apo B**

Data signed: (hfarmer1) 30 Mar 2015 13:33:36

Generated On: 20 Jul 2016 22:28:45

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	04 APR 2014
---------------------	-------------

Time hour:min 24-hour clock	06:30
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day 0)

Form: 24 hour urine collections

Data signed: (hfarmer1) 30 Mar 2015 13:33:37

Generated On: 20 Jul 2016 22:28:45

Start Date	04 APR 2014 DD/MMM/YYYY
------------	----------------------------

Start Time	06:41 hour:min 24-hour clock
------------	---------------------------------

End Date	05 APR 2014 DD/MMM/YYYY
----------	----------------------------

End Time	06:14 hour:min 24-hour clock
----------	---------------------------------

Volume	3747 mL
--------	------------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day 0)

Form: Sample Urine Collection

Data signed: (hfarmer1) 30 Mar 2015 13:33:37

Generated On: 20 Jul 2016 22:28:45

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: 1252

Folder: Baseline (Day 0)

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Data signed: (hfarmer1) 30 Mar 2015 13:33:38

Generated On: 20 Jul 2016 22:28:45

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

Date of assessment DD/MMM/YYYY	2014 APR 04 DD/MMM/YYYY
-----------------------------------	----------------------------

Time of assessment	06:07 hour:min 24-hour clock
--------------------	---------------------------------

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

Please indicate for each of the items below, how you have been feeling over the past 24 hours

How have you been feeling over the past 24 hours?	None <input type="radio"/>
---	----------------------------

1. Angry, irritable, frustrated

How have you been feeling over the past 24 hours?	Slight <input type="radio"/>
---	------------------------------

2. Anxious, nervous

How have you been feeling over the past 24 hours?	None <input type="radio"/>
---	----------------------------

3. Depressed Mood, sad

How have you been feeling over the past 24 hours?	Slight <input type="radio"/>
---	------------------------------

4. Desire or craving to smoke

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Baseline (Day 0)

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Data signed: (hfarmer1) 30 Mar 2015 13:33:38

Generated On: 20 Jul 2016 22:28:45

How have you been feeling over the past 24 hours? None ☐

5. Difficulty concentrating

How have you been feeling over the past 24 hours? None ☐

6. Increased appetite, hungry, weight gain

How have you been feeling over the past 24 hours? Slight ☐

7. Insomnia, sleep problems, awakening at night

How have you been feeling over the past 24 hours? 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: 1252**

Folder: Baseline (Day 0)

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Data signed: (hfarmer1) 30 Mar 2015 13:33:38

Generated On: 20 Jul 2016 22:28:45

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: 1252

Folder: Baseline (Day 0)

Form: Cough Assessment

Data signed: (hfarmer1) 30 Mar 2015 13:33:38

Generated On: 20 Jul 2016 22:28:45

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

Date of assessment DD/MMM/YYYY	2014 APR 04 DD/MMM/YYYY
-----------------------------------	----------------------------

Time of assessment	06:03 hour:min 24-hour clock
--------------------	---------------------------------

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

Have you experienced a regular need to cough e.g. coughing several times in the last 24 hrs?	Yes <input checked="" type="radio"/>
--	--------------------------------------

If YES, please answer the following questions:

First Question: Cough Impact Scale How much is your cough bothering you?	48
---	----

Second Question: Cough Intensity Scale: How intense is your cough?	Moderate <input checked="" type="radio"/>
---	---

Third Question: Cough Frequency Scale: How frequently do you normally have to cough each day?	Sometimes <input checked="" type="radio"/>
--	--

Fourth Question: Sputum Production To what extent do you produce sputum when coughing?	A moderate amount of sputum <input checked="" type="radio"/>
---	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day 0)

Form: Bio-banking (Transcriptomics)

Data signed: (hcoleman1) 18 Jun 2015 21:27:18

Generated On: 20 Jul 2016 22:28:45

Was a Bio-banking sample for transcriptomics taken?

Yes ☒

Time of Sample Collection

06:30
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: 1252**

Folder: Baseline (Day 0)

Form: Bio-banking (Biomarkers of exposure and risk markers)

Data signed: (hfarmer1) 30 Mar 2015 13:33:37

Generated On: 20 Jul 2016 22:28:45

Was a Bio-banking sample for biomarkers of exposure
and risk markers taken?

Yes ☒

Time of Sample Collection

06:30
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: 1252**

Folder: Baseline (Day 0)

Form: Bio-banking (nasal epithelial collection/buccal collection)

Data signed: (hfarmer1) 30 Mar 2015 13:33:38

Generated On: 20 Jul 2016 22:28:45

Was a Bio-banking sample for nasal epithelial
collection/buccal collection taken?

Yes ☒

Time of Buccal Collection

14:23
hour:min 24-hour clock

Time of Nasal Epithelial Collection

14:20
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: 1252**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (1)

Data signed: (hfarmer1) 30 Mar 2015 13:33:43

Generated On: 20 Jul 2016 22:28:45

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6) _____

Visit Name _____

Visit Type Scheduled ☒

Accession ID W715953

Actual Collection Date 2014 04 04

Actual Collection Time 06:30

Specimen Condition _____

Battery ID RC1029

Battery Name TRIGLYCERIDES

Lab Test ID RCT19

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (1)

Data signed: (hfarmer1) 30 Mar 2015 13:33:43

Generated On: 20 Jul 2016 22:28:45

Lab Test Name	TRIGLYCERIDES (GPO)
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	210
Reported Numeric Result	210
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: 1252**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (1)

Data signed: (hfarmer1) 30 Mar 2015 13:33:43

Generated On: 20 Jul 2016 22:28:45

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (2)

Data signed: (hfarmer1) 30 Mar 2015 13:33:43

Generated On: 20 Jul 2016 22:28:45

Transmission Type Cumulative ☐

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6) 

Visit Name _____

Visit Type Scheduled ☐

Accession ID W715953

Actual Collection Date 2014 04 04

Actual Collection Time 06:30

Specimen Condition _____

Battery ID RC1092

Battery Name FASTING GLUCOSE

Lab Test ID RCT142

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (2)

Data signed: (hfarmer1) 30 Mar 2015 13:33:43

Generated On: 20 Jul 2016 22:28:45

Lab Test Name	FASTING GLUCOSE
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	98
Reported Numeric Result	98
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: 1252**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (2)

Data signed: (hfarmer1) 30 Mar 2015 13:33:43

Generated On: 20 Jul 2016 22:28:45

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (3)


Data signed: (hfarmer1) 30 Mar 2015 13:33:43

Generated On: 20 Jul 2016 22:28:45

Transmission Type Cumulative ☐

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6) 

Visit Name _____

Visit Type Scheduled ☐

Accession ID W715953

Actual Collection Date 2014 04 04

Actual Collection Time 06:30

Specimen Condition _____

Battery ID RC272

Battery Name TOTAL CHOLESTEROL

Lab Test ID RCT20

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (3)

Data signed: (hfarmer1) 30 Mar 2015 13:33:43

Generated On: 20 Jul 2016 22:28:45

Lab Test Name	CHOLESTEROL (HIGH PERFORMANCE)
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	278
Reported Numeric Result	278
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: 1252**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (3)

Data signed: (hfarmer1) 30 Mar 2015 13:33:43

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (4)

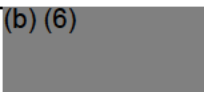
Data signed: (hfarmer1) 30 Mar 2015 13:33:43

Generated On: 20 Jul 2016 22:28:45

Transmission Type Cumulative ☐

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6) 

Visit Name _____

Visit Type Scheduled ☐

Accession ID W715953

Actual Collection Date 2014 04 04

Actual Collection Time 06:30

Specimen Condition _____

Battery ID RC9255

Battery Name CHEMISTRY PANEL

Lab Test ID RCT1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (4)

Data signed: (hfarmer1) 30 Mar 2015 13:33:43

Generated On: 20 Jul 2016 22:28:45

Lab Test Name	TOTAL BILIRUBIN
Test ID	
Test Status	Done <input checked="" type="checkbox"/>
Reported Text Result	0.4
Reported Numeric Result	0.4
Reference Range low	0.2
Reference Range high	1.2
Range Units	MG/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (4)

Data signed: (hfarmer1) 30 Mar 2015 13:33:43

Generated On: 20 Jul 2016 22:28:45

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (5)

Data signed: (hfarmer1) 30 Mar 2015 13:33:43

Generated On: 20 Jul 2016 22:28:45

Transmission Type Cumulative ☐

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6) 

Visit Name _____

Visit Type Scheduled ☐

Accession ID W715953

Actual Collection Date 2014 04 04

Actual Collection Time 06:30

Specimen Condition _____

Battery ID RC9255

Battery Name CHEMISTRY PANEL

Lab Test ID RCT12

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (5)

Data signed: (hfarmer1) 30 Mar 2015 13:33:43

Generated On: 20 Jul 2016 22:28:45

Lab Test Name	TOTAL PROTEIN
Test ID	
Test Status	Done <input type="checkbox"/>
Reported Text Result	7.4
Reported Numeric Result	7.4
Reference Range low	6.1
Reference Range high	8.4
Range Units	G/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (5)

Data signed: (hfarmer1) 30 Mar 2015 13:33:43

Generated On: 20 Jul 2016 22:28:45

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (6)

Data signed: (hfarmer1) 30 Mar 2015 13:33:43

Generated On: 20 Jul 2016 22:28:45

Transmission Type Cumulative ☐

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6)

Visit Name _____

Visit Type Scheduled ☐

Accession ID W715953

Actual Collection Date 2014 04 04

Actual Collection Time 06:30

Specimen Condition _____

Battery ID RC9255

Battery Name CHEMISTRY PANEL

Lab Test ID RCT13

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (6)

Data signed: (hfarmer1) 30 Mar 2015 13:33:43

Generated On: 20 Jul 2016 22:28:45

Lab Test Name	ALBUMIN
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	4.2
Reported Numeric Result	4.2
Reference Range low	3.3
Reference Range high	4.9
Range Units	G/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (6)

Data signed: (hfarmer1) 30 Mar 2015 13:33:43

Generated On: 20 Jul 2016 22:28:45

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (7)

Data signed: (hfarmer1) 30 Mar 2015 13:33:43

Generated On: 20 Jul 2016 22:28:45

Transmission Type Cumulative ☐

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6)

Visit Name _____

Visit Type Scheduled ☐

Accession ID W715953

Actual Collection Date 2014 04 04

Actual Collection Time 06:30

Specimen Condition _____

Battery ID RC9255

Battery Name CHEMISTRY PANEL

Lab Test ID RCT1407

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (7)

Data signed: (hfarmer1) 30 Mar 2015 13:33:43

Generated On: 20 Jul 2016 22:28:45

Lab Test Name	ALKALINE PHOSPHATASE
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	60
Reported Numeric Result	60
Reference Range low	31
Reference Range high	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: 1252**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (7)

Data signed: (hfarmer1) 30 Mar 2015 13:33:43

Generated On: 20 Jul 2016 22:28:45

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (8)

Data signed: (hfarmer1) 30 Mar 2015 13:33:43

Generated On: 20 Jul 2016 22:28:45

Transmission Type Cumulative ☒

Subject ID or Number

Subject Sex M

Subject Date of Birth (b) (6) 

Visit Name

Visit Type Scheduled ☒

Accession ID W715953

Actual Collection Date 2014 04 04

Actual Collection Time 06:30

Specimen Condition

Battery ID RC9255

Battery Name CHEMISTRY PANEL

Lab Test ID RCT1408

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (8)

Data signed: (hfarmer1) 30 Mar 2015 13:33:43

Generated On: 20 Jul 2016 22:28:45

Lab Test Name	LDH
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	141
Reported Numeric Result	141
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: 1252**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (8)

Data signed: (hfarmer1) 30 Mar 2015 13:33:43

Generated On: 20 Jul 2016 22:28:45

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (9)

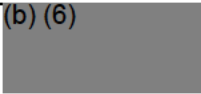
Data signed: (hfarmer1) 30 Mar 2015 13:33:43

Generated On: 20 Jul 2016 22:28:45

Transmission Type Cumulative ☐

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6) 

Visit Name _____

Visit Type Scheduled ☐

Accession ID W715953

Actual Collection Date 2014 04 04

Actual Collection Time 06:30

Specimen Condition _____

Battery ID RC9255

Battery Name CHEMISTRY PANEL

Lab Test ID RCT15

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (9)

Data signed: (hfarmer1) 30 Mar 2015 13:33:43

Generated On: 20 Jul 2016 22:28:45

Lab Test Name	SERUM SODIUM
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	137
Reported Numeric Result	137
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: 1252**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (9)

Data signed: (hfarmer1) 30 Mar 2015 13:33:43

Generated On: 20 Jul 2016 22:28:45

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (10)

Data signed: (hfarmer1) 30 Mar 2015 13:33:43

Generated On: 20 Jul 2016 22:28:45

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6) 

Visit Name _____

Visit Type Scheduled ☒

Accession ID W715953

Actual Collection Date 2014 04 04

Actual Collection Time 06:30

Specimen Condition _____

Battery ID RC9255

Battery Name CHEMISTRY PANEL

Lab Test ID RCT16

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (10)

Data signed: (hfarmer1) 30 Mar 2015 13:33:43

Generated On: 20 Jul 2016 22:28:45

Lab Test Name	SERUM POTASSIUM
Test ID	
Test Status	Done <input checked="" type="checkbox"/>
Reported Text Result	4.4
Reported Numeric Result	4.4
Reference Range low	3.4
Reference Range high	5.4
Range Units	MEQ/L
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (10)

Data signed: (hfarmer1) 30 Mar 2015 13:33:43

Generated On: 20 Jul 2016 22:28:45

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (11)

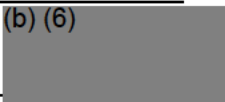
Data signed: (hfarmer1) 30 Mar 2015 13:33:43

Generated On: 20 Jul 2016 22:28:45

Transmission Type Cumulative ☐

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6) 

Visit Name _____

Visit Type Scheduled ☐

Accession ID W715953

Actual Collection Date 2014 04 04

Actual Collection Time 06:30

Specimen Condition _____

Battery ID RC9255

Battery Name CHEMISTRY PANEL

Lab Test ID RCT29

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (11)

Data signed: (hfarmer1) 30 Mar 2015 13:33:43

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (11)

Data signed: (hfarmer1) 30 Mar 2015 13:33:43

Generated On: 20 Jul 2016 22:28:45

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (12)

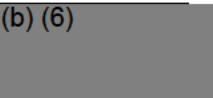
Data signed: (hfarmer1) 30 Mar 2015 13:33:43

Generated On: 20 Jul 2016 22:28:45

Transmission Type Cumulative ☐

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6) 

Visit Name _____

Visit Type Scheduled ☐

Accession ID W715953

Actual Collection Date 2014 04 04

Actual Collection Time 06:30

Specimen Condition _____

Battery ID RC9255

Battery Name CHEMISTRY PANEL

Lab Test ID RCT3

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (12)

Data signed: (hfarmer1) 30 Mar 2015 13:33:43

Generated On: 20 Jul 2016 22:28:45

Lab Test Name	GGT
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	36
Reported Numeric Result	36
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: 1252**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (12)

Data signed: (hfarmer1) 30 Mar 2015 13:33:43

Generated On: 20 Jul 2016 22:28:45

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (13)

Data signed: (hfarmer1) 30 Mar 2015 13:33:43

Generated On: 20 Jul 2016 22:28:45

Transmission Type Cumulative ☐

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6) 

Visit Name _____

Visit Type Scheduled ☐

Accession ID W715953

Actual Collection Date 2014 04 04

Actual Collection Time 06:30

Specimen Condition _____

Battery ID RC9255

Battery Name CHEMISTRY PANEL

Lab Test ID RCT392

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (13)

Data signed: (hfarmer1) 30 Mar 2015 13:33:43

Generated On: 20 Jul 2016 22:28:45

Lab Test Name	CREATININE (RATE BLANKED)
Test ID	
Test Status	Done <input type="checkbox"/>
Reported Text Result	0.9
Reported Numeric Result	0.9
Reference Range low	0.5
Reference Range high	1.2
Range Units	MG/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (13)

Data signed: (hfarmer1) 30 Mar 2015 13:33:43

Generated On: 20 Jul 2016 22:28:45

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (14)

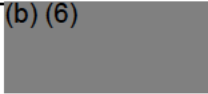
Data signed: (hfarmer1) 30 Mar 2015 13:33:43

Generated On: 20 Jul 2016 22:28:45

Transmission Type Cumulative ☐

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6) 

Visit Name _____

Visit Type Scheduled ☐

Accession ID W715953

Actual Collection Date 2014 04 04

Actual Collection Time 06:30

Specimen Condition _____

Battery ID RC9255

Battery Name CHEMISTRY PANEL

Lab Test ID RCT4

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (14)

Data signed: (hfarmer1) 30 Mar 2015 13:33:43

Generated On: 20 Jul 2016 22:28:45

Lab Test Name	ALT (SGPT)
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	27
Reported Numeric Result	27
Reference Range low	6
Reference Range high	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: 1252**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (14)

Data signed: (hfarmer1) 30 Mar 2015 13:33:43

Generated On: 20 Jul 2016 22:28:45

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (15)


Data signed: (hfarmer1) 30 Mar 2015 13:33:43

Generated On: 20 Jul 2016 22:28:45

Transmission Type Cumulative ☐

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6) 

Visit Name _____

Visit Type Scheduled ☐

Accession ID W715953

Actual Collection Date 2014 04 04

Actual Collection Time 06:30

Specimen Condition _____

Battery ID RC9255

Battery Name CHEMISTRY PANEL

Lab Test ID RCT5

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (15)

Data signed: (hfarmer1) 30 Mar 2015 13:33:43

Generated On: 20 Jul 2016 22:28:45

Lab Test Name	AST (SGOT)
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	20
Reported Numeric Result	20
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: 1252**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (15)

Data signed: (hfarmer1) 30 Mar 2015 13:33:43

Generated On: 20 Jul 2016 22:28:45

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (16)

Data signed: (hfarmer1) 30 Mar 2015 13:33:43

Generated On: 20 Jul 2016 22:28:45

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6) 

Visit Name _____

Visit Type Scheduled ☒

Accession ID W715953

Actual Collection Date 2014 04 04

Actual Collection Time 06:30

Specimen Condition _____

Battery ID RC9255

Battery Name CHEMISTRY PANEL

Lab Test ID RCT6

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (16)

Data signed: (hfarmer1) 30 Mar 2015 13:33:43

Generated On: 20 Jul 2016 22:28:45

Lab Test Name	UREA NITROGEN
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	17
Reported Numeric Result	17
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: 1252**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (16)

Data signed: (hfarmer1) 30 Mar 2015 13:33:43

Generated On: 20 Jul 2016 22:28:45

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (17)

Data signed: (hfarmer1) 30 Mar 2015 13:33:43

Generated On: 20 Jul 2016 22:28:45

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6) 

Visit Name _____

Visit Type Scheduled ☒

Accession ID W715953

Actual Collection Date 2014 04 04

Actual Collection Time 06:30

Specimen Condition _____

Battery ID HM1604

Battery Name HEMATOLOGY
&DIFFERENTIAL PANEL

Lab Test ID HMT10

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (17)

Data signed: (hfarmer1) 30 Mar 2015 13:33:43

Generated On: 20 Jul 2016 22:28:45

Lab Test Name	MONOCYTES
Test ID	
Test Status	Done <input checked="" type="checkbox"/>
Reported Text Result	0.54
Reported Numeric Result	0.54
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: 1252**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (17)

Data signed: (hfarmer1) 30 Mar 2015 13:33:43

Generated On: 20 Jul 2016 22:28:45

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (18)

Data signed: (hfarmer1) 30 Mar 2015 13:33:43

Generated On: 20 Jul 2016 22:28:45

Transmission Type Cumulative ☐

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6) 

Visit Name _____

Visit Type Scheduled ☐

Accession ID W715953

Actual Collection Date 2014 04 04

Actual Collection Time 06:30

Specimen Condition _____

Battery ID HM1604

Battery Name HEMATOLOGY
&DIFFERENTIAL PANEL

Lab Test ID HMT100

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (18)

Data signed: (hfarmer1) 30 Mar 2015 13:33:43

Generated On: 20 Jul 2016 22:28:45

Lab Test Name	MCH
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	34
Reported Numeric Result	34
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: 1252**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (18)

Data signed: (hfarmer1) 30 Mar 2015 13:33:43

Generated On: 20 Jul 2016 22:28:45

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (19)

Data signed: (hfarmer1) 30 Mar 2015 13:33:43

Generated On: 20 Jul 2016 22:28:45

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6)

Visit Name _____

Visit Type Scheduled ☒

Accession ID W715953

Actual Collection Date 2014 04 04

Actual Collection Time 06:30

Specimen Condition _____

Battery ID HM1604

Battery Name HEMATOLOGY
&DIFFERENTIAL PANEL

Lab Test ID HMT102

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (19)

Data signed: (hfarmer1) 30 Mar 2015 13:33:43

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (19)

Data signed: (hfarmer1) 30 Mar 2015 13:33:43

Generated On: 20 Jul 2016 22:28:45

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (20)

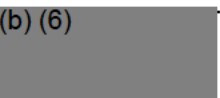
Data signed: (hfarmer1) 30 Mar 2015 13:33:43

Generated On: 20 Jul 2016 22:28:45

Transmission Type Cumulative ☐

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6) 

Visit Name _____

Visit Type Scheduled ☐

Accession ID W715953

Actual Collection Date 2014 04 04

Actual Collection Time 06:30

Specimen Condition _____

Battery ID HM1604

Battery Name HEMATOLOGY
&DIFFERENTIAL PANEL

Lab Test ID HMT11

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (20)

Data signed: (hfarmer1) 30 Mar 2015 13:33:43

Generated On: 20 Jul 2016 22:28:45

Lab Test Name	EOSINOPHILS
Test ID	
Test Status	Done <input checked="" type="checkbox"/>
Reported Text Result	0.27
Reported Numeric Result	0.27
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: 1252**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (20)

Data signed: (hfarmer1) 30 Mar 2015 13:33:43

Generated On: 20 Jul 2016 22:28:45

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (21)

Data signed: (hfarmer1) 30 Mar 2015 13:33:43

Generated On: 20 Jul 2016 22:28:45

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) <div></div>
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	W715953
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Actual Collection Date	2014 04 04
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Actual Collection Time	06:30
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Specimen Condition	<hr/>
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Battery ID	HM1604
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Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
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Lab Test ID	HMT12
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (21)

Data signed: (hfarmer1) 30 Mar 2015 13:33:43

Generated On: 20 Jul 2016 22:28:45

Lab Test Name	BASOPHILS
Test ID	
Test Status	Done <input checked="" type="checkbox"/>
Reported Text Result	0.06
Reported Numeric Result	0.06
Reference Range low	0.00
Reference Range high	0.20
Range Units	X10^3/UL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (21)

Data signed: (hfarmer1) 30 Mar 2015 13:33:43

Generated On: 20 Jul 2016 22:28:45

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (22)

Data signed: (hfarmer1) 30 Mar 2015 13:33:43

Generated On: 20 Jul 2016 22:28:45

Transmission Type Cumulative ☐

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6)

Visit Name _____

Visit Type Scheduled ☐

Accession ID W715953

Actual Collection Date 2014 04 04

Actual Collection Time 06:30

Specimen Condition _____

Battery ID HM1604

Battery Name HEMATOLOGY
&DIFFERENTIAL PANEL

Lab Test ID HMT13

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (22)

Data signed: (hfarmer1) 30 Mar 2015 13:33:43

Generated On: 20 Jul 2016 22:28:45

Lab Test Name	PLATELETS
Test ID	
Test Status	Done <input type="checkbox"/>
Reported Text Result	320
Reported Numeric Result	320
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: 1252**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (22)

Data signed: (hfarmer1) 30 Mar 2015 13:33:43

Generated On: 20 Jul 2016 22:28:45

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (23)

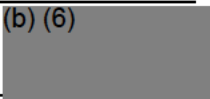
Data signed: (hfarmer1) 30 Mar 2015 13:33:43

Generated On: 20 Jul 2016 22:28:45

Transmission Type Cumulative ☐

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6) 

Visit Name _____

Visit Type Scheduled ☐

Accession ID W715953

Actual Collection Date 2014 04 04

Actual Collection Time 06:30

Specimen Condition _____

Battery ID HM1604

Battery Name HEMATOLOGY
&DIFFERENTIAL PANEL

Lab Test ID HMT15

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (23)

Data signed: (hfarmer1) 30 Mar 2015 13:33:43

Generated On: 20 Jul 2016 22:28:45

Lab Test Name	NEUTROPHILS (%)
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	65.6
Reported Numeric Result	65.6
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: 1252**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (23)

Data signed: (hfarmer1) 30 Mar 2015 13:33:43

Generated On: 20 Jul 2016 22:28:45

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (24)

Data signed: (hfarmer1) 30 Mar 2015 13:33:43

Generated On: 20 Jul 2016 22:28:45

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	W715953
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Actual Collection Date	2014 04 04
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Actual Collection Time	06:30
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Specimen Condition	<hr/>
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Battery ID	HM1604
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Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
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Lab Test ID	HMT16
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (24)

Data signed: (hfarmer1) 30 Mar 2015 13:33:43

Generated On: 20 Jul 2016 22:28:45

Lab Test Name	LYMPHOCYTES (%)
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	22.0
Reported Numeric Result	22.0
Reference Range low	15.4
Reference Range high	48.5
Range Units	%
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (24)

Data signed: (hfarmer1) 30 Mar 2015 13:33:43

Generated On: 20 Jul 2016 22:28:45

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (25)

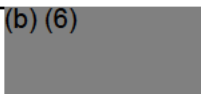
Data signed: (hfarmer1) 30 Mar 2015 13:33:43

Generated On: 20 Jul 2016 22:28:45

Transmission Type Cumulative ☐

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6) 

Visit Name _____

Visit Type Scheduled ☐

Accession ID W715953

Actual Collection Date 2014 04 04

Actual Collection Time 06:30

Specimen Condition _____

Battery ID HM1604

Battery Name HEMATOLOGY
&DIFFERENTIAL PANEL

Lab Test ID HMT17

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (25)

Data signed: (hfarmer1) 30 Mar 2015 13:33:43

Generated On: 20 Jul 2016 22:28:45

Lab Test Name	MONOCYTES (%)
Test ID	
Test Status	Done <input checked="" type="checkbox"/>
Reported Text Result	7.7
Reported Numeric Result	7.7
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: 1252**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (25)

Data signed: (hfarmer1) 30 Mar 2015 13:33:43

Generated On: 20 Jul 2016 22:28:45

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (26)


Data signed: (hfarmer1) 30 Mar 2015 13:33:43

Generated On: 20 Jul 2016 22:28:45

Transmission Type Cumulative ☐

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6) 

Visit Name _____

Visit Type Scheduled ☐

Accession ID W715953

Actual Collection Date 2014 04 04

Actual Collection Time 06:30

Specimen Condition _____

Battery ID HM1604

Battery Name HEMATOLOGY
&DIFFERENTIAL PANEL

Lab Test ID HMT18

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (26)

Data signed: (hfarmer1) 30 Mar 2015 13:33:43

Generated On: 20 Jul 2016 22:28:45

Lab Test Name	EOSINOPHILS (%)
Test ID	
Test Status	Done <input checked="" type="checkbox"/>
Reported Text Result	3.8
Reported Numeric Result	3.8
Reference Range low	0.0
Reference Range high	6.8
Range Units	%
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (26)

Data signed: (hfarmer1) 30 Mar 2015 13:33:43

Generated On: 20 Jul 2016 22:28:45

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (27)

Data signed: (hfarmer1) 30 Mar 2015 13:33:43

Generated On: 20 Jul 2016 22:28:45

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6)

Visit Name _____

Visit Type Scheduled ☒

Accession ID W715953

Actual Collection Date 2014 04 04

Actual Collection Time 06:30

Specimen Condition _____

Battery ID HM1604

Battery Name HEMATOLOGY
&DIFFERENTIAL PANEL

Lab Test ID HMT19

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (27)

Data signed: (hfarmer1) 30 Mar 2015 13:33:43

Generated On: 20 Jul 2016 22:28:45

Lab Test Name	BASOPHILS (%)
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	0.8
Reported Numeric Result	0.8
Reference Range low	0.0
Reference Range high	2.0
Range Units	%
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (27)

Data signed: (hfarmer1) 30 Mar 2015 13:33:43

Generated On: 20 Jul 2016 22:28:45

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (28)

Data signed: (hfarmer1) 30 Mar 2015 13:33:43

Generated On: 20 Jul 2016 22:28:45

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6) 

Visit Name _____

Visit Type Scheduled ☒

Accession ID W715953

Actual Collection Date 2014 04 04

Actual Collection Time 06:30

Specimen Condition _____

Battery ID HM1604

Battery Name HEMATOLOGY
&DIFFERENTIAL PANEL

Lab Test ID HMT2

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (28)

Data signed: (hfarmer1) 30 Mar 2015 13:33:43

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (28)

Data signed: (hfarmer1) 30 Mar 2015 13:33:43

Generated On: 20 Jul 2016 22:28:45

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (29)


Data signed: (hfarmer1) 30 Mar 2015 13:33:43

Generated On: 20 Jul 2016 22:28:45

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6) 

Visit Name _____

Visit Type Scheduled ☒

Accession ID W715953

Actual Collection Date 2014 04 04

Actual Collection Time 06:30

Specimen Condition _____

Battery ID HM1604

Battery Name HEMATOLOGY
&DIFFERENTIAL PANEL

Lab Test ID HMT3

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (29)

Data signed: (hfarmer1) 30 Mar 2015 13:33:43

Generated On: 20 Jul 2016 22:28:45

Lab Test Name	RBC
Test ID	
Test Status	Done <input checked="" type="checkbox"/>
Reported Text Result	4.6
Reported Numeric Result	4.6
Reference Range low	4.5
Reference Range high	6.4
Range Units	X10^6/UL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (29)

Data signed: (hfarmer1) 30 Mar 2015 13:33:43

Generated On: 20 Jul 2016 22:28:45

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (30)


Data signed: (hfarmer1) 30 Mar 2015 13:33:43

Generated On: 20 Jul 2016 22:28:45

Transmission Type Cumulative ☐

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6) 

Visit Name _____

Visit Type Scheduled ☐

Accession ID W715953

Actual Collection Date 2014 04 04

Actual Collection Time 06:30

Specimen Condition _____

Battery ID HM1604

Battery Name HEMATOLOGY
&DIFFERENTIAL PANEL

Lab Test ID HMT4

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (30)

Data signed: (hfarmer1) 30 Mar 2015 13:33:43

Generated On: 20 Jul 2016 22:28:45

Lab Test Name	MCV
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	101
Reported Numeric Result	101
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: 1252**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (30)

Data signed: (hfarmer1) 30 Mar 2015 13:33:43

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (31)

Data signed: (hfarmer1) 30 Mar 2015 13:33:43

Generated On: 20 Jul 2016 22:28:45

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	W715953
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Actual Collection Date	2014 04 04
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Actual Collection Time	06:30
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Specimen Condition	<hr/>
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Battery ID	HM1604
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Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
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Lab Test ID	HMT40
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (31)

Data signed: (hfarmer1) 30 Mar 2015 13:33:43

Generated On: 20 Jul 2016 22:28:45

Lab Test Name	HEMOGLOBIN
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	15.6
Reported Numeric Result	15.6
Reference Range low	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: 1252**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (31)

Data signed: (hfarmer1) 30 Mar 2015 13:33:43

Generated On: 20 Jul 2016 22:28:45

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (32)

Data signed: (hfarmer1) 30 Mar 2015 13:33:43

Generated On: 20 Jul 2016 22:28:45

Transmission Type Cumulative ☐

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6)

Visit Name _____

Visit Type Scheduled ☐

Accession ID W715953

Actual Collection Date 2014 04 04

Actual Collection Time 06:30

Specimen Condition _____

Battery ID HM1604

Battery Name HEMATOLOGY
&DIFFERENTIAL PANEL

Lab Test ID HMT7

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (32)

Data signed: (hfarmer1) 30 Mar 2015 13:33:43

Generated On: 20 Jul 2016 22:28:45

Lab Test Name	WBC
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	7.04
Reported Numeric Result	7.04
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: 1252**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (32)

Data signed: (hfarmer1) 30 Mar 2015 13:33:43

Generated On: 20 Jul 2016 22:28:45

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (33)

Data signed: (hfarmer1) 30 Mar 2015 13:33:43

Generated On: 20 Jul 2016 22:28:45

Transmission Type Cumulative ☐

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6)

Visit Name _____

Visit Type Scheduled ☐

Accession ID W715953

Actual Collection Date 2014 04 04

Actual Collection Time 06:30

Specimen Condition _____

Battery ID HM1604

Battery Name HEMATOLOGY
&DIFFERENTIAL PANEL

Lab Test ID HMT71

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (33)

Data signed: (hfarmer1) 30 Mar 2015 13:33:43


Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (33)

Data signed: (hfarmer1) 30 Mar 2015 13:33:43

Generated On: 20 Jul 2016 22:28:45

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (34)

Data signed: (hfarmer1) 30 Mar 2015 13:33:43

Generated On: 20 Jul 2016 22:28:45

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6) 

Visit Name _____

Visit Type Scheduled ☒

Accession ID W715953

Actual Collection Date 2014 04 04

Actual Collection Time 06:30

Specimen Condition _____

Battery ID HM1604

Battery Name HEMATOLOGY
&DIFFERENTIAL PANEL

Lab Test ID HMT8

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (34)

Data signed: (hfarmer1) 30 Mar 2015 13:33:43

Generated On: 20 Jul 2016 22:28:45

Lab Test Name	NEUTROPHILS
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	4.62
Reported Numeric Result	4.62
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: 1252**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (34)

Data signed: (hfarmer1) 30 Mar 2015 13:33:43

Generated On: 20 Jul 2016 22:28:45

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (35)

Data signed: (hfarmer1) 30 Mar 2015 13:33:43

Generated On: 20 Jul 2016 22:28:45

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6) 

Visit Name _____

Visit Type Scheduled ☒

Accession ID W715953

Actual Collection Date 2014 04 04

Actual Collection Time 06:30

Specimen Condition _____

Battery ID HM1604

Battery Name HEMATOLOGY
&DIFFERENTIAL PANEL

Lab Test ID HMT9

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (35)

Data signed: (hfarmer1) 30 Mar 2015 13:33:43

Generated On: 20 Jul 2016 22:28:45

Lab Test Name	LYMPHOCYTES
Test ID	
Test Status	Done <input checked="" type="checkbox"/>
Reported Text Result	1.55
Reported Numeric Result	1.55
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: 1252**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (35)

Data signed: (hfarmer1) 30 Mar 2015 13:33:43

Generated On: 20 Jul 2016 22:28:45

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (36)

Data signed: (hfarmer1) 30 Mar 2015 13:33:43

Generated On: 20 Jul 2016 22:28:45

Transmission Type Cumulative ☐

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6)

Visit Name _____

Visit Type Scheduled ☐

Accession ID W715953

Actual Collection Date 2014 04 04

Actual Collection Time 06:30

Specimen Condition _____

Battery ID UA1538

Battery Name URINE MACRO PANEL

Lab Test ID UAT10

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (36)

Data signed: (hfarmer1) 30 Mar 2015 13:33:43


Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (36)

Data signed: (hfarmer1) 30 Mar 2015 13:33:43

Generated On: 20 Jul 2016 22:28:45

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (37)

Data signed: (hfarmer1) 30 Mar 2015 13:33:43

Generated On: 20 Jul 2016 22:28:45

Transmission Type Cumulative ☐

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6) 

Visit Name _____

Visit Type Scheduled ☐

Accession ID W715953

Actual Collection Date 2014 04 04

Actual Collection Time 06:30

Specimen Condition _____

Battery ID UA1538

Battery Name URINE MACRO PANEL

Lab Test ID UAT2

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (37)

Data signed: (hfarmer1) 30 Mar 2015 13:33:43

Generated On: 20 Jul 2016 22:28:45

Lab Test Name	UR SPECIFIC GRAVITY
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	1.015
Reported Numeric Result	1.015
Reference Range low	1.003
Reference Range high	1.035
Range Units	
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (37)

Data signed: (hfarmer1) 30 Mar 2015 13:33:43

Generated On: 20 Jul 2016 22:28:45

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (38)


Data signed: (hfarmer1) 30 Mar 2015 13:33:43

Generated On: 20 Jul 2016 22:28:45

Transmission Type Cumulative ☐

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6) 

Visit Name _____

Visit Type Scheduled ☐

Accession ID W715953

Actual Collection Date 2014 04 04

Actual Collection Time 06:30

Specimen Condition _____

Battery ID UA1538

Battery Name URINE MACRO PANEL

Lab Test ID UAT3

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (38)

Data signed: (hfarmer1) 30 Mar 2015 13:33:43

Generated On: 20 Jul 2016 22:28:45

Lab Test Name	UR PH
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	5.5
Reported Numeric Result	5.5
Reference Range low	5.0
Reference Range high	8.0
Range Units	
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (38)

Data signed: (hfarmer1) 30 Mar 2015 13:33:43

Generated On: 20 Jul 2016 22:28:45

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (39)


Data signed: (hfarmer1) 30 Mar 2015 13:33:43

Generated On: 20 Jul 2016 22:28:45

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6) 

Visit Name _____

Visit Type Scheduled ☒

Accession ID W715953

Actual Collection Date 2014 04 04

Actual Collection Time 06:30

Specimen Condition _____

Battery ID UA1538

Battery Name URINE MACRO PANEL

Lab Test ID UAT43

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (39)

Data signed: (hfarmer1) 30 Mar 2015 13:33:43


Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (39)

Data signed: (hfarmer1) 30 Mar 2015 13:33:43

Generated On: 20 Jul 2016 22:28:45

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (40)

Data signed: (hfarmer1) 30 Mar 2015 13:33:43

Generated On: 20 Jul 2016 22:28:45

Transmission Type Cumulative ☐

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6) _____

Visit Name _____

Visit Type Scheduled ☐

Accession ID W715953

Actual Collection Date 2014 04 04

Actual Collection Time 06:30

Specimen Condition _____

Battery ID UA1538

Battery Name URINE MACRO PANEL

Lab Test ID UAT49

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (40)

Data signed: (hfarmer1) 30 Mar 2015 13:33:43


Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (40)

Data signed: (hfarmer1) 30 Mar 2015 13:33:43

Generated On: 20 Jul 2016 22:28:45

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (41)

Data signed: (hfarmer1) 30 Mar 2015 13:33:43

Generated On: 20 Jul 2016 22:28:45

Transmission Type Cumulative ☐

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6) 

Visit Name _____

Visit Type Scheduled ☐

Accession ID W715953

Actual Collection Date 2014 04 04

Actual Collection Time 06:30

Specimen Condition _____

Battery ID UA1538

Battery Name URINE MACRO PANEL

Lab Test ID UAT5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (41)

Data signed: (hfarmer1) 30 Mar 2015 13:33:43


Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (41)

Data signed: (hfarmer1) 30 Mar 2015 13:33:43

Generated On: 20 Jul 2016 22:28:45

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (42)


Data signed: (hfarmer1) 30 Mar 2015 13:33:43

Generated On: 20 Jul 2016 22:28:45

Transmission Type Cumulative ☐

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6) 

Visit Name _____

Visit Type Scheduled ☐

Accession ID W715953

Actual Collection Date 2014 04 04

Actual Collection Time 06:30

Specimen Condition _____

Battery ID UA1538

Battery Name URINE MACRO PANEL

Lab Test ID UAT7

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (42)

Data signed: (hfarmer1) 30 Mar 2015 13:33:43


Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (42)

Data signed: (hfarmer1) 30 Mar 2015 13:33:43

Generated On: 20 Jul 2016 22:28:45

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day 0)

Form: Oxysterol results (1)

Generated On: 20 Jul 2016 22:28:45

Sample Accession number	3271595339
-------------------------	------------

Analyte	22(R)-HYDROXYCHOLESTERO L
---------	------------------------------

Analyte code	22RHCR L
--------------	----------

Result	
--------	--

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

Comment	NOT ANALYSED, INCOMPLETE SAMPLE SET
---------	--

Lower limit of quantification	9.46
-------------------------------	------

Date of Collection DD MMM YYYY	
-----------------------------------	--

Collection time hh:mm 24 hour clock	
--	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day 0)

Form: Oxysterol results (2)

Generated On: 20 Jul 2016 22:28:45

Sample Accession number	3271595339
-------------------------	------------

Analyte	24(R)-HYDROXYCHOLESTERO L
---------	------------------------------

Analyte code	24RHCRL
--------------	---------

Result	
--------	--

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

Comment	NOT ANALYSED, INCOMPLETE SAMPLE SET
---------	--

Lower limit of quantification	6.56
-------------------------------	------

Date of Collection DD MMM YYYY	
-----------------------------------	--

Collection time hh:mm 24 hour clock	
--	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day 0)

Form: Oxysterol results (3)

Generated On: 20 Jul 2016 22:28:45

Sample Accession number	3271595339
-------------------------	------------

Analyte	25-HYDROXYCHOLESTEROL
---------	-----------------------

Analyte code	25HCRL
--------------	--------

Result	
--------	--

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

Comment	NOT ANALYSED, INCOMPLETE SAMPLE SET
---------	--

Lower limit of quantification	4.70
-------------------------------	------

Date of Collection DD MMM YYYY	
-----------------------------------	--

Collection time hh:mm 24 hour clock	
--	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day 0)

Form: Oxysterol results (4)

Generated On: 20 Jul 2016 22:28:45

Sample Accession number	3271595339
-------------------------	------------

Analyte	27-HYDROXYCHOLESTEROL
---------	-----------------------

Analyte code	27HCRL
--------------	--------

Result	
--------	--

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

Comment	NOT ANALYSED, INCOMPLETE SAMPLE SET
---------	--

Lower limit of quantification	11.60
-------------------------------	-------

Date of Collection DD MMM YYYY	
-----------------------------------	--

Collection time hh:mm 24 hour clock	
--	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day 0)

Form: Oxysterol results (5)

Generated On: 20 Jul 2016 22:28:45

Sample Accession number	3271595339
-------------------------	------------

Analyte	4B-HYDROXYCHOLESTEROL
---------	-----------------------

Analyte code	4BHCRL
--------------	--------

Result	
--------	--

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

Comment	NOT ANALYSED, INCOMPLETE SAMPLE SET
---------	--

Lower limit of quantification	10.66
-------------------------------	-------

Date of Collection DD MMM YYYY	
-----------------------------------	--

Collection time hh:mm 24 hour clock	
--	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day 0)

Form: Oxysterol results (6)

Generated On: 20 Jul 2016 22:28:45

Sample Accession number	3271595339
-------------------------	------------

Analyte	5A,6A-EPOXYCHOLESTANOL
---------	------------------------

Analyte code	5A6AECNL
--------------	----------

Result	
--------	--

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

Comment	NOT ANALYSED, INCOMPLETE SAMPLE SET
---------	--

Lower limit of quantification	12.46
-------------------------------	-------

Date of Collection DD MMM YYYY	
-----------------------------------	--

Collection time hh:mm 24 hour clock	
--	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day 0)

Form: Oxysterol results (7)

Generated On: 20 Jul 2016 22:28:45

Sample Accession number	3271595339
-------------------------	------------

Analyte	5B,6B-EPOXYCHOLESTANOL
---------	------------------------

Analyte code	5B6BECNL
--------------	----------

Result	
--------	--

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

Comment	NOT ANALYSED, INCOMPLETE SAMPLE SET
---------	--

Lower limit of quantification	26.83
-------------------------------	-------

Date of Collection DD MMM YYYY	
-----------------------------------	--

Collection time hh:mm 24 hour clock	
--	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day 0)

Form: Oxysterol results (8)

Generated On: 20 Jul 2016 22:28:45

Sample Accession number	3271595339
-------------------------	------------

Analyte	6A-HYDROXY-5A-CHOLESTAN OL
---------	-------------------------------

Analyte code	6AH5ACNL
--------------	----------

Result	
--------	--

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

Comment	NOT ANALYSED, INCOMPLETE SAMPLE SET
---------	--

Lower limit of quantification	13.70
-------------------------------	-------

Date of Collection DD MMM YYYY	
-----------------------------------	--

Collection time hh:mm 24 hour clock	
--	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day 0)

Form: Oxysterol results (9)

Generated On: 20 Jul 2016 22:28:45

Sample Accession number	3271595339
-------------------------	------------

Analyte	7-KETOCHOLESTEROL
---------	-------------------

Analyte code	7KCRL
--------------	-------

Result	
--------	--

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

Comment	NOT ANALYSED, INCOMPLETE SAMPLE SET
---------	--

Lower limit of quantification	15.43
-------------------------------	-------

Date of Collection DD MMM YYYY	
-----------------------------------	--

Collection time hh:mm 24 hour clock	
--	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day 0)

Form: Oxysterol results (10)

Generated On: 20 Jul 2016 22:28:45

Sample Accession number	3271595339
-------------------------	------------

Analyte	7A-HYDROXYCHOLESTEROL
---------	-----------------------

Analyte code	7AHCRL
--------------	--------

Result	
--------	--

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

Comment	NOT ANALYSED, INCOMPLETE SAMPLE SET
---------	--

Lower limit of quantification	13.46
-------------------------------	-------

Date of Collection DD MMM YYYY	
-----------------------------------	--

Collection time hh:mm 24 hour clock	
--	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day 0)

Form: Oxysterol results (11)

Generated On: 20 Jul 2016 22:28:45

Sample Accession number	3271595339
-------------------------	------------

Analyte	7B-HYDROXYCHOLESTEROL
---------	-----------------------

Analyte code	7BHCRL
--------------	--------

Result	
--------	--

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

Comment	NOT ANALYSED, INCOMPLETE SAMPLE SET
---------	--

Lower limit of quantification	12.86
-------------------------------	-------

Date of Collection DD MMM YYYY	
-----------------------------------	--

Collection time hh:mm 24 hour clock	
--	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day 0)

Form: Oxysterol results (12)

Generated On: 20 Jul 2016 22:28:45

Sample Accession number	3271595339
-------------------------	------------

Analyte	CHOLESTEROL
---------	-------------

Analyte code	CHOL
--------------	------

Result	
--------	--

Result Unit	MG/ML
-------------	-------

Comment	NOT ANALYSED, INCOMPLETE SAMPLE SET
---------	--

Lower limit of quantification	0.50
-------------------------------	------

Date of Collection DD MMM YYYY	
-----------------------------------	--

Collection time hh:mm 24 hour clock	
--	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day 0)

Form: Lab_BU_COHB (1)

Data signed: (hfarmer1) 30 Mar 2015 13:34:02

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05115150004498
Analyte	CARBOXYHEMOGLOBIN
Sample type	BLOOD
Result	4.50
Result Unit	%
Lab Status	OK
Sample comment	.
Detection method	SPECTROPHOTOMETRIC
Lower limit of quantification	0.500
Planned time point (Hour)	6
Day of Visit	0
Celerion Study Number	AA99128-16
Date of Collection	2014-APR-04
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day 0)

Form: Lab_BU_COHB (1)

Data signed: (hfarmer1) 30 Mar 2015 13:34:02

Generated On: 20 Jul 2016 22:28:45

Start Day (24 hour urine only)

End Day (24 hour Urine Only)

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day 0)

Form: Lab_BU_COHB (2)

Data signed: (hfarmer1) 30 Mar 2015 13:34:02

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05115150004499
Analyte	CARBOXYHEMOGLOBIN
Sample type	BLOOD
Result	8.50
Result Unit	%
Lab Status	OK
Sample comment	.
Detection method	SPECTROPHOTOMETRIC
Lower limit of quantification	0.500
Planned time point (Hour)	20
Day of Visit	0
Celerion Study Number	AA99128-16
Date of Collection	2014-APR-04
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day 0)

Form: Lab_BU_COHB (2)

Data signed: (hfarmer1) 30 Mar 2015 13:34:02

Generated On: 20 Jul 2016 22:28:45

Start Day (24 hour urine only) _____

End Day (24 hour Urine Only) _____

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Baseline (Day 0)

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)

Data signed: (hfarmer1) 30 Mar 2015 13:33:38

Generated On: 20 Jul 2016 22:28:45

Date of Birth

(b) (6)

Date of assessment

2014 APR 04
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?

Not at all ☒

4. Did smoking calm you down?

Moderately ☒

5. Did smoking make you feel more awake?

Moderately ☒

6. Did smoking make you feel less irritable?

Moderately ☒

7. Did smoking help you concentrate?

Not at all ☒

8. Did smoking reduce your hunger for food?

Moderately ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day 0)

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)

Data signed: (hfarmer1) 30 Mar 2015 13:33:38

Generated On: 20 Jul 2016 22:28:45

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: 1252

Folder: Baseline (Day 0)

Form: Human Smoking Topography Questionnaire

Data signed: (hfarmer1) 30 Mar 2015 13:33:37

Generated On: 20 Jul 2016 22:28:45

Type	HUMAN SMOKING TOPOGRAPHY QUESTIONNAIRE
------	--

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

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

Date of assessment	04 APR 2014 DD/MMM/YYYY
--------------------	----------------------------

Time of assessment	20:47 hour:min 24-hour clock
--------------------	---------------------------------

How do you agree with the following sentences/affirmations :

1. The smoking of the conventional cigarettes/products is different with the device.	Disagree <input type="radio"/>
--	--------------------------------

If you agree or strongly agree, please describe :	<hr/>
---	-------

2. You enjoy smoking with the device as much as without it.	Disagree <input type="radio"/>
---	--------------------------------

If you disagree or strongly disagree, please describe :	MAKES SMOKING DIFFICULT
---	-------------------------

3. The taste of the conventional cigarettes/products is different with the device.	Strongly disagree <input type="radio"/>
--	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day 0)

Form: Human Smoking Topography Questionnaire

Data signed: (hfarmer1) 30 Mar 2015 13:33:37

Generated On: 20 Jul 2016 22:28:45

If you agree or strongly agree, please describe : _____

4. The device is easy to use.

Agree ☒

If you disagree or strongly disagree, please describe : _____

5. Your smoking is disturbed by the device.

Disagree ☒

If you agree or strongly agree, please describe : _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day 0)

Form: Questionnaire on smoking urges (QSU)

Data signed: (hfarmer1) 30 Mar 2015 13:33:38

Generated On: 20 Jul 2016 22:28:45

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

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

Date of assessment	2014 APR 04
--------------------	-------------

DD/MMM/YYYY

Time of assessment	20:03
--------------------	-------

hour:min 24-hour clock

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

1. I have a desire for a cigarette right now	Disagree <input type="radio"/>
--	--------------------------------

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

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

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

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

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day 0)

Form: Questionnaire on smoking urges (QSU)

Data signed: (hfarmer1) 30 Mar 2015 13:33:38

Generated On: 20 Jul 2016 22:28:45

7. A cigarette would taste good now Disagree ☐

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

9. Smoking would make me less depressed Strongly disagree ☐

10. I am going to smoke as soon as possible Agree ☐

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (1)

Data signed: (hfarmer1) 30 Mar 2015 13:33:38

Generated On: 20 Jul 2016 22:28:45

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	1252
----------------------	------

Subject Sex	M
-------------	---

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

Visit Name	DAY0
------------	------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	W715953
--------------	---------

Actual Collection Date	2014 04 04
------------------------	------------

Actual Collection Time	06:30
------------------------	-------

Specimen Condition	
--------------------	--

Battery ID	HM1054
------------	--------

Battery Name	HEMOGLOBIN A1C
--------------	----------------

Lab Test ID	HMT370
-------------	--------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (1)

Data signed: (hfarmer1) 30 Mar 2015 13:33:38


Generated On: 20 Jul 2016 22:28:45

Lab Test Name

HEMOGLOBIN
A1C,VARIANT(-70)

Test ID

Test Status

Done 

Reported Text Result

5.7

Reported Numeric Result

5.7

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: 1252**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (1)

Data signed: (hfarmer1) 30 Mar 2015 13:33:38

Generated On: 20 Jul 2016 22:28:45

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: 1252

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (2)

Data signed: (hfarmer1) 30 Mar 2015 13:33:38

Generated On: 20 Jul 2016 22:28:45

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	1252
----------------------	------

Subject Sex	M
-------------	---

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

Visit Name	DAY0
------------	------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	W715953
--------------	---------

Actual Collection Date	2014 04 04
------------------------	------------

Actual Collection Time	06:30
------------------------	-------

Specimen Condition	
--------------------	--

Battery ID	RC6871
------------	--------

Battery Name	HDL
--------------	-----

Lab Test ID	RCT1684
-------------	---------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (2)

Data signed: (hfarmer1) 30 Mar 2015 13:33:38

Generated On: 20 Jul 2016 22:28:45

Lab Test Name

DIRECT HDL-C 3RD
GENERATION

Test ID

Test Status

Done ☒

Reported Text Result

51

Reported Numeric Result

51

Reference Range low

30

Reference Range high

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: 1252**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (2)

Data signed: (hfarmer1) 30 Mar 2015 13:33:38

Generated On: 20 Jul 2016 22:28:45

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: 1252

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (3)

Data signed: (hfarmer1) 30 Mar 2015 13:33:38

Generated On: 20 Jul 2016 22:28:45

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	1252
----------------------	------

Subject Sex	M
-------------	---

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

Visit Name	DAY0
------------	------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	W715953
--------------	---------

Actual Collection Date	2014 04 04
------------------------	------------

Actual Collection Time	06:30
------------------------	-------

Specimen Condition	
--------------------	--

Battery ID	SC3249
------------	--------

Battery Name	HS-CRP
--------------	--------

Lab Test ID	SCT1528
-------------	---------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (3)

Data signed: (hfarmer1) 30 Mar 2015 13:33:38

Generated On: 20 Jul 2016 22:28:45

Lab Test Name	C-REACTIVE PROTEIN (NHS)-QT
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	0.172
Reported Numeric Result	0.172
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: 1252**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (3)

Data signed: (hfarmer1) 30 Mar 2015 13:33:38

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (4)

Data signed: (hfarmer1) 30 Mar 2015 13:33:38

Generated On: 20 Jul 2016 22:28:45

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	1252
----------------------	------

Subject Sex	M
-------------	---

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

Visit Name	DAY0
------------	------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	W715953
--------------	---------

Actual Collection Date	2014 04 04
------------------------	------------

Actual Collection Time	06:30
------------------------	-------

Specimen Condition	
--------------------	--

Battery ID	SC3582
------------	--------

Battery Name	APOLIPOPROTEIN
--------------	----------------

Lab Test ID	SCT3639
-------------	---------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (4)

Data signed: (hfarmer1) 30 Mar 2015 13:33:38

Generated On: 20 Jul 2016 22:28:45

Lab Test Name	APOLIPOPROTEIN A1, RAND
---------------	-------------------------

Test ID	<hr/>
---------	-------

Test Status	Done <input checked="" type="radio"/>
-------------	---------------------------------------

Reported Text Result	161
----------------------	-----

Reported Numeric Result	161
-------------------------	-----

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/>
----------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (4)

Data signed: (hfarmer1) 30 Mar 2015 13:33:38

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (5)

Data signed: (hfarmer1) 30 Mar 2015 13:33:38

Generated On: 20 Jul 2016 22:28:45

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	1252
----------------------	------

Subject Sex	M
-------------	---

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

Visit Name	DAY0
------------	------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	W715953
--------------	---------

Actual Collection Date	2014 04 04
------------------------	------------

Actual Collection Time	06:30
------------------------	-------

Specimen Condition	
--------------------	--

Battery ID	SC3582
------------	--------

Battery Name	APOLIPOPROTEIN
--------------	----------------

Lab Test ID	SCT3643
-------------	---------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (5)

Data signed: (hfarmer1) 30 Mar 2015 13:33:38

Generated On: 20 Jul 2016 22:28:45

Lab Test Name	APOLIPOPROTEIN B, RAND
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	148
Reported Numeric Result	148
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: 1252**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (5)

Data signed: (hfarmer1) 30 Mar 2015 13:33:38

Generated On: 20 Jul 2016 22:28:45

SI Numeric Result


SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

High 

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (6)

Data signed: (hfarmer1) 30 Mar 2015 13:33:38

Generated On: 20 Jul 2016 22:28:45

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	1252
----------------------	------

Subject Sex	M
-------------	---

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

Visit Name	DAY0
------------	------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	W715953
--------------	---------

Actual Collection Date	2014 04 04
------------------------	------------

Actual Collection Time	06:30
------------------------	-------

Specimen Condition	
--------------------	--

Battery ID	CG267
------------	-------

Battery Name	FIBRINOGEN
--------------	------------

Lab Test ID	CGT285
-------------	--------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (6)

Data signed: (hfarmer1) 30 Mar 2015 13:33:38

Generated On: 20 Jul 2016 22:28:45

Lab Test Name	FIBRINOGEN
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	307
Reported Numeric Result	307
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: 1252**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (6)

Data signed: (hfarmer1) 30 Mar 2015 13:33:38

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (7)

Data signed: (hfarmer1) 30 Mar 2015 13:33:38

Generated On: 20 Jul 2016 22:28:45

Transmission Type	Cumulative <input type="radio"/>
-------------------	----------------------------------

Subject ID or Number	1252
----------------------	------

Subject Sex	M
-------------	---

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

Visit Name	DAY0
------------	------

Visit Type	Scheduled <input type="radio"/>
------------	---------------------------------

Accession ID	W715953
--------------	---------

Actual Collection Date	2014 04 04
------------------------	------------

Actual Collection Time	06:30
------------------------	-------

Specimen Condition	
--------------------	--

Battery ID	CN236
------------	-------

Battery Name	HOMOCYSTEINE
--------------	--------------

Lab Test ID	CNT145
-------------	--------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (7)

Data signed: (hfarmer1) 30 Mar 2015 13:33:38

Generated On: 20 Jul 2016 22:28:45

Lab Test Name	HOMOCYSTEINE, EDTAPL
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	10.75
Reported Numeric Result	10.75
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: 1252**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (7)

Data signed: (hfarmer1) 30 Mar 2015 13:33:38

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (8)

Data signed: (hfarmer1) 30 Mar 2015 13:33:38

Generated On: 20 Jul 2016 22:28:45

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	1252
----------------------	------

Subject Sex	M
-------------	---

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

Visit Name	DAY0
------------	------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	W715953
--------------	---------

Actual Collection Date	2014 04 04
------------------------	------------

Actual Collection Time	06:30
------------------------	-------

Specimen Condition	
--------------------	--

Battery ID	IM2293
------------	--------

Battery Name	SICAM-1
--------------	---------

Lab Test ID	IMT1768
-------------	---------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (8)

Data signed: (hfarmer1) 30 Mar 2015 13:33:38

Generated On: 20 Jul 2016 22:28:45

Lab Test Name	SICAM-1-RUO
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	232.5
Reported Numeric Result	232.5
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: 1252**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (8)

Data signed: (hfarmer1) 30 Mar 2015 13:33:38

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (9)

Data signed: (hfarmer1) 30 Mar 2015 13:33:38

Generated On: 20 Jul 2016 22:28:45

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	1252
----------------------	------

Subject Sex	M
-------------	---

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

Visit Name	DAY0
------------	------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	W715953
--------------	---------

Actual Collection Date	2014 04 04
------------------------	------------

Actual Collection Time	06:30
------------------------	-------

Specimen Condition	
--------------------	--

Battery ID	RC9267
------------	--------

Battery Name	LDL
--------------	-----

Lab Test ID	RCT2394
-------------	---------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (9)

Data signed: (hfarmer1) 30 Mar 2015 13:33:38

Generated On: 20 Jul 2016 22:28:45

Lab Test Name	DIRECT LDL-C 2ND GEN (-70)
---------------	----------------------------

Test ID	<hr/>
---------	-------

Test Status	Done <input checked="" type="radio"/>
-------------	---------------------------------------

Reported Text Result	192
----------------------	-----

Reported Numeric Result	192
-------------------------	-----

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: 1252**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (9)

Data signed: (hfarmer1) 30 Mar 2015 13:33:38

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Baseline (Day 0)

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

Data signed: (hfarmer1) 30 Mar 2015 13:34:04

Generated On: 20 Jul 2016 22:28:45

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day 0)

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

Data signed: (hfarmer1) 30 Mar 2015 13:34:04

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112450002853
Analyte	HPMA
Sample type	URINE
Result	607
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	0
Celerion Study Number	AA99128-03
Date of Collection	2014-APR-04
Timepoint-minutes	
Urine Start Day	0

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day 0)

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

Data signed: (hfarmer1) 30 Mar 2015 13:34:04

Generated On: 20 Jul 2016 22:28:45

Urine End Day	1
---------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day 0)

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

Data signed: (hfarmer1) 30 Mar 2015 13:34:04

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112450002853
Analyte	CEMA
Sample type	URINE
Result	128
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	0
Celerion Study Number	AA99128-03
Date of Collection	2014-APR-04
Timepoint-minutes	
Urine Start Day	0

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day 0)

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

Data signed: (hfarmer1) 30 Mar 2015 13:34:04

Generated On: 20 Jul 2016 22:28:45

Urine End Day	1
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day 0)

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

Data signed: (hfarmer1) 30 Mar 2015 13:34:04

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112450002853
Analyte	HBMA
Sample type	URINE
Result	390
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	0
Celerion Study Number	AA99128-03
Date of Collection	2014-APR-04
Timepoint-minutes	
Urine Start Day	0

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day 0)

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

Data signed: (hfarmer1) 30 Mar 2015 13:34:04

Generated On: 20 Jul 2016 22:28:45

Urine End Day

1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (NNN, NNAL)

Data signed: (hfarmer1) 30 Mar 2015 13:34:02

Generated On: 20 Jul 2016 22:28:45

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day 0)

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

Data signed: (hfarmer1) 30 Mar 2015 13:34:02

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112460003424
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Analyte	NNAL
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Sample type	URINE
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Result	.
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Result Unit	PG/ML
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Lab Status	OK
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Sample comment	ANALYSIS NOT PERFORMED IN ERROR
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Detection method	LC-MS/MS
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Planned time point (Hour)	0
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Day of Visit	0
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Celerion Study Number	AA99128-04
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Date of Collection	2014-APR-04
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Timepoint-minutes	
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day 0)

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

Data signed: (hfarmer1) 30 Mar 2015 13:34:02

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Baseline (Day 0)

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

Data signed: (hfarmer1) 30 Mar 2015 13:34:02

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112460003424
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Analyte	NNN
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Sample type	URINE
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Result	.
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Result Unit	PG/ML
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Lab Status	OK
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Sample comment	ANALYSIS NOT PERFORMED IN ERROR
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Detection method	LC-MS/MS
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Planned time point (Hour)	0
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Day of Visit	0
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Celerion Study Number	AA99128-04
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Date of Collection	2014-APR-04
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Timepoint-minutes	
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day 0)

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

Data signed: (hfarmer1) 30 Mar 2015 13:34:02

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (HEMA)

Data signed: (hfarmer1) 30 Mar 2015 13:34:02

Generated On: 20 Jul 2016 22:28:45

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (HEMA) (1)

Data signed: (hfarmer1) 30 Mar 2015 13:34:02

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112470001708
Analyte	HEMA
Sample type	URINE
Result	1.35
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	0
Celerion Study Number	AA99128-05
Date of Collection	2014-APR-04
Timepoint-minutes	
Urine Start Day	0

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (HEMA) (1)

Data signed: (hfarmer1) 30 Mar 2015 13:34:02

Generated On: 20 Jul 2016 22:28:45

Urine End Day	1
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day 0)

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

Data signed: (hfarmer1) 30 Mar 2015 13:34:05

Generated On: 20 Jul 2016 22:28:45

Sample type

URINE

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Baseline (Day 0)

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

Data signed: (hfarmer1) 30 Mar 2015 13:34:05

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112480000773
Analyte	COT
Sample type	URINE
Result	892
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	0
Celerion Study Number	AA99128-06
Date of Collection	2014-APR-05
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day 0)

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

Data signed: (hfarmer1) 30 Mar 2015 13:34:05

Generated On: 20 Jul 2016 22:28:45

Urine Start Day	0
<hr/>	
Urine End Day	1
<hr/>	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day 0)

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

Data signed: (hfarmer1) 30 Mar 2015 13:34:05

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112480000773
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Analyte	COT-GLUC
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Sample type	URINE
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Result	2760
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Result Unit	NG/ML
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Lab Status	OK
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Sample comment	ANALYZED IN ERROR
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Detection method	LC-MS/MS
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Planned time point (Hour)	0
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Day of Visit	0
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Celerion Study Number	AA99128-06
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Date of Collection	2014-APR-05
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Timepoint-minutes	
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day 0)

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

Data signed: (hfarmer1) 30 Mar 2015 13:34:05

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Baseline (Day 0)

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

Data signed: (hfarmer1) 30 Mar 2015 13:34:05

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112480000773
Analyte	NIC
Sample type	URINE
Result	416
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	0
Celerion Study Number	AA99128-06
Date of Collection	2014-APR-05
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day 0)

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

Data signed: (hfarmer1) 30 Mar 2015 13:34:05

Generated On: 20 Jul 2016 22:28:45

Urine Start Day	0
<hr/>	
Urine End Day	1
<hr/>	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day 0)

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

Data signed: (hfarmer1) 30 Mar 2015 13:34:05

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112480000773
Analyte	NIC-GLUC
Sample type	URINE
Result	564
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	0
Celerion Study Number	AA99128-06
Date of Collection	2014-APR-05
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day 0)

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

Data signed: (hfarmer1) 30 Mar 2015 13:34:05

Generated On: 20 Jul 2016 22:28:45

Urine Start Day	0
<hr/>	
Urine End Day	1
<hr/>	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day 0)

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

Data signed: (hfarmer1) 30 Mar 2015 13:34:05

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112480000773
Analyte	THCOT
Sample type	URINE
Result	1680
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	0
Celerion Study Number	AA99128-06
Date of Collection	2014-APR-05
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day 0)

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

Data signed: (hfarmer1) 30 Mar 2015 13:34:05

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Baseline (Day 0)

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(6)**

Data signed: (hfarmer1) 30 Mar 2015 13:34:05

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112480000773
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Analyte	THCOT-GLUC
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Sample type	URINE
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Result	1140
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Result Unit	NG/ML
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Lab Status	OK
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Sample comment	ANALYZED IN ERROR
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Detection method	LC-MS/MS
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Planned time point (Hour)	0
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Day of Visit	0
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Celerion Study Number	AA99128-06
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Date of Collection	2014-APR-05
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Timepoint-minutes	
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day 0)

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(6)**

Data signed: (hfarmer1) 30 Mar 2015 13:34:05

Generated On: 20 Jul 2016 22:28:45

Urine Start Day	0
<hr/>	
Urine End Day	1
<hr/>	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (3-OH BaP)

Data signed: (hfarmer1) 30 Mar 2015 13:34:05

Generated On: 20 Jul 2016 22:28:45

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (3-OH BaP) (1)

Data signed: (hfarmer1) 30 Mar 2015 13:34:05

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112490001708
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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	OK
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Sample comment	ANALYSIS NOT PERFORMED IN ERROR
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Detection method	LC-MS/MS
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Planned time point (Hour)	0
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Day of Visit	0
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Celerion Study Number	AA99128-07
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Date of Collection	2014-APR-04
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Timepoint-minutes	
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (3-OH BaP) (1)

Data signed: (hfarmer1) 30 Mar 2015 13:34:05

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Baseline (Day 0)

Form: Biomarker-Plasma (Caffeine, Paraxanthine)

Generated On: 20 Jul 2016 22:28:45

Sample type

PLASMA

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day 0)

Form: Biomarker-Plasma (Caffeine, Paraxanthine) (1)

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112500000466
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Analyte	CAFFEINE
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Sample type	PLASMA
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Result	448
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Result Unit	NG/ML
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Lab Status	OK
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Sample comment	ANALYZED IN ERROR
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Detection method	LC-MS/MS
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Planned time point (Hour)	6
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Day of Visit	0
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Celerion Study Number	AA99128-08
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Date of Collection	2014-APR-04
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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: 1252**

Folder: Baseline (Day 0)

Form: Biomarker-Plasma (Caffeine, Paraxanthine) (1)

Generated On: 20 Jul 2016 22:28:45

Urine End Day	0
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day 0)

Form: Biomarker-Plasma (Caffeine, Paraxanthine) (2)

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112500000466
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Analyte	PARAXANTHINE
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Sample type	PLASMA
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Result	860
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Result Unit	NG/ML
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Lab Status	OK
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Sample comment	ANALYZED IN ERROR
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Detection method	LC-MS/MS
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Planned time point (Hour)	6
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Day of Visit	0
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Celerion Study Number	AA99128-08
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Date of Collection	2014-APR-04
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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: 1252**

Folder: Baseline (Day 0)

Form: Biomarker-Plasma (Caffeine, Paraxanthine) (2)

Generated On: 20 Jul 2016 22:28:45

Urine End Day	0
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP)

Data signed: (hfarmer1) 30 Mar 2015 13:34:05

Generated On: 20 Jul 2016 22:28:45

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (1)

Data signed: (hfarmer1) 30 Mar 2015 13:34:05

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112510001730
Analyte	1-NA
Sample type	URINE
Result	49.4
Result Unit	PG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	0
Celerion Study Number	AA99128-09
Date of Collection	2014-APR-04
Timepoint-minutes	
Urine Start Day	0

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (1)

Data signed: (hfarmer1) 30 Mar 2015 13:34:05

Generated On: 20 Jul 2016 22:28:45

Urine End Day	1
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (2)

Data signed: (hfarmer1) 30 Mar 2015 13:34:05

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112510001730
Analyte	2-NA
Sample type	URINE
Result	16.7
Result Unit	PG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	0
Celerion Study Number	AA99128-09
Date of Collection	2014-APR-04
Timepoint-minutes	
Urine Start Day	0

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (2)

Data signed: (hfarmer1) 30 Mar 2015 13:34:05

Generated On: 20 Jul 2016 22:28:45

Urine End Day	1
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (3)

Data signed: (hfarmer1) 30 Mar 2015 13:34:05

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112510001730
Analyte	4-ABP
Sample type	URINE
Result	12.4
Result Unit	PG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	0
Celerion Study Number	AA99128-09
Date of Collection	2014-APR-04
Timepoint-minutes	
Urine Start Day	0

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (3)

Data signed: (hfarmer1) 30 Mar 2015 13:34:05

Generated On: 20 Jul 2016 22:28:45

Urine End Day	1
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (4)

Data signed: (hfarmer1) 30 Mar 2015 13:34:05

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112510001730
Analyte	O-TOL
Sample type	URINE
Result	87.9
Result Unit	PG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	0
Celerion Study Number	AA99128-09
Date of Collection	2014-APR-04
Timepoint-minutes	
Urine Start Day	0

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (4)

Data signed: (hfarmer1) 30 Mar 2015 13:34:05

Generated On: 20 Jul 2016 22:28:45

Urine End Day	1
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (11-dTXb2)

Data signed: (hfarmer1) 30 Mar 2015 13:34:03

Generated On: 20 Jul 2016 22:28:45

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (11-dTXb2) (1)

Data signed: (hfarmer1) 30 Mar 2015 13:34:03

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112530000542
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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	OK
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Sample comment	ANALYSIS NOT PERFORMED IN ERROR
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Detection method	LC-MS/MS
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Planned time point (Hour)	0
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Day of Visit	0
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Celerion Study Number	AA99128-11
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Date of Collection	2014-APR-04
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Timepoint-minutes	
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (11-dTXb2) (1)

Data signed: (hfarmer1) 30 Mar 2015 13:34:03

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (iPF2a-III)

Data signed: (hfarmer1) 30 Mar 2015 13:34:03

Generated On: 20 Jul 2016 22:28:45

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (iPF2a-III) (1)

Data signed: (hfarmer1) 30 Mar 2015 13:34:03

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112540000535
Analyte	IPF2A-III
Sample type	URINE
Result	218
Result Unit	PG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	0
Celerion Study Number	AA99128-12
Date of Collection	2014-APR-04
Timepoint-minutes	
Urine Start Day	0

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (iPF2a-III) (1)

Data signed: (hfarmer1) 30 Mar 2015 13:34:03

Generated On: 20 Jul 2016 22:28:45

Urine End Day

1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (Ames)

Data signed: (hfarmer1) 30 Mar 2015 13:34:06

Generated On: 20 Jul 2016 22:28:45

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (Ames) (1)

Data signed: (hfarmer1) 30 Mar 2015 13:34:06

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05113320000232
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Analyte	AMES
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Sample type	URINE
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Result	.
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Result Unit	REV/ML
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Lab Status	OK
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Sample comment	ANALYSIS NOT PERFORMED IN ERROR
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Detection method	COUNT
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Planned time point (Hour)	0
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Day of Visit	0
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Celerion Study Number	AA99128-15
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Date of Collection	2014-APR-04
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Timepoint-minutes	
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (Ames) (1)

Data signed: (hfarmer1) 30 Mar 2015 13:34:06

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (1-OHP)

Data signed: (hfarmer1) 30 Mar 2015 13:34:06

Generated On: 20 Jul 2016 22:28:45

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (1-OHP) (1)

Data signed: (hfarmer1) 30 Mar 2015 13:34:06

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05115190003732
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Analyte	1-OHP
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Sample type	URINE
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Result	.
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Result Unit	PG/ML
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Lab Status	OK
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Sample comment	NOT ANALYZED IN ERROR
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Detection method	LC-MS/MS
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Planned time point (Hour)	0
---------------------------	---

Day of Visit	0
--------------	---

Celerion Study Number	AA99598-03
-----------------------	------------

Date of Collection	2014-APR-04
--------------------	-------------

Timepoint-minutes	
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Urine Start Day	0
-----------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (1-OHP) (1)

Data signed: (hfarmer1) 30 Mar 2015 13:34:06

Generated On: 20 Jul 2016 22:28:45

Urine End Day	1
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (SPMA, SBMA)

Data signed: (hfarmer1) 30 Mar 2015 13:34:03

Generated On: 20 Jul 2016 22:28:45

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (SPMA, SBMA) (1)

Data signed: (hfarmer1) 30 Mar 2015 13:34:03

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05115170003723
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Analyte	SPMA
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Sample type	URINE
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Result	.
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Result Unit	NG/ML
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Lab Status	OK
------------	----

Sample comment	NOT ANALYZED IN ERROR
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Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	0
--------------	---

Celerion Study Number	AA99598-01
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Date of Collection	2014-APR-04
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Timepoint-minutes	
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Urine Start Day	0
-----------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (SPMA, SBMA) (1)

Data signed: (hfarmer1) 30 Mar 2015 13:34:03

Generated On: 20 Jul 2016 22:28:45

Urine End Day	1
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (SPMA, SBMA) (2)

Data signed: (hfarmer1) 30 Mar 2015 13:34:03

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05115170003732
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Analyte	SBMA
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Sample type	URINE
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Result	.
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Result Unit	NG/ML
-------------	-------

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

Sample comment	NOT ANALYZED IN ERROR
----------------	-----------------------

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	0
--------------	---

Celerion Study Number	AA99598-01
-----------------------	------------

Date of Collection	2014-APR-04
--------------------	-------------

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

Urine Start Day	0
-----------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (SPMA, SBMA) (2)

Data signed: (hfarmer1) 30 Mar 2015 13:34:03

Generated On: 20 Jul 2016 22:28:45

Urine End Day

1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (MHBMA)

Data signed: (hfarmer1) 30 Mar 2015 13:34:03

Generated On: 20 Jul 2016 22:28:45

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (MHBMA) (1)

Data signed: (hfarmer1) 30 Mar 2015 13:34:03

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05115180003732
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Analyte	MHBMA
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Sample type	URINE
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Result	.
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Result Unit	NG/ML
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Lab Status	OK
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Sample comment	NOT ANALYZED IN ERROR
----------------	-----------------------

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	0
--------------	---

Celerion Study Number	AA99598-02
-----------------------	------------

Date of Collection	2014-APR-04
--------------------	-------------

Timepoint-minutes	
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Urine Start Day	0
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (MHBMA) (1)

Data signed: (hfarmer1) 30 Mar 2015 13:34:03

Generated On: 20 Jul 2016 22:28:45

Urine End Day	1
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (Creatinine)

Data signed: (hfarmer1) 30 Mar 2015 13:34:06

Generated On: 20 Jul 2016 22:28:45

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (Creatinine) (1)

Data signed: (hfarmer1) 30 Mar 2015 13:34:06

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05115160001708
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Analyte	CREATININE
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Sample type	URINE
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Result	.
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Result Unit	MG/DL
-------------	-------

Lab Status	OK
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Sample comment	ANALYSIS NOT PERFORMED IN ERROR
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Detection method	SPECTROPHOTOMETRIC
------------------	--------------------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	0
--------------	---

Celerion Study Number	AA99128-14
-----------------------	------------

Date of Collection	2014-APR-04
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Timepoint-minutes	
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (Creatinine) (1)

Data signed: (hfarmer1) 30 Mar 2015 13:34:06

Generated On: 20 Jul 2016 22:28:45

Urine Start Day	0
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Urine End Day	1
---------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day 0)

Form: Biomarker-Plasma (Nic, Cot, tHCot)

Generated On: 20 Jul 2016 22:28:45

Sample type

PLASMA

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day 0)

Form: Biomarker-Plasma (Nic, Cot, tHCot) (1)

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112430001806
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Analyte	COT
---------	-----

Sample type	PLASMA
-------------	--------

Result	223
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Result Unit	NG/ML
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Lab Status	OK
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Sample comment	ANALYZED IN ERROR
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Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	0
--------------	---

Celerion Study Number	AA99128-01
-----------------------	------------

Date of Collection	2014-APR-04
--------------------	-------------

Timepoint-minutes	0
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Urine Start Day	
-----------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day 0)

Form: Biomarker-Plasma (Nic, Cot, tHCot) (1)

Generated On: 20 Jul 2016 22:28:45

Urine End Day	0
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day 0)

Form: Biomarker-Plasma (Nic, Cot, tHCot) (2)

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112430001806
----------------	----------------

Analyte	NIC
---------	-----

Sample type	PLASMA
-------------	--------

Result	21.9
--------	------

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

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

Sample comment	ANALYZED IN ERROR
----------------	-------------------

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	0
--------------	---

Celerion Study Number	AA99128-01
-----------------------	------------

Date of Collection	2014-APR-04
--------------------	-------------

Timepoint-minutes	0
-------------------	---

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day 0)

Form: Biomarker-Plasma (Nic, Cot, tHCot) (2)

Generated On: 20 Jul 2016 22:28:45

Urine End Day	0
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day 0)

Form: Biomarker-Plasma (Nic, Cot, tHCot) (3)

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112520000466
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Analyte	COT
---------	-----

Sample type	PLASMA
-------------	--------

Result	172
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Result Unit	NG/ML
-------------	-------

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

Sample comment	ANALYZED IN ERROR
----------------	-------------------

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	0
--------------	---

Celerion Study Number	AA99128-10
-----------------------	------------

Date of Collection	2014-APR-04
--------------------	-------------

Timepoint-minutes	0
-------------------	---

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day 0)

Form: Biomarker-Plasma (Nic, Cot, tHCot) (3)

Generated On: 20 Jul 2016 22:28:45

Urine End Day	0
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day 0)

Form: Biomarker-Plasma (Nic, Cot, tHCot) (4)

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112520000466
----------------	----------------

Analyte	THCOT
---------	-------

Sample type	PLASMA
-------------	--------

Result	66.1
--------	------

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

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

Sample comment	ANALYZED IN ERROR
----------------	-------------------

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	0
--------------	---

Celerion Study Number	AA99128-10
-----------------------	------------

Date of Collection	2014-APR-04
--------------------	-------------

Timepoint-minutes	0
-------------------	---

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Baseline (Day 0)

Form: Biomarker-Plasma (Nic, Cot, tHCot) (4)

Generated On: 20 Jul 2016 22:28:45

Urine End Day	0
---------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 1

Form: Date of Visit

Data signed: (hfarmer1) 30 Mar 2015 13:34:07

Generated On: 20 Jul 2016 22:28:45

Date of Visit

05 APR 2014
DD/MMM/YYYY

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 1

Form: Vital Signs

Data signed: (hfarmer1) 30 Mar 2015 13:34:07

Generated On: 20 Jul 2016 22:28:45

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 09:48
hour:min 24-hour clock

Pulse rate 64
beats per minute

Respiratory rate 20
breaths per minute

Blood Pressure (systolic) 121
mmHg

Blood Pressure (diastolic) 75
mmHg

Vital Signs Position of Subject Supine ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 1

Form: Plasma Nicotine Sample

Data signed: (hfarmer1) 30 Mar 2015 13:34:06

Generated On: 20 Jul 2016 22:28:45

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	05 APR 2014
---------------------	-------------

Time hour:min 24-hour clock	20:28
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 1

Form: Plasma Cotinine Sample

Data signed: (hfarmer1) 30 Mar 2015 13:34:06

Generated On: 20 Jul 2016 22:28:45

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	05 APR 2014
---------------------	-------------

Time hour:min 24-hour clock	20:28
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 1

Form: CoHb Blood Sample

Data signed: (hfarmer1) 30 Mar 2015 13:34:06

Generated On: 20 Jul 2016 22:28:45

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	05 APR 2014
---------------------	-------------

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

Time hour:min 24-hour clock	20:28
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 1

Form: CO Breath Test (1)

Data signed: (hfarmer1) 30 Mar 2015 13:34:07

Generated On: 20 Jul 2016 22:28:45

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	07:25
---	-------

Result(ppm)	11
-------------	----

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 1

Form: CO Breath Test (2)

Data signed: (hfarmer1) 30 Mar 2015 13:34:07

Generated On: 20 Jul 2016 22:28:45

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

If Not Done, please specify the reason: _____

Scheduled Time	12:00 - 13:30 <input checked="" type="radio"/>
----------------	--

Actual Time of Assessment hour:min 24-hour clock	12:10
---	-------

Result(ppm)	5
-------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 1

Form: CO Breath Test (3)

Data signed: (hfarmer1) 30 Mar 2015 13:34:07

Generated On: 20 Jul 2016 22:28:45

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	16:32
---	-------

Result(ppm)	6
-------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 1

Form: CO Breath Test (4)

Data signed: (hfarmer1) 30 Mar 2015 13:34:07

Generated On: 20 Jul 2016 22:28:45

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	20:14
---	-------

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 1

Form: 24 hour urine collections

Data signed: (hfarmer1) 30 Mar 2015 13:34:07

Generated On: 20 Jul 2016 22:28:45

Start Time	06:14
	hour:min 24-hour clock

End Date	06 APR 2014
	DD/MMM/YYYY

End Time	06:08
	hour:min 24-hour clock

Volume	2661
	mL

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 1

Form: Sample Urine Collection

Data signed: (hfarmer1) 30 Mar 2015 13:34:06

Generated On: 20 Jul 2016 22:28:45

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: 1252

Folder: Day 1

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Data signed: (hfarmer1) 30 Mar 2015 13:34:08

Generated On: 20 Jul 2016 22:28:45

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

Date of assessment DD/MMM/YYYY	2014 APR 05 DD/MMM/YYYY
-----------------------------------	----------------------------

Time of assessment	06:35 hour:min 24-hour clock
--------------------	---------------------------------

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

Please indicate for each of the items below, how you have been feeling over the past 24 hours

How have you been feeling over the past 24 hours?	None <input type="radio"/>
---	----------------------------

1. Angry, irritable, frustrated

How have you been feeling over the past 24 hours?	Slight <input type="radio"/>
---	------------------------------

2. Anxious, nervous

How have you been feeling over the past 24 hours?	None <input type="radio"/>
---	----------------------------

3. Depressed Mood, sad

How have you been feeling over the past 24 hours?	Slight <input type="radio"/>
---	------------------------------

4. Desire or craving to smoke

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Day 1

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Data signed: (hfarmer1) 30 Mar 2015 13:34:08

Generated On: 20 Jul 2016 22:28:45

How have you been feeling over the past 24 hours? None ☐

5. Difficulty concentrating

How have you been feeling over the past 24 hours? None ☐

6. Increased appetite, hungry, weight gain

How have you been feeling over the past 24 hours? None ☐

7. Insomnia, sleep problems, awakening at night

How have you been feeling over the past 24 hours? None ☐

8. Restless

How have you been feeling over the past 24 hours? None ☐

9. Impatient

How have you been feeling over the past 24 hours? None ☐

10. Constipation

How have you been feeling over the past 24 hours? None ☐

11. Dizziness

How have you been feeling over the past 24 hours? Slight ☐

12. Coughing

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 1

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Data signed: (hfarmer1) 30 Mar 2015 13:34:08

Generated On: 20 Jul 2016 22:28:45

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: 1252

Folder: Day 1

Form: Cough Assessment

Data signed: (hfarmer1) 30 Mar 2015 13:34:07

Generated On: 20 Jul 2016 22:28:45

Date of Birth

(b) (6)

Date of assessment
DD/MMM/YYYY

2014 APR 05
DD/MMM/YYYY

Time of assessment

06:33
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?

35

Second Question: Cough Intensity Scale:
How intense is your cough?

Mild ☒

Third Question: Cough Frequency Scale:
How frequently do you normally have to cough each
day?

Sometimes ☒

Fourth Question: Sputum Production
To what extent do you produce sputum when coughing?

A moderate amount of
sputum ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 1

Form: Lab_BU_COHB (1)

Data signed: (hfarmer1) 30 Mar 2015 13:34:08

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05115150004500
Analyte	CARBOXYHEMOGLOBIN
Sample type	BLOOD
Result	2.70
Result Unit	%
Lab Status	OK
Sample comment	.
Detection method	SPECTROPHOTOMETRIC
Lower limit of quantification	0.500
Planned time point (Hour)	20
Day of Visit	1
Celerion Study Number	AA99128-16
Date of Collection	2014-APR-05
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 1

Form: Lab_BU_COHB (1)

Data signed: (hfarmer1) 30 Mar 2015 13:34:08

Generated On: 20 Jul 2016 22:28:45

Start Day (24 hour urine only) _____

End Day (24 hour Urine Only) _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 1

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)

Data signed: (hfarmer1) 30 Mar 2015 13:34:07

Generated On: 20 Jul 2016 22:28:45

Date of Birth

(b) (6)

Date of assessment

2014 APR 05

DD/MMM/YYYY

DD/MMM/YYYY

Time of assessment

20:05

hour:min 24-hour clock

Assessment Status

Completed

1. Was smoking satisfying?

A lot

2. Did cigarettes taste good?

Not at all

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

Not at all

4. Did smoking calm you down?

Not at all

5. Did smoking make you feel more awake?

Not at all

6. Did smoking make you feel less irritable?

Not at all

7. Did smoking help you concentrate?

Not at all

8. Did smoking reduce your hunger for food?

Little

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 1

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)

Data signed: (hfarmer1) 30 Mar 2015 13:34:07

Generated On: 20 Jul 2016 22:28:45

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

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

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

12. Did you enjoy smoking? Moderately ☐

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 1

Form: Questionnaire on smoking urges (QSU)

Data signed: (hfarmer1) 30 Mar 2015 13:34:08

Generated On: 20 Jul 2016 22:28:45

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

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

Date of assessment	2014 APR 05
--------------------	-------------

DD/MMM/YYYY

Time of assessment	20:03
--------------------	-------

hour:min 24-hour clock

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

1. I have a desire for a cigarette right now	Strongly agree <input checked="" type="radio"/>
--	---

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

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

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

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

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 1

Form: Questionnaire on smoking urges (QSU)

Data signed: (hfarmer1) 30 Mar 2015 13:34:08

Generated On: 20 Jul 2016 22:28:45

7. A cigarette would taste good now Strongly disagree ☐

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

9. Smoking would make me less depressed Strongly disagree ☐

10. I am going to smoke as soon as possible Strongly agree ☐

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 1

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

Data signed: (hfarmer1) 30 Mar 2015 13:34:09

Generated On: 20 Jul 2016 22:28:45

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 1

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

Data signed: (hfarmer1) 30 Mar 2015 13:34:09

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112450002854
Analyte	HPMA
Sample type	URINE
Result	362
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	1
Celerion Study Number	AA99128-03
Date of Collection	2014-APR-05
Timepoint-minutes	
Urine Start Day	1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 1

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

Data signed: (hfarmer1) 30 Mar 2015 13:34:09

Generated On: 20 Jul 2016 22:28:45

Urine End Day

2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 1

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

Data signed: (hfarmer1) 30 Mar 2015 13:34:09

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112450002854
Analyte	CEMA
Sample type	URINE
Result	80.8
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	1
Celerion Study Number	AA99128-03
Date of Collection	2014-APR-05
Timepoint-minutes	
Urine Start Day	1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 1

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

Data signed: (hfarmer1) 30 Mar 2015 13:34:09

Generated On: 20 Jul 2016 22:28:45

Urine End Day

2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 1

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

Data signed: (hfarmer1) 30 Mar 2015 13:34:09

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112450002854
Analyte	HBMA
Sample type	URINE
Result	140
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	1
Celerion Study Number	AA99128-03
Date of Collection	2014-APR-05
Timepoint-minutes	
Urine Start Day	1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 1

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

Data signed: (hfarmer1) 30 Mar 2015 13:34:09

Generated On: 20 Jul 2016 22:28:45

Urine End Day

2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 1

Form: Biomarker-Urine (NNN, NNAL)

Data signed: (hfarmer1) 30 Mar 2015 13:34:08

Generated On: 20 Jul 2016 22:28:45

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 1

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

Data signed: (hfarmer1) 30 Mar 2015 13:34:08

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112460003425
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Analyte	NNAL
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Sample type	URINE
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Result	.
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Result Unit	PG/ML
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Lab Status	OK
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Sample comment	ANALYSIS NOT PERFORMED IN ERROR
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Detection method	LC-MS/MS
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Planned time point (Hour)	0
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Day of Visit	1
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Celerion Study Number	AA99128-04
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Date of Collection	2014-APR-05
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Timepoint-minutes	
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 1

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

Data signed: (hfarmer1) 30 Mar 2015 13:34:08

Generated On: 20 Jul 2016 22:28:45

Urine Start Day	1
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Urine End Day	2
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 1

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

Data signed: (hfarmer1) 30 Mar 2015 13:34:08

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112460003425
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Analyte	NNN
---------	-----

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

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

Result Unit	PG/ML
-------------	-------

Lab Status	OK
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Sample comment	ANALYSIS NOT PERFORMED IN ERROR
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Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

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

Celerion Study Number	AA99128-04
-----------------------	------------

Date of Collection	2014-APR-05
--------------------	-------------

Timepoint-minutes	
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 1

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

Data signed: (hfarmer1) 30 Mar 2015 13:34:08

Generated On: 20 Jul 2016 22:28:45

Urine Start Day	1
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Urine End Day	2
---------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 1

Form: Biomarker-Urine (HEMA)

Data signed: (hfarmer1) 30 Mar 2015 13:34:08

Generated On: 20 Jul 2016 22:28:45

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 1

Form: Biomarker-Urine (HEMA) (1)

Data signed: (hfarmer1) 30 Mar 2015 13:34:08

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112470001709
Analyte	HEMA
Sample type	URINE
Result	1.02
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	1
Celerion Study Number	AA99128-05
Date of Collection	2014-APR-05
Timepoint-minutes	
Urine Start Day	1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 1

Form: Biomarker-Urine (HEMA) (1)

Data signed: (hfarmer1) 30 Mar 2015 13:34:08

Generated On: 20 Jul 2016 22:28:45

Urine End Day

2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 1

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

Data signed: (hfarmer1) 30 Mar 2015 13:34:10

Generated On: 20 Jul 2016 22:28:45

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 1

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

Data signed: (hfarmer1) 30 Mar 2015 13:34:10

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112480000774
Analyte	COT
Sample type	URINE
Result	1160
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	1
Celerion Study Number	AA99128-06
Date of Collection	2014-APR-06
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 1

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

Data signed: (hfarmer1) 30 Mar 2015 13:34:10

Generated On: 20 Jul 2016 22:28:45

Urine Start Day	1
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Urine End Day	2
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 1

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

Data signed: (hfarmer1) 30 Mar 2015 13:34:10

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112480000774
Analyte	COT-GLUC
Sample type	URINE
Result	3800
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	1
Celerion Study Number	AA99128-06
Date of Collection	2014-APR-06
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 1

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

Data signed: (hfarmer1) 30 Mar 2015 13:34:10

Generated On: 20 Jul 2016 22:28:45

Urine Start Day	1
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Urine End Day	2
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 1

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

Data signed: (hfarmer1) 30 Mar 2015 13:34:10

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112480000774
Analyte	NIC
Sample type	URINE
Result	494
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	1
Celerion Study Number	AA99128-06
Date of Collection	2014-APR-06
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 1

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

Data signed: (hfarmer1) 30 Mar 2015 13:34:10

Generated On: 20 Jul 2016 22:28:45

Urine Start Day	1
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Urine End Day	2
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 1

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

Data signed: (hfarmer1) 30 Mar 2015 13:34:10

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112480000774
Analyte	NIC-GLUC
Sample type	URINE
Result	579
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	1
Celerion Study Number	AA99128-06
Date of Collection	2014-APR-06
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 1

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

Data signed: (hfarmer1) 30 Mar 2015 13:34:10

Generated On: 20 Jul 2016 22:28:45

Urine Start Day	1
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Urine End Day	2
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 1

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

Data signed: (hfarmer1) 30 Mar 2015 13:34:10

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112480000774
Analyte	THCOT
Sample type	URINE
Result	3580
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	1
Celerion Study Number	AA99128-06
Date of Collection	2014-APR-06
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 1

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

Data signed: (hfarmer1) 30 Mar 2015 13:34:10

Generated On: 20 Jul 2016 22:28:45

Urine Start Day	1
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Urine End Day	2
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 1

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(6)**

Data signed: (hfarmer1) 30 Mar 2015 13:34:10

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112480000774
Analyte	THCOT-GLUC
Sample type	URINE
Result	2270
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	1
Celerion Study Number	AA99128-06
Date of Collection	2014-APR-06
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 1

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(6)**

Data signed: (hfarmer1) 30 Mar 2015 13:34:10

Generated On: 20 Jul 2016 22:28:45

Urine Start Day	1
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Urine End Day	2
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 1

Form: Biomarker-Urine (3-OH BaP)

Data signed: (hfarmer1) 30 Mar 2015 13:34:10

Generated On: 20 Jul 2016 22:28:45

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 1

Form: Biomarker-Urine (3-OH BaP) (1)

Data signed: (hfarmer1) 30 Mar 2015 13:34:10

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112490001709
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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	OK
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Sample comment	ANALYSIS NOT PERFORMED IN ERROR
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Detection method	LC-MS/MS
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Planned time point (Hour)	0
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Day of Visit	1
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Celerion Study Number	AA99128-07
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Date of Collection	2014-APR-05
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Timepoint-minutes	
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 1

Form: Biomarker-Urine (3-OH BaP) (1)

Data signed: (hfarmer1) 30 Mar 2015 13:34:10

Generated On: 20 Jul 2016 22:28:45

Urine Start Day	1
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Urine End Day	2
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 1

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP)

Data signed: (hfarmer1) 30 Mar 2015 13:34:10

Generated On: 20 Jul 2016 22:28:45

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 1

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (1)

Data signed: (hfarmer1) 30 Mar 2015 13:34:10

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112510001731
Analyte	1-NA
Sample type	URINE
Result	13.3
Result Unit	PG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	1
Celerion Study Number	AA99128-09
Date of Collection	2014-APR-05
Timepoint-minutes	
Urine Start Day	1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 1

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (1)

Data signed: (hfarmer1) 30 Mar 2015 13:34:10

Generated On: 20 Jul 2016 22:28:45

Urine End Day

2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 1

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (2)

Data signed: (hfarmer1) 30 Mar 2015 13:34:10

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112510001731
Analyte	2-NA
Sample type	URINE
Result	6.17
Result Unit	PG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	1
Celerion Study Number	AA99128-09
Date of Collection	2014-APR-05
Timepoint-minutes	
Urine Start Day	1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 1

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (2)

Data signed: (hfarmer1) 30 Mar 2015 13:34:10

Generated On: 20 Jul 2016 22:28:45

Urine End Day

2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 1

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (3)

Data signed: (hfarmer1) 30 Mar 2015 13:34:10

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112510001731
Analyte	4-ABP
Sample type	URINE
Result	10.5
Result Unit	PG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	1
Celerion Study Number	AA99128-09
Date of Collection	2014-APR-05
Timepoint-minutes	
Urine Start Day	1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 1

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (3)

Data signed: (hfarmer1) 30 Mar 2015 13:34:10

Generated On: 20 Jul 2016 22:28:45

Urine End Day

2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 1

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (4)

Data signed: (hfarmer1) 30 Mar 2015 13:34:10

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112510001731
Analyte	O-TOL
Sample type	URINE
Result	BLQ<(50.0)
Result Unit	PG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	1
Celerion Study Number	AA99128-09
Date of Collection	2014-APR-05
Timepoint-minutes	
Urine Start Day	1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 1

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (4)

Data signed: (hfarmer1) 30 Mar 2015 13:34:10

Generated On: 20 Jul 2016 22:28:45

Urine End Day

2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 1

Form: Biomarker-Urine (1-OHP)

Data signed: (hfarmer1) 30 Mar 2015 13:34:11

Generated On: 20 Jul 2016 22:28:45

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 1

Form: Biomarker-Urine (1-OHP) (1)

Data signed: (hfarmer1) 30 Mar 2015 13:34:11

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05115190003733
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Analyte	1-OHP
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Sample type	URINE
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Result	.
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Result Unit	PG/ML
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Lab Status	OK
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Sample comment	NOT ANALYZED IN ERROR
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Detection method	LC-MS/MS
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Planned time point (Hour)	0
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Day of Visit	1
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Celerion Study Number	AA99598-03
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Date of Collection	2014-APR-05
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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: 1252**

Folder: Day 1

Form: Biomarker-Urine (1-OHP) (1)

Data signed: (hfarmer1) 30 Mar 2015 13:34:11

Generated On: 20 Jul 2016 22:28:45

Urine End Day

2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 1

Form: Biomarker-Urine (SPMA, SBMA)

Data signed: (hfarmer1) 30 Mar 2015 13:34:09

Generated On: 20 Jul 2016 22:28:45

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 1

Form: Biomarker-Urine (SPMA, SBMA) (1)

Data signed: (hfarmer1) 30 Mar 2015 13:34:09

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05115170003724
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Analyte	SPMA
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Sample type	URINE
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Result	.
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Result Unit	NG/ML
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Lab Status	OK
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Sample comment	NOT ANALYZED IN ERROR
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Detection method	LC-MS/MS
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Planned time point (Hour)	0
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Day of Visit	1
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Celerion Study Number	AA99598-01
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Date of Collection	2014-APR-05
--------------------	-------------

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: 1252**

Folder: Day 1

Form: Biomarker-Urine (SPMA, SBMA) (1)

Data signed: (hfarmer1) 30 Mar 2015 13:34:09

Generated On: 20 Jul 2016 22:28:45

Urine End Day

2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 1

Form: Biomarker-Urine (SPMA, SBMA) (2)

Data signed: (hfarmer1) 30 Mar 2015 13:34:09

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05115170003733
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Analyte	SBMA
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Sample type	URINE
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Result	.
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Result Unit	NG/ML
-------------	-------

Lab Status	OK
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Sample comment	NOT ANALYZED IN ERROR
----------------	-----------------------

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

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

Celerion Study Number	AA99598-01
-----------------------	------------

Date of Collection	2014-APR-05
--------------------	-------------

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: 1252**

Folder: Day 1

Form: Biomarker-Urine (SPMA, SBMA) (2)

Data signed: (hfarmer1) 30 Mar 2015 13:34:09

Generated On: 20 Jul 2016 22:28:45

Urine End Day

2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 1

Form: Biomarker-Urine (MHBMA)

Data signed: (hfarmer1) 30 Mar 2015 13:34:09

Generated On: 20 Jul 2016 22:28:45

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 1

Form: Biomarker-Urine (MHBMA) (1)

Data signed: (hfarmer1) 30 Mar 2015 13:34:09

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05115180003733
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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
-------------	-------

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

Sample comment	NOT ANALYZED IN ERROR
----------------	-----------------------

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

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

Celerion Study Number	AA99598-02
-----------------------	------------

Date of Collection	2014-APR-05
--------------------	-------------

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

Urine Start Day	1
-----------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 1

Form: Biomarker-Urine (MHBMA) (1)

Data signed: (hfarmer1) 30 Mar 2015 13:34:09

Generated On: 20 Jul 2016 22:28:45

Urine End Day

2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 1

Form: Biomarker-Urine (Creatinine)

Data signed: (hfarmer1) 30 Mar 2015 13:34:11

Generated On: 20 Jul 2016 22:28:45

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 1

Form: Biomarker-Urine (Creatinine) (1)

Data signed: (hfarmer1) 30 Mar 2015 13:34:11

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05115160001709
----------------	----------------

Analyte	CREATININE
---------	------------

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

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

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

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

Sample comment	ANALYSIS NOT PERFORMED IN ERROR
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Detection method	SPECTROPHOTOMETRIC
------------------	--------------------

Planned time point (Hour)	0
---------------------------	---

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

Celerion Study Number	AA99128-14
-----------------------	------------

Date of Collection	2014-APR-05
--------------------	-------------

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 1

Form: Biomarker-Urine (Creatinine) (1)

Data signed: (hfarmer1) 30 Mar 2015 13:34:11

Generated On: 20 Jul 2016 22:28:45

Urine Start Day	1
-----------------	---

Urine End Day	2
---------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 1

Form: Biomarker-Plasma (Nic, Cot, tHCot)

Data signed: (hfarmer1) 30 Mar 2015 13:34:09

Generated On: 20 Jul 2016 22:28:45

Sample type

PLASMA

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 1

Form: Biomarker-Plasma (Nic, Cot, tHCot) (1)

Data signed: (hfarmer1) 30 Mar 2015 13:34:09

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112430001807
Analyte	COT
Sample type	PLASMA
Result	208
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	1
Celerion Study Number	AA99128-01
Date of Collection	2014-APR-05
Timepoint-minutes	0
Urine Start Day	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 1

Form: Biomarker-Plasma (Nic, Cot, tHCot) (1)

Data signed: (hfarmer1) 30 Mar 2015 13:34:09

Generated On: 20 Jul 2016 22:28:45

Urine End Day

1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 1

Form: Biomarker-Plasma (Nic, Cot, tHCot) (2)

Data signed: (hfarmer1) 30 Mar 2015 13:34:09

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112430001807
----------------	----------------

Analyte	NIC
---------	-----

Sample type	PLASMA
-------------	--------

Result	12.1
--------	------

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

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

Sample comment	ANALYZED IN ERROR
----------------	-------------------

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

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

Celerion Study Number	AA99128-01
-----------------------	------------

Date of Collection	2014-APR-05
--------------------	-------------

Timepoint-minutes	0
-------------------	---

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 1

Form: Biomarker-Plasma (Nic, Cot, tHCot) (2)

Data signed: (hfarmer1) 30 Mar 2015 13:34:09

Generated On: 20 Jul 2016 22:28:45

Urine End Day

1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 2

Form: Date of Visit

Data signed: (hfarmer1) 30 Mar 2015 13:34:12

Generated On: 20 Jul 2016 22:28:45

Date of Visit

06 APR 2014
DD/MMM/YYYY

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 2

Form: Vital Signs

Data signed: (hfarmer1) 30 Mar 2015 13:34:12

Generated On: 20 Jul 2016 22:28:45

Were Vitals Signs assessed?

Yes ☒

If No, please specify the reason: _____

Has the subject smoked within 15 minutes prior to
assessment

No ☒

Time of assessment

10:12
hour:min 24-hour clock

Pulse rate

61
beats per minute

Respiratory rate

16
breaths per minute

Blood Pressure (systolic)

120
mmHg

Blood Pressure (diastolic)

78
mmHg

Vital Signs Position of Subject

Supine ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 2

Form: Plasma Nicotine Sample

Data signed: (hfarmer1) 30 Mar 2015 13:34:12

Generated On: 20 Jul 2016 22:28:45

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	06 APR 2014
---------------------	-------------

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 2

Form: Plasma Cotinine Sample

Data signed: (hfarmer1) 30 Mar 2015 13:34:12

Generated On: 20 Jul 2016 22:28:45

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	06 APR 2014
---------------------	-------------

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 2

Form: CoHb Blood Sample

Data signed: (hfarmer1) 30 Mar 2015 13:34:11

Generated On: 20 Jul 2016 22:28:45

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	06 APR 2014
---------------------	-------------

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

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 2

Form: CO Breath Test (1)

Data signed: (hfarmer1) 30 Mar 2015 13:34:13

Generated On: 20 Jul 2016 22:28:45

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

If Not Done, please specify the reason: _____

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

Actual Time of Assessment hour:min 24-hour clock	06:39
---	-------

Result(ppm)	2
-------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 2

Form: CO Breath Test (2)

Data signed: (hfarmer1) 30 Mar 2015 13:34:13

Generated On: 20 Jul 2016 22:28:45

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

If Not Done, please specify the reason: _____

Scheduled Time	12:00 - 13:30	<input checked="" type="radio"/>
----------------	---------------	----------------------------------

Actual Time of Assessment hour:min 24-hour clock	12:15
---	-------

Result(ppm)	2
-------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 2

Form: CO Breath Test (3)

Data signed: (hfarmer1) 30 Mar 2015 13:34:13

Generated On: 20 Jul 2016 22:28:45

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	16:04
---	-------

Result(ppm)	2
-------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 2

Form: CO Breath Test (4)

Data signed: (hfarmer1) 30 Mar 2015 13:34:13

Generated On: 20 Jul 2016 22:28:45

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	20:07
---	-------

Result(ppm)	2
-------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 2

Form: 24 hour urine collections

Data signed: (hfarmer1) 30 Mar 2015 13:34:12

Generated On: 20 Jul 2016 22:28:45

Start Time	06:08
	hour:min 24-hour clock

End Date	07 APR 2014
	DD/MMM/YYYY

End Time	06:06
	hour:min 24-hour clock

Volume	2688
	mL

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 2

Form: Sample Urine Collection

Data signed: (hfarmer1) 30 Mar 2015 13:34:12

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Day 2

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Data signed: (hfarmer1) 30 Mar 2015 13:34:14

Generated On: 20 Jul 2016 22:28:45

Date of Birth

(b) (6)

Date of assessment
DD/MMM/YYYY

2014 APR 06
DD/MMM/YYYY

Time of assessment

06:15
hour:min 24-hour clock

Assessment Status

Completed ☒

Please indicate for each of the items below, how you have been feeling over the past 24 hours

How have you been feeling over the past 24 hours?

None ☐

1. Angry, irritable, frustrated

How have you been feeling over the past 24 hours?

Slight ☐

2. Anxious, nervous

How have you been feeling over the past 24 hours?

None ☐

3. Depressed Mood, sad

How have you been feeling over the past 24 hours?

Slight ☐

4. Desire or craving to smoke

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 2

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Data signed: (hfarmer1) 30 Mar 2015 13:34:14

Generated On: 20 Jul 2016 22:28:45

How have you been feeling over the past 24 hours? None ☐

5. Difficulty concentrating

How have you been feeling over the past 24 hours? None ☐

6. Increased appetite, hungry, weight gain

How have you been feeling over the past 24 hours? None ☐

7. Insomnia, sleep problems, awakening at night

How have you been feeling over the past 24 hours? None ☐

8. Restless

How have you been feeling over the past 24 hours? None ☐

9. Impatient

How have you been feeling over the past 24 hours? None ☐

10. Constipation

How have you been feeling over the past 24 hours? None ☐

11. Dizziness

How have you been feeling over the past 24 hours? Slight ☐

12. Coughing

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 2

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Data signed: (hfarmer1) 30 Mar 2015 13:34:14

Generated On: 20 Jul 2016 22:28:45

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: 1252

Folder: Day 2

Form: Cough Assessment

Data signed: (hfarmer1) 30 Mar 2015 13:34:13

Generated On: 20 Jul 2016 22:28:45

Date of Birth

(b) (6)

Date of assessment
DD/MMM/YYYY

2014 APR 06
DD/MMM/YYYY

Time of assessment

06:13
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?

48

Second Question: Cough Intensity Scale:
How intense is your cough?

Mild ☒

Third Question: Cough Frequency Scale:
How frequently do you normally have to cough each
day?

Fairly often ☒

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: 1252**

Folder: Day 2

Form: Lab_BU_COHB (1)

Data signed: (hfarmer1) 30 Mar 2015 13:34:15

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05115150004501
Analyte	CARBOXYHEMOGLOBIN
Sample type	BLOOD
Result	2.50
Result Unit	%
Lab Status	OK
Sample comment	.
Detection method	SPECTROPHOTOMETRIC
Lower limit of quantification	0.500
Planned time point (Hour)	20
Day of Visit	2
Celerion Study Number	AA99128-16
Date of Collection	2014-APR-06
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 2

Form: Lab_BU_COHB (1)

Data signed: (hfarmer1) 30 Mar 2015 13:34:15

Generated On: 20 Jul 2016 22:28:45

Start Day (24 hour urine only) _____

End Day (24 hour Urine Only) _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 2

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)

Data signed: (hfarmer1) 30 Mar 2015 13:34:14

Generated On: 20 Jul 2016 22:28:45

Date of Birth	(b) (6)
Date of assessment DD/MMM/YYYY	2014 APR 06 DD/MMM/YYYY
Time of assessment	20:03 hour:min 24-hour clock
Assessment Status	Completed <input type="radio"/>
1. Was smoking satisfying?	Moderately <input type="radio"/>
2. Did cigarettes taste good?	Not at all <input type="radio"/>
3. Did you enjoy the sensation in your throat and chest?	Not at all <input type="radio"/>
4. Did smoking calm you down?	Moderately <input type="radio"/>
5. Did smoking make you feel more awake?	Not at all <input type="radio"/>
6. Did smoking make you feel less irritable?	Moderately <input type="radio"/>
7. Did smoking help you concentrate?	Not at all <input type="radio"/>
8. Did smoking reduce your hunger for food?	Moderately <input type="radio"/>

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 2

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)

Data signed: (hfarmer1) 30 Mar 2015 13:34:14

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Day 2

Form: Questionnaire on smoking urges (QSU)

Data signed: (hfarmer1) 30 Mar 2015 13:34:15

Generated On: 20 Jul 2016 22:28:45

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

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

Date of assessment	2014 APR 06
--------------------	-------------

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	Somewhat agree <input checked="" type="radio"/>
--	---

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

3. If it were possible I would probably smoke now	Do not agree or disagree <input checked="" type="radio"/>
---	---

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

5. All I want right now is a cigarette	Strongly disagree <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: 1252**

Folder: Day 2

Form: Questionnaire on smoking urges (QSU)

Data signed: (hfarmer1) 30 Mar 2015 13:34:15

Generated On: 20 Jul 2016 22:28:45

7. A cigarette would taste good now Strongly disagree ☐

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

9. Smoking would make me less depressed Strongly disagree ☐

10. I am going to smoke as soon as possible Do not agree or disagree ☐

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 2

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

Data signed: (hfarmer1) 30 Mar 2015 13:34:17

Generated On: 20 Jul 2016 22:28:45

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 2

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

Data signed: (hfarmer1) 30 Mar 2015 13:34:17

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112450002855
Analyte	HPMA
Sample type	URINE
Result	294
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	2
Celerion Study Number	AA99128-03
Date of Collection	2014-APR-06
Timepoint-minutes	
Urine Start Day	2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 2

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

Data signed: (hfarmer1) 30 Mar 2015 13:34:17

Generated On: 20 Jul 2016 22:28:45

Urine End Day

3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 2

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

Data signed: (hfarmer1) 30 Mar 2015 13:34:17

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112450002855
Analyte	CEMA
Sample type	URINE
Result	50.4
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	2
Celerion Study Number	AA99128-03
Date of Collection	2014-APR-06
Timepoint-minutes	
Urine Start Day	2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 2

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

Data signed: (hfarmer1) 30 Mar 2015 13:34:17

Generated On: 20 Jul 2016 22:28:45

Urine End Day

3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 2

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

Data signed: (hfarmer1) 30 Mar 2015 13:34:17

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112450002855
Analyte	HBMA
Sample type	URINE
Result	64.6
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	2
Celerion Study Number	AA99128-03
Date of Collection	2014-APR-06
Timepoint-minutes	
Urine Start Day	2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 2

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

Data signed: (hfarmer1) 30 Mar 2015 13:34:17

Generated On: 20 Jul 2016 22:28:45

Urine End Day

3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 2

Form: Biomarker-Urine (NNN, NNAL)

Data signed: (hfarmer1) 30 Mar 2015 13:34:15

Generated On: 20 Jul 2016 22:28:45

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 2

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

Data signed: (hfarmer1) 30 Mar 2015 13:34:15

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112460003426
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Analyte	NNAL
---------	------

Sample type	URINE
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Result	.
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Result Unit	PG/ML
-------------	-------

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

Sample comment	ANALYSIS NOT PERFORMED IN ERROR
----------------	------------------------------------

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	2
--------------	---

Celerion Study Number	AA99128-04
-----------------------	------------

Date of Collection	2014-APR-06
--------------------	-------------

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 2

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

Data signed: (hfarmer1) 30 Mar 2015 13:34:15

Generated On: 20 Jul 2016 22:28:45

Urine Start Day	2
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Urine End Day	3
---------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 2

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

Data signed: (hfarmer1) 30 Mar 2015 13:34:15

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112460003426
----------------	----------------

Analyte	NNN
---------	-----

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

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

Result Unit	PG/ML
-------------	-------

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

Sample comment	ANALYSIS NOT PERFORMED IN ERROR
----------------	------------------------------------

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	2
--------------	---

Celerion Study Number	AA99128-04
-----------------------	------------

Date of Collection	2014-APR-06
--------------------	-------------

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 2

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

Data signed: (hfarmer1) 30 Mar 2015 13:34:15

Generated On: 20 Jul 2016 22:28:45

Urine Start Day	2
-----------------	---

Urine End Day	3
---------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 2

Form: Biomarker-Urine (HEMA)

Data signed: (hfarmer1) 30 Mar 2015 13:34:16

Generated On: 20 Jul 2016 22:28:45

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 2

Form: Biomarker-Urine (HEMA) (1)

Data signed: (hfarmer1) 30 Mar 2015 13:34:16

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112470001710
Analyte	HEMA
Sample type	URINE
Result	0.734
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	2
Celerion Study Number	AA99128-05
Date of Collection	2014-APR-06
Timepoint-minutes	
Urine Start Day	2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 2

Form: Biomarker-Urine (HEMA) (1)

Data signed: (hfarmer1) 30 Mar 2015 13:34:16

Generated On: 20 Jul 2016 22:28:45

Urine End Day

3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 2

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

Data signed: (hfarmer1) 30 Mar 2015 13:34:17

Generated On: 20 Jul 2016 22:28:45

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 2

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

Data signed: (hfarmer1) 30 Mar 2015 13:34:17

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112480000775
Analyte	COT
Sample type	URINE
Result	1200
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	2
Celerion Study Number	AA99128-06
Date of Collection	2014-APR-07
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 2

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

Data signed: (hfarmer1) 30 Mar 2015 13:34:17

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Day 2

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

Data signed: (hfarmer1) 30 Mar 2015 13:34:17

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112480000775
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Analyte	COT-GLUC
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Sample type	URINE
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Result	4150
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Result Unit	NG/ML
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Lab Status	OK
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Sample comment	ANALYZED IN ERROR
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Detection method	LC-MS/MS
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Planned time point (Hour)	0
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Day of Visit	2
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Celerion Study Number	AA99128-06
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Date of Collection	2014-APR-07
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Timepoint-minutes	
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 2

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

Data signed: (hfarmer1) 30 Mar 2015 13:34:17

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Day 2

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

Data signed: (hfarmer1) 30 Mar 2015 13:34:17

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112480000775
Analyte	NIC
Sample type	URINE
Result	469
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	2
Celerion Study Number	AA99128-06
Date of Collection	2014-APR-07
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 2

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

Data signed: (hfarmer1) 30 Mar 2015 13:34:17

Generated On: 20 Jul 2016 22:28:45

Urine Start Day	2
-----------------	---

Urine End Day	3
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 2

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

Data signed: (hfarmer1) 30 Mar 2015 13:34:17

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112480000775
Analyte	NIC-GLUC
Sample type	URINE
Result	680
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	2
Celerion Study Number	AA99128-06
Date of Collection	2014-APR-07
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 2

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

Data signed: (hfarmer1) 30 Mar 2015 13:34:17

Generated On: 20 Jul 2016 22:28:45

Urine Start Day	2
-----------------	---

Urine End Day	3
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 2

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

Data signed: (hfarmer1) 30 Mar 2015 13:34:17

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112480000775
Analyte	THCOT
Sample type	URINE
Result	3700
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	2
Celerion Study Number	AA99128-06
Date of Collection	2014-APR-07
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 2

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

Data signed: (hfarmer1) 30 Mar 2015 13:34:17

Generated On: 20 Jul 2016 22:28:45

Urine Start Day	2
-----------------	---

Urine End Day	3
---------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 2

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(6)**

Data signed: (hfarmer1) 30 Mar 2015 13:34:17

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112480000775
Analyte	THCOT-GLUC
Sample type	URINE
Result	2340
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	2
Celerion Study Number	AA99128-06
Date of Collection	2014-APR-07
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 2

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(6)**

Data signed: (hfarmer1) 30 Mar 2015 13:34:17

Generated On: 20 Jul 2016 22:28:45

Urine Start Day	2
-----------------	---

Urine End Day	3
---------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 2

Form: Biomarker-Urine (3-OH BaP)

Data signed: (hfarmer1) 30 Mar 2015 13:34:18

Generated On: 20 Jul 2016 22:28:45

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 2

Form: Biomarker-Urine (3-OH BaP) (1)

Data signed: (hfarmer1) 30 Mar 2015 13:34:18

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112490001710
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Analyte	3-OH BAP
---------	----------

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

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

Result Unit	FG/ML
-------------	-------

Lab Status	OK
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Sample comment	ANALYSIS NOT PERFORMED IN ERROR
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Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	2
--------------	---

Celerion Study Number	AA99128-07
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Date of Collection	2014-APR-06
--------------------	-------------

Timepoint-minutes	
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 2

Form: Biomarker-Urine (3-OH BaP) (1)

Data signed: (hfarmer1) 30 Mar 2015 13:34:18

Generated On: 20 Jul 2016 22:28:45

Urine Start Day	2
-----------------	---

Urine End Day	3
---------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 2

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP)

Data signed: (hfarmer1) 30 Mar 2015 13:34:19

Generated On: 20 Jul 2016 22:28:45

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 2

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (1)

Data signed: (hfarmer1) 30 Mar 2015 13:34:19

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112510001732
Analyte	1-NA
Sample type	URINE
Result	5.76
Result Unit	PG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	2
Celerion Study Number	AA99128-09
Date of Collection	2014-APR-06
Timepoint-minutes	
Urine Start Day	2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 2

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (1)

Data signed: (hfarmer1) 30 Mar 2015 13:34:19

Generated On: 20 Jul 2016 22:28:45

Urine End Day

3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 2

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (2)

Data signed: (hfarmer1) 30 Mar 2015 13:34:19

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112510001732
Analyte	2-NA
Sample type	URINE
Result	2.98
Result Unit	PG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	2
Celerion Study Number	AA99128-09
Date of Collection	2014-APR-06
Timepoint-minutes	
Urine Start Day	2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 2

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (2)

Data signed: (hfarmer1) 30 Mar 2015 13:34:19

Generated On: 20 Jul 2016 22:28:45

Urine End Day

3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 2

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (3)

Data signed: (hfarmer1) 30 Mar 2015 13:34:19

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112510001732
Analyte	4-ABP
Sample type	URINE
Result	5.71
Result Unit	PG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	2
Celerion Study Number	AA99128-09
Date of Collection	2014-APR-06
Timepoint-minutes	
Urine Start Day	2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 2

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (3)

Data signed: (hfarmer1) 30 Mar 2015 13:34:19

Generated On: 20 Jul 2016 22:28:45

Urine End Day

3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 2

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (4)

Data signed: (hfarmer1) 30 Mar 2015 13:34:19

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112510001732
Analyte	O-TOL
Sample type	URINE
Result	BLQ<(50.0)
Result Unit	PG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	2
Celerion Study Number	AA99128-09
Date of Collection	2014-APR-06
Timepoint-minutes	
Urine Start Day	2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 2

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (4)

Data signed: (hfarmer1) 30 Mar 2015 13:34:19

Generated On: 20 Jul 2016 22:28:45

Urine End Day

3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 2

Form: Biomarker-Urine (1-OHP)

Data signed: (hfarmer1) 30 Mar 2015 13:34:19

Generated On: 20 Jul 2016 22:28:45

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 2

Form: Biomarker-Urine (1-OHP) (1)

Data signed: (hfarmer1) 30 Mar 2015 13:34:19

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05115190003734
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Analyte	1-OHP
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Sample type	URINE
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Result	.
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Result Unit	PG/ML
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Lab Status	OK
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Sample comment	NOT ANALYZED IN ERROR
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Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
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Day of Visit	2
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Celerion Study Number	AA99598-03
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Date of Collection	2014-APR-06
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Timepoint-minutes	
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Urine Start Day	2
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 2

Form: Biomarker-Urine (1-OHP) (1)

Data signed: (hfarmer1) 30 Mar 2015 13:34:19

Generated On: 20 Jul 2016 22:28:45

Urine End Day

3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 2

Form: Biomarker-Urine (SPMA, SBMA)

Data signed: (hfarmer1) 30 Mar 2015 13:34:16

Generated On: 20 Jul 2016 22:28:45

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 2

Form: Biomarker-Urine (SPMA, SBMA) (1)

Data signed: (hfarmer1) 30 Mar 2015 13:34:16

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05115170003725
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Analyte	SPMA
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Sample type	URINE
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Result	.
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Result Unit	NG/ML
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Lab Status	OK
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Sample comment	NOT ANALYZED IN ERROR
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Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
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Day of Visit	2
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Celerion Study Number	AA99598-01
-----------------------	------------

Date of Collection	2014-APR-06
--------------------	-------------

Timepoint-minutes	
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Urine Start Day	2
-----------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 2

Form: Biomarker-Urine (SPMA, SBMA) (1)

Data signed: (hfarmer1) 30 Mar 2015 13:34:16

Generated On: 20 Jul 2016 22:28:45

Urine End Day

3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 2

Form: Biomarker-Urine (SPMA, SBMA) (2)

Data signed: (hfarmer1) 30 Mar 2015 13:34:16

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05115170003734
----------------	----------------

Analyte	SBMA
---------	------

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

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

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

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

Sample comment	NOT ANALYZED IN ERROR
----------------	-----------------------

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	2
--------------	---

Celerion Study Number	AA99598-01
-----------------------	------------

Date of Collection	2014-APR-06
--------------------	-------------

Timepoint-minutes	
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Urine Start Day	2
-----------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 2

Form: Biomarker-Urine (SPMA, SBMA) (2)

Data signed: (hfarmer1) 30 Mar 2015 13:34:16

Generated On: 20 Jul 2016 22:28:45

Urine End Day

3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 2

Form: Biomarker-Urine (MHBMA)

Data signed: (hfarmer1) 30 Mar 2015 13:34:16

Generated On: 20 Jul 2016 22:28:45

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 2

Form: Biomarker-Urine (MHBMA) (1)

Data signed: (hfarmer1) 30 Mar 2015 13:34:16

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05115180003734
Analyte	MHBMA
Sample type	URINE
Result	.
Result Unit	NG/ML
Lab Status	OK
Sample comment	NOT ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	2
Celerion Study Number	AA99598-02
Date of Collection	2014-APR-06
Timepoint-minutes	
Urine Start Day	2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 2

Form: Biomarker-Urine (MHBMA) (1)

Data signed: (hfarmer1) 30 Mar 2015 13:34:16

Generated On: 20 Jul 2016 22:28:45

Urine End Day

3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 2

Form: Biomarker-Urine (Creatinine)

Data signed: (hfarmer1) 30 Mar 2015 13:34:19

Generated On: 20 Jul 2016 22:28:45

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 2

Form: Biomarker-Urine (Creatinine) (1)

Data signed: (hfarmer1) 30 Mar 2015 13:34:19

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05115160001710
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Analyte	CREATININE
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Sample type	URINE
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Result	.
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Result Unit	MG/DL
-------------	-------

Lab Status	OK
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Sample comment	ANALYSIS NOT PERFORMED IN ERROR
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Detection method	SPECTROPHOTOMETRIC
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Planned time point (Hour)	0
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Day of Visit	2
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Celerion Study Number	AA99128-14
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Date of Collection	2014-APR-06
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Timepoint-minutes	
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 2

Form: Biomarker-Urine (Creatinine) (1)

Data signed: (hfarmer1) 30 Mar 2015 13:34:19

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Day 2

Form: Biomarker-Plasma (Nic, Cot, tHCot)

Data signed: (hfarmer1) 30 Mar 2015 13:34:16

Generated On: 20 Jul 2016 22:28:45

Sample type

PLASMA

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 2

Form: Biomarker-Plasma (Nic, Cot, tHCot) (1)

Data signed: (hfarmer1) 30 Mar 2015 13:34:16

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112430001808
Analyte	COT
Sample type	PLASMA
Result	238
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	2
Celerion Study Number	AA99128-01
Date of Collection	2014-APR-06
Timepoint-minutes	0
Urine Start Day	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 2

Form: Biomarker-Plasma (Nic, Cot, tHCot) (1)

Data signed: (hfarmer1) 30 Mar 2015 13:34:16

Generated On: 20 Jul 2016 22:28:45

Urine End Day

2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 2

Form: Biomarker-Plasma (Nic, Cot, tHCot) (2)

Data signed: (hfarmer1) 30 Mar 2015 13:34:16

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112430001808
----------------	----------------

Analyte	NIC
---------	-----

Sample type	PLASMA
-------------	--------

Result	18.2
--------	------

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

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

Sample comment	ANALYZED IN ERROR
----------------	-------------------

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	2
--------------	---

Celerion Study Number	AA99128-01
-----------------------	------------

Date of Collection	2014-APR-06
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Timepoint-minutes	0
-------------------	---

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 2

Form: Biomarker-Plasma (Nic, Cot, tHCot) (2)

Data signed: (hfarmer1) 30 Mar 2015 13:34:16

Generated On: 20 Jul 2016 22:28:45

Urine End Day

2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 3

Form: Date of Visit

Data signed: (hfarmer1) 30 Mar 2015 13:34:20

Generated On: 20 Jul 2016 22:28:45

Date of Visit

07 APR 2014
DD/MMM/YYYY

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 3

Form: Vital Signs

Data signed: (hfarmer1) 30 Mar 2015 13:34:20

Generated On: 20 Jul 2016 22:28:45

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 10:11
hour:min 24-hour clock

Pulse rate 61
beats per minute

Respiratory rate 20
breaths per minute

Blood Pressure (systolic) 121
mmHg

Blood Pressure (diastolic) 73
mmHg

Vital Signs Position of Subject Supine ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 3

Form: Plasma Nicotine Sample

Data signed: (hfarmer1) 30 Mar 2015 13:34:19

Generated On: 20 Jul 2016 22:28:45

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	07 APR 2014
---------------------	-------------

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 3

Form: Plasma Cotinine Sample

Data signed: (hfarmer1) 30 Mar 2015 13:34:19

Generated On: 20 Jul 2016 22:28:45

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	07 APR 2014
---------------------	-------------

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 3

Form: CoHb Blood Sample

Data signed: (hfarmer1) 30 Mar 2015 13:34:19

Generated On: 20 Jul 2016 22:28:45

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	07 APR 2014
---------------------	-------------

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

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 3

Form: CO Breath Test (1)

Data signed: (hfarmer1) 30 Mar 2015 13:34:20

Generated On: 20 Jul 2016 22:28:45

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

If Not Done, please specify the reason: _____

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

Actual Time of Assessment hour:min 24-hour clock	06:28
---	-------

Result(ppm)	2
-------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 3

Form: CO Breath Test (2)

Data signed: (hfarmer1) 30 Mar 2015 13:34:20

Generated On: 20 Jul 2016 22:28:45

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	12:16
---	-------

Result(ppm)	2
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 3

Form: CO Breath Test (3)

Data signed: (hfarmer1) 30 Mar 2015 13:34:20

Generated On: 20 Jul 2016 22:28:45

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

If Not Done, please specify the reason: _____

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

Actual Time of Assessment hour:min 24-hour clock	16:08
---	-------

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 3

Form: CO Breath Test (4)

Data signed: (hfarmer1) 30 Mar 2015 13:34:20

Generated On: 20 Jul 2016 22:28:45

Assessment not done	False
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If Not Done, please specify the reason: _____

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

Actual Time of Assessment hour:min 24-hour clock	20:26
---	-------

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 3

Form: 24 hour urine collections

Data signed: (hfarmer1) 30 Mar 2015 13:34:20

Generated On: 20 Jul 2016 22:28:45

Start Time	06:06
	hour:min 24-hour clock

End Date	08 APR 2014
	DD/MMM/YYYY

End Time	06:08
	hour:min 24-hour clock

Volume	3048
	mL

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 3

Form: Sample Urine Collection

Data signed: (hfarmer1) 30 Mar 2015 13:34:19

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Day 3

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Data signed: (hfarmer1) 30 Mar 2015 13:34:21

Generated On: 20 Jul 2016 22:28:45

Date of Birth

(b) (6)

Date of assessment
DD/MMM/YYYY

2014 APR 07
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?

None ☐

1. Angry, irritable, frustrated

How have you been feeling over the past 24 hours?

Slight ☐

2. Anxious, nervous

How have you been feeling over the past 24 hours?

None ☐

3. Depressed Mood, sad

How have you been feeling over the past 24 hours?

Slight ☐

4. Desire or craving to smoke

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Day 3

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Data signed: (hfarmer1) 30 Mar 2015 13:34:21

Generated On: 20 Jul 2016 22:28:45

How have you been feeling over the past 24 hours? None ☐

5. Difficulty concentrating

How have you been feeling over the past 24 hours? Slight ☐

6. Increased appetite, hungry, weight gain

How have you been feeling over the past 24 hours? Slight ☐

7. Insomnia, sleep problems, awakening at night

How have you been feeling over the past 24 hours? 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: 1252**

Folder: Day 3

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Data signed: (hfarmer1) 30 Mar 2015 13:34:21

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Day 3

Form: Cough Assessment

Data signed: (hfarmer1) 30 Mar 2015 13:34:21

Generated On: 20 Jul 2016 22:28:45

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

Date of assessment DD/MMM/YYYY	2014 APR 07 DD/MMM/YYYY
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Time of assessment	06:02 hour:min 24-hour clock
--------------------	---------------------------------

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

Have you experienced a regular need to cough e.g. coughing several times in the last 24 hrs?	Yes <input checked="" type="radio"/>
---	--------------------------------------

If YES, please answer the following questions:

First Question: Cough Impact Scale How much is your cough bothering you?	47
---	----

Second Question: Cough Intensity Scale: How intense is your cough?	Mild <input checked="" type="radio"/>
---	---------------------------------------

Third Question: Cough Frequency Scale: How frequently do you normally have to cough each day?	Fairly often <input checked="" type="radio"/>
---	---

Fourth Question: Sputum Production To what extent do you produce sputum when coughing?	A moderate amount of sputum <input checked="" type="radio"/>
---	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 3

Form: Lab_BU_COHB (1)

Data signed: (hfarmer1) 30 Mar 2015 13:34:21

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05115150004502
Analyte	CARBOXYHEMOGLOBIN
Sample type	BLOOD
Result	2.40
Result Unit	%
Lab Status	OK
Sample comment	.
Detection method	SPECTROPHOTOMETRIC
Lower limit of quantification	0.500
Planned time point (Hour)	20
Day of Visit	3
Celerion Study Number	AA99128-16
Date of Collection	2014-APR-07
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 3

Form: Lab_BU_COHB (1)

Data signed: (hfarmer1) 30 Mar 2015 13:34:21

Generated On: 20 Jul 2016 22:28:45

Start Day (24 hour urine only) _____

End Day (24 hour Urine Only) _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 3

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)

Data signed: (hfarmer1) 30 Mar 2015 13:34:21

Generated On: 20 Jul 2016 22:28:45

Date of Birth

(b) (6)

Date of assessment

2014 APR 07

DD/MMM/YYYY

DD/MMM/YYYY

Time of assessment

20:04

hour:min 24-hour clock

Assessment Status

Completed ☒

1. Was smoking satisfying?

Extremely ☐

2. Did cigarettes taste good?

Not at all ☐

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

Not at all ☐

4. Did smoking calm you down?

Not at all ☐

5. Did smoking make you feel more awake?

Not at all ☐

6. Did smoking make you feel less irritable?

Extremely ☐

7. Did smoking help you concentrate?

Not at all ☐

8. Did smoking reduce your hunger for food?

Moderately ☐

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 3

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)

Data signed: (hfarmer1) 30 Mar 2015 13:34:21

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Day 3

Form: Questionnaire on smoking urges (QSU)

Data signed: (hfarmer1) 30 Mar 2015 13:34:21

Generated On: 20 Jul 2016 22:28:45

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

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

Date of assessment	2014 APR 07
--------------------	-------------

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

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

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

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

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

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 3

Form: Questionnaire on smoking urges (QSU)

Data signed: (hfarmer1) 30 Mar 2015 13:34:21

Generated On: 20 Jul 2016 22:28:45

7. A cigarette would taste good now Strongly disagree ☐

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

9. Smoking would make me less depressed Strongly disagree ☐

10. I am going to smoke as soon as possible Strongly agree ☐

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 3

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

Data signed: (hfarmer1) 30 Mar 2015 13:34:22

Generated On: 20 Jul 2016 22:28:45

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 3

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

Data signed: (hfarmer1) 30 Mar 2015 13:34:22

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112450002856
Analyte	HPMA
Sample type	URINE
Result	207
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	3
Celerion Study Number	AA99128-03
Date of Collection	2014-APR-07
Timepoint-minutes	
Urine Start Day	3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 3

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

Data signed: (hfarmer1) 30 Mar 2015 13:34:22

Generated On: 20 Jul 2016 22:28:45

Urine End Day

4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 3

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

Data signed: (hfarmer1) 30 Mar 2015 13:34:22

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112450002856
Analyte	CEMA
Sample type	URINE
Result	34.4
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	3
Celerion Study Number	AA99128-03
Date of Collection	2014-APR-07
Timepoint-minutes	
Urine Start Day	3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 3

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

Data signed: (hfarmer1) 30 Mar 2015 13:34:22

Generated On: 20 Jul 2016 22:28:45

Urine End Day

4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 3

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

Data signed: (hfarmer1) 30 Mar 2015 13:34:22

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112450002856
Analyte	HBMA
Sample type	URINE
Result	132
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	3
Celerion Study Number	AA99128-03
Date of Collection	2014-APR-07
Timepoint-minutes	
Urine Start Day	3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 3

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

Data signed: (hfarmer1) 30 Mar 2015 13:34:22

Generated On: 20 Jul 2016 22:28:45

Urine End Day

4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 3

Form: Biomarker-Urine (NNN, NNAL)

Data signed: (hfarmer1) 30 Mar 2015 13:34:22

Generated On: 20 Jul 2016 22:28:45

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 3

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

Data signed: (hfarmer1) 30 Mar 2015 13:34:22

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112460003427
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Analyte	NNAL
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Sample type	URINE
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Result	.
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Result Unit	PG/ML
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Lab Status	OK
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Sample comment	ANALYSIS NOT PERFORMED IN ERROR
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Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	3
--------------	---

Celerion Study Number	AA99128-04
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Date of Collection	2014-APR-07
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Timepoint-minutes	
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 3

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

Data signed: (hfarmer1) 30 Mar 2015 13:34:22

Generated On: 20 Jul 2016 22:28:45

Urine Start Day	3
-----------------	---

Urine End Day	4
---------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 3

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

Data signed: (hfarmer1) 30 Mar 2015 13:34:22

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112460003427
----------------	----------------

Analyte	NNN
---------	-----

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

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

Result Unit	PG/ML
-------------	-------

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

Sample comment	ANALYSIS NOT PERFORMED IN ERROR
----------------	------------------------------------

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	3
--------------	---

Celerion Study Number	AA99128-04
-----------------------	------------

Date of Collection	2014-APR-07
--------------------	-------------

Timepoint-minutes	
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 3

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

Data signed: (hfarmer1) 30 Mar 2015 13:34:22

Generated On: 20 Jul 2016 22:28:45

Urine Start Day	3
-----------------	---

Urine End Day	4
---------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 3

Form: Biomarker-Urine (HEMA)

Data signed: (hfarmer1) 30 Mar 2015 13:34:22

Generated On: 20 Jul 2016 22:28:45

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 3

Form: Biomarker-Urine (HEMA) (1)

Data signed: (hfarmer1) 30 Mar 2015 13:34:22

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112470001711
Analyte	HEMA
Sample type	URINE
Result	0.375
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	3
Celerion Study Number	AA99128-05
Date of Collection	2014-APR-07
Timepoint-minutes	
Urine Start Day	3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 3

Form: Biomarker-Urine (HEMA) (1)

Data signed: (hfarmer1) 30 Mar 2015 13:34:22

Generated On: 20 Jul 2016 22:28:45

Urine End Day

4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 3

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

Data signed: (hfarmer1) 30 Mar 2015 13:34:22

Generated On: 20 Jul 2016 22:28:45

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 3

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

Data signed: (hfarmer1) 30 Mar 2015 13:34:22

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112480000776
Analyte	COT
Sample type	URINE
Result	1370
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	3
Celerion Study Number	AA99128-06
Date of Collection	2014-APR-08
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 3

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

Data signed: (hfarmer1) 30 Mar 2015 13:34:22

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Day 3

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

Data signed: (hfarmer1) 30 Mar 2015 13:34:22

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112480000776
Analyte	COT-GLUC
Sample type	URINE
Result	3670
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	3
Celerion Study Number	AA99128-06
Date of Collection	2014-APR-08
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 3

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

Data signed: (hfarmer1) 30 Mar 2015 13:34:22

Generated On: 20 Jul 2016 22:28:45

Urine Start Day	3
-----------------	---

Urine End Day	4
---------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 3

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

Data signed: (hfarmer1) 30 Mar 2015 13:34:22

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112480000776
Analyte	NIC
Sample type	URINE
Result	516
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	3
Celerion Study Number	AA99128-06
Date of Collection	2014-APR-08
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 3

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

Data signed: (hfarmer1) 30 Mar 2015 13:34:22

Generated On: 20 Jul 2016 22:28:45

Urine Start Day	3
-----------------	---

Urine End Day	4
---------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 3

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

Data signed: (hfarmer1) 30 Mar 2015 13:34:22

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112480000776
Analyte	NIC-GLUC
Sample type	URINE
Result	591
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	3
Celerion Study Number	AA99128-06
Date of Collection	2014-APR-08
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 3

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

Data signed: (hfarmer1) 30 Mar 2015 13:34:22

Generated On: 20 Jul 2016 22:28:45

Urine Start Day	3
-----------------	---

Urine End Day	4
---------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 3

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

Data signed: (hfarmer1) 30 Mar 2015 13:34:22

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112480000776
Analyte	THCOT
Sample type	URINE
Result	2920
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	3
Celerion Study Number	AA99128-06
Date of Collection	2014-APR-08
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 3

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

Data signed: (hfarmer1) 30 Mar 2015 13:34:22

Generated On: 20 Jul 2016 22:28:45

Urine Start Day	3
-----------------	---

Urine End Day	4
---------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 3

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(6)**

Data signed: (hfarmer1) 30 Mar 2015 13:34:22

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112480000776
Analyte	THCOT-GLUC
Sample type	URINE
Result	1940
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	3
Celerion Study Number	AA99128-06
Date of Collection	2014-APR-08
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 3

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(6)**

Data signed: (hfarmer1) 30 Mar 2015 13:34:22

Generated On: 20 Jul 2016 22:28:45

Urine Start Day	3
-----------------	---

Urine End Day	4
---------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 3

Form: Biomarker-Urine (3-OH BaP)

Data signed: (hfarmer1) 30 Mar 2015 13:34:22

Generated On: 20 Jul 2016 22:28:45

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 3

Form: Biomarker-Urine (3-OH BaP) (1)

Data signed: (hfarmer1) 30 Mar 2015 13:34:22

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112490001711
----------------	----------------

Analyte	3-OH BAP
---------	----------

Sample type	URINE
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Result	.
--------	---

Result Unit	FG/ML
-------------	-------

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

Sample comment	ANALYSIS NOT PERFORMED IN ERROR
----------------	------------------------------------

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	3
--------------	---

Celerion Study Number	AA99128-07
-----------------------	------------

Date of Collection	2014-APR-07
--------------------	-------------

Timepoint-minutes	
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 3

Form: Biomarker-Urine (3-OH BaP) (1)

Data signed: (hfarmer1) 30 Mar 2015 13:34:22

Generated On: 20 Jul 2016 22:28:45

Urine Start Day	3
-----------------	---

Urine End Day	4
---------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 3

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP)

Data signed: (hfarmer1) 30 Mar 2015 13:34:22

Generated On: 20 Jul 2016 22:28:45

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 3

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (1)

Data signed: (hfarmer1) 30 Mar 2015 13:34:22

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112510001733
Analyte	1-NA
Sample type	URINE
Result	2.93
Result Unit	PG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	3
Celerion Study Number	AA99128-09
Date of Collection	2014-APR-07
Timepoint-minutes	
Urine Start Day	3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 3

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (1)

Data signed: (hfarmer1) 30 Mar 2015 13:34:22

Generated On: 20 Jul 2016 22:28:45

Urine End Day

4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 3

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (2)

Data signed: (hfarmer1) 30 Mar 2015 13:34:22

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112510001733
Analyte	2-NA
Sample type	URINE
Result	BLQ<(2.50)
Result Unit	PG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	3
Celerion Study Number	AA99128-09
Date of Collection	2014-APR-07
Timepoint-minutes	
Urine Start Day	3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 3

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (2)

Data signed: (hfarmer1) 30 Mar 2015 13:34:22

Generated On: 20 Jul 2016 22:28:45

Urine End Day

4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 3

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (3)

Data signed: (hfarmer1) 30 Mar 2015 13:34:22

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112510001733
Analyte	4-ABP
Sample type	URINE
Result	2.79
Result Unit	PG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	3
Celerion Study Number	AA99128-09
Date of Collection	2014-APR-07
Timepoint-minutes	
Urine Start Day	3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 3

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (3)

Data signed: (hfarmer1) 30 Mar 2015 13:34:22

Generated On: 20 Jul 2016 22:28:45

Urine End Day

4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 3

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (4)

Data signed: (hfarmer1) 30 Mar 2015 13:34:22

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112510001733
Analyte	O-TOL
Sample type	URINE
Result	BLQ<(50.0)
Result Unit	PG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	3
Celerion Study Number	AA99128-09
Date of Collection	2014-APR-07
Timepoint-minutes	
Urine Start Day	3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 3

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (4)

Data signed: (hfarmer1) 30 Mar 2015 13:34:22

Generated On: 20 Jul 2016 22:28:45

Urine End Day

4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 3

Form: Biomarker-Urine (1-OHP)

Data signed: (hfarmer1) 30 Mar 2015 13:34:23

Generated On: 20 Jul 2016 22:28:45

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 3

Form: Biomarker-Urine (1-OHP) (1)

Data signed: (hfarmer1) 30 Mar 2015 13:34:23

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05115190003735
----------------	----------------

Analyte	1-OHP
---------	-------

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

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

Result Unit	PG/ML
-------------	-------

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

Sample comment	NOT ANALYZED IN ERROR
----------------	-----------------------

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	3
--------------	---

Celerion Study Number	AA99598-03
-----------------------	------------

Date of Collection	2014-APR-07
--------------------	-------------

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

Urine Start Day	3
-----------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 3

Form: Biomarker-Urine (1-OHP) (1)

Data signed: (hfarmer1) 30 Mar 2015 13:34:23

Generated On: 20 Jul 2016 22:28:45

Urine End Day

4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 3

Form: Biomarker-Urine (SPMA, SBMA)

Data signed: (hfarmer1) 30 Mar 2015 13:34:22

Generated On: 20 Jul 2016 22:28:45

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 3

Form: Biomarker-Urine (SPMA, SBMA) (1)

Data signed: (hfarmer1) 30 Mar 2015 13:34:22

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05115170003726
----------------	----------------

Analyte	SPMA
---------	------

Sample type	URINE
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Result	.
--------	---

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

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

Sample comment	NOT ANALYZED IN ERROR
----------------	-----------------------

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	3
--------------	---

Celerion Study Number	AA99598-01
-----------------------	------------

Date of Collection	2014-APR-07
--------------------	-------------

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

Urine Start Day	3
-----------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 3

Form: Biomarker-Urine (SPMA, SBMA) (1)

Data signed: (hfarmer1) 30 Mar 2015 13:34:22

Generated On: 20 Jul 2016 22:28:45

Urine End Day

4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 3

Form: Biomarker-Urine (SPMA, SBMA) (2)

Data signed: (hfarmer1) 30 Mar 2015 13:34:22

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05115170003735
----------------	----------------

Analyte	SBMA
---------	------

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

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

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

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

Sample comment	NOT ANALYZED IN ERROR
----------------	-----------------------

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	3
--------------	---

Celerion Study Number	AA99598-01
-----------------------	------------

Date of Collection	2014-APR-07
--------------------	-------------

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

Urine Start Day	3
-----------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 3

Form: Biomarker-Urine (SPMA, SBMA) (2)

Data signed: (hfarmer1) 30 Mar 2015 13:34:22

Generated On: 20 Jul 2016 22:28:45

Urine End Day

4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 3

Form: Biomarker-Urine (MHBMA)

Data signed: (hfarmer1) 30 Mar 2015 13:34:22

Generated On: 20 Jul 2016 22:28:45

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 3

Form: Biomarker-Urine (MHBMA) (1)

Data signed: (hfarmer1) 30 Mar 2015 13:34:22

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05115180003735
Analyte	MHBMA
Sample type	URINE
Result	.
Result Unit	NG/ML
Lab Status	OK
Sample comment	NOT ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	3
Celerion Study Number	AA99598-02
Date of Collection	2014-APR-07
Timepoint-minutes	
Urine Start Day	3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 3

Form: Biomarker-Urine (MHBMA) (1)

Data signed: (hfarmer1) 30 Mar 2015 13:34:22

Generated On: 20 Jul 2016 22:28:45

Urine End Day

4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 3

Form: Biomarker-Urine (Creatinine)

Data signed: (hfarmer1) 30 Mar 2015 13:34:23

Generated On: 20 Jul 2016 22:28:45

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 3

Form: Biomarker-Urine (Creatinine) (1)

Data signed: (hfarmer1) 30 Mar 2015 13:34:23

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05115160001711
----------------	----------------

Analyte	CREATININE
---------	------------

Sample type	URINE
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Result	.
--------	---

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

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

Sample comment	ANALYSIS NOT PERFORMED IN ERROR
----------------	------------------------------------

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

Planned time point (Hour)	0
---------------------------	---

Day of Visit	3
--------------	---

Celerion Study Number	AA99128-14
-----------------------	------------

Date of Collection	2014-APR-07
--------------------	-------------

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 3

Form: Biomarker-Urine (Creatinine) (1)

Data signed: (hfarmer1) 30 Mar 2015 13:34:23

Generated On: 20 Jul 2016 22:28:45

Urine Start Day	3
-----------------	---

Urine End Day	4
---------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 3

Form: Biomarker-Plasma (Nic, Cot, tHCot)

Data signed: (hfarmer1) 30 Mar 2015 13:34:22

Generated On: 20 Jul 2016 22:28:45

Sample type

PLASMA

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 3

Form: Biomarker-Plasma (Nic, Cot, tHCot) (1)

Data signed: (hfarmer1) 30 Mar 2015 13:34:22

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112430001809
Analyte	COT
Sample type	PLASMA
Result	315
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	3
Celerion Study Number	AA99128-01
Date of Collection	2014-APR-07
Timepoint-minutes	0
Urine Start Day	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 3

Form: Biomarker-Plasma (Nic, Cot, tHCot) (1)

Data signed: (hfarmer1) 30 Mar 2015 13:34:22

Generated On: 20 Jul 2016 22:28:45

Urine End Day

3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 3

Form: Biomarker-Plasma (Nic, Cot, tHCot) (2)

Data signed: (hfarmer1) 30 Mar 2015 13:34:22

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112430001809
Analyte	NIC
Sample type	PLASMA
Result	21.8
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	3
Celerion Study Number	AA99128-01
Date of Collection	2014-APR-07
Timepoint-minutes	0
Urine Start Day	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 3

Form: Biomarker-Plasma (Nic, Cot, tHCot) (2)

Data signed: (hfarmer1) 30 Mar 2015 13:34:22

Generated On: 20 Jul 2016 22:28:45

Urine End Day

3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 4

Form: Date of Visit

Data signed: (hfarmer1) 30 Mar 2015 13:34:23

Generated On: 20 Jul 2016 22:28:45

Date of Visit

08 APR 2014
DD/MMM/YYYY

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 4

Form: Vital Signs

Data signed: (hfarmer1) 30 Mar 2015 13:34:23

Generated On: 20 Jul 2016 22:28:45

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

10:25
hour:min 24-hour clock

Pulse rate

64
beats per minute

Respiratory rate

14
breaths per minute

Blood Pressure (systolic)

118
mmHg

Blood Pressure (diastolic)

73
mmHg

Vital Signs Position of Subject

Supine ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 4

Form: Socio-Economic Status

Data signed: (hfarmer1) 30 Mar 2015 13:34:23

Generated On: 20 Jul 2016 22:28:45

Was paper questionnaire used? Yes ☒

Reason not done _____

Date 08 APR 2014
DD/MMM/YYYY

Time 06:21
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? Retired ☒

SPECIFY _____

Q3. How many people are currently living in your household, including yourself? 02

Q4. Of these people, how many are children? 00

Q5. Of these people, how many are adults? 02

Q6. Of the adults, how many bring income into the household? 02

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 4

Form: Socio-Economic Status

Data signed: (hfarmer1) 30 Mar 2015 13:34:23

Generated On: 20 Jul 2016 22:28:45

Q7. Which of these categories best describes your total combined family income for the past 12 months? This should include income (before taxes) from all sources, wages, rent from properties, social security, disability and/or veteran's benefits, unemployment benefits, workman's compensation, help from relatives (including child payments and alimony), and so on.

\$10,000 to \$29,999 ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 4

Form: Plasma Nicotine Sample

Data signed: (hfarmer1) 30 Mar 2015 13:34:23

Generated On: 20 Jul 2016 22:28:45

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	08 APR 2014
---------------------	-------------

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 4

Form: Plasma Cotinine Sample

Data signed: (hfarmer1) 30 Mar 2015 13:34:23

Generated On: 20 Jul 2016 22:28:45

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	08 APR 2014
---------------------	-------------

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 4

Form: CoHb Blood Sample

Data signed: (hfarmer1) 30 Mar 2015 13:34:23

Generated On: 20 Jul 2016 22:28:45

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	08 APR 2014
---------------------	-------------

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

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 4

Form: CO Breath Test (1)

Data signed: (hfarmer1) 30 Mar 2015 13:34:23

Generated On: 20 Jul 2016 22:28:45

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	07:12
---	-------

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 4

Form: CO Breath Test (2)

Data signed: (hfarmer1) 30 Mar 2015 13:34:23

Generated On: 20 Jul 2016 22:28:45

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

If Not Done, please specify the reason: _____

Scheduled Time	12:00 - 13:30 <input checked="" type="radio"/>
----------------	--

Actual Time of Assessment hour:min 24-hour clock	12:09
---	-------

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 4

Form: CO Breath Test (3)

Data signed: (hfarmer1) 30 Mar 2015 13:34:23

Generated On: 20 Jul 2016 22:28:45

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	16:13
---	-------

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 4

Form: CO Breath Test (4)

Data signed: (hfarmer1) 30 Mar 2015 13:34:23

Generated On: 20 Jul 2016 22:28:45

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	20:24
---	-------

Result(ppm)	1
-------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 4

Form: 24 hour urine collections

Data signed: (hfarmer1) 30 Mar 2015 13:34:23

Generated On: 20 Jul 2016 22:28:45

Start Time	06:08
	hour:min 24-hour clock

End Date	09 APR 2014
	DD/MMM/YYYY

End Time	06:02
	hour:min 24-hour clock

Volume	2792
	mL

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 4

Form: Sample Urine Collection

Data signed: (hfarmer1) 30 Mar 2015 13:34:23

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Day 4

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Data signed: (hfarmer1) 30 Mar 2015 13:34:24

Generated On: 20 Jul 2016 22:28:45

Date of Birth

(b) (6)

Date of assessment
DD/MMM/YYYY

2014 APR 08
DD/MMM/YYYY

Time of assessment

06:05
hour:min 24-hour clock

Assessment Status

Completed ☒

Please indicate for each of the items below, how you have been feeling over the past 24 hours

How have you been feeling over the past 24 hours?

Slight ☒

1. Angry, irritable, frustrated

How have you been feeling over the past 24 hours?

Moderate ☒

2. Anxious, nervous

How have you been feeling over the past 24 hours?

None ☒

3. Depressed Mood, sad

How have you been feeling over the past 24 hours?

Moderate ☒

4. Desire or craving to smoke

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 4

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Data signed: (hfarmer1) 30 Mar 2015 13:34:24

Generated On: 20 Jul 2016 22:28:45

How have you been feeling over the past 24 hours? None ☐

5. Difficulty concentrating

How have you been feeling over the past 24 hours? None ☐

6. Increased appetite, hungry, weight gain

How have you been feeling over the past 24 hours? None ☐

7. Insomnia, sleep problems, awakening at night

How have you been feeling over the past 24 hours? Moderate ☐

8. Restless

How have you been feeling over the past 24 hours? Moderate ☐

9. Impatient

How have you been feeling over the past 24 hours? None ☐

10. Constipation

How have you been feeling over the past 24 hours? None ☐

11. Dizziness

How have you been feeling over the past 24 hours? Mild ☐

12. Coughing

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 4

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Data signed: (hfarmer1) 30 Mar 2015 13:34:24

Generated On: 20 Jul 2016 22:28:45

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: 1252

Folder: Day 4

Form: Cough Assessment

Data signed: (hfarmer1) 30 Mar 2015 13:34:23

Generated On: 20 Jul 2016 22:28:45

Date of Birth

(b) (6)

Date of assessment
DD/MMM/YYYY

2014 APR 08
DD/MMM/YYYY

Time of assessment

06:03
hour:min 24-hour clock

Assessment Status

Completed ☒

Have you experienced a regular need to cough e.g.
coughing several times in the last 24 hrs?

Yes ☒

If YES, please answer the following questions:

First Question: Cough Impact Scale
How much is your cough bothering you?

64

Second Question: Cough Intensity Scale:
How intense is your cough?

Moderate ☒

Third Question: Cough Frequency Scale:
How frequently do you normally have to cough each
day?

Fairly often ☒

Fourth Question: Sputum Production
To what extent do you produce sputum when coughing?

A moderate amount of
sputum ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 4

Form: Lab_BU_COHB (1)

Data signed: (hfarmer1) 30 Mar 2015 13:34:24

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05115150004503
Analyte	CARBOXYHEMOGLOBIN
Sample type	BLOOD
Result	2.60
Result Unit	%
Lab Status	OK
Sample comment	.
Detection method	SPECTROPHOTOMETRIC
Lower limit of quantification	0.500
Planned time point (Hour)	20
Day of Visit	4
Celerion Study Number	AA99128-16
Date of Collection	2014-APR-08
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 4

Form: Lab_BU_COHB (1)

Data signed: (hfarmer1) 30 Mar 2015 13:34:24

Generated On: 20 Jul 2016 22:28:45

Start Day (24 hour urine only) _____

End Day (24 hour Urine Only) _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 4

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)

Data signed: (hfarmer1) 30 Mar 2015 13:34:23

Generated On: 20 Jul 2016 22:28:45

Date of Birth

(b) (6)

Date of assessment

2014 APR 08

DD/MMM/YYYY

DD/MMM/YYYY

Time of assessment

20:02

hour:min 24-hour clock

Assessment Status

Completed ☒

1. Was smoking satisfying?

Moderately ☐

2. Did cigarettes taste good?

Not at all ☐

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

Not at all ☐

4. Did smoking calm you down?

Not at all ☐

5. Did smoking make you feel more awake?

Not at all ☐

6. Did smoking make you feel less irritable?

Not at all ☐

7. Did smoking help you concentrate?

Not at all ☐

8. Did smoking reduce your hunger for food?

Little ☐

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 4

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)

Data signed: (hfarmer1) 30 Mar 2015 13:34:23

Generated On: 20 Jul 2016 22:28:45

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: 1252

Folder: Day 4

Form: Human Smoking Topography Questionnaire

Data signed: (hfarmer1) 30 Mar 2015 13:34:23

Generated On: 20 Jul 2016 22:28:45

Type	HUMAN SMOKING TOPOGRAPHY QUESTIONNAIRE
------	--

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

Reason not done	
-----------------	--

Date of assessment	08 APR 2014 DD/MMM/YYYY
--------------------	----------------------------

Time of assessment	20:25 hour:min 24-hour clock
--------------------	---------------------------------

How do you agree with the following sentences/affirmations :

1. The smoking of the conventional cigarettes/products is different with the device.	Strongly agree <input checked="" type="radio"/>
--	---

If you agree or strongly agree, please describe :	IT'S DIFFICULT TO USE AND CHANGES THE TASTE.
---	---

2. You enjoy smoking with the device as much as without it.	Strongly disagree <input checked="" type="radio"/>
---	--

If you disagree or strongly disagree, please describe :	IT'S JUST A HASSLE
---	--------------------

3. The taste of the conventional cigarettes/products is different with the device.	Strongly agree <input checked="" type="radio"/>
--	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 4

Form: Human Smoking Topography Questionnaire

Data signed: (hfarmer1) 30 Mar 2015 13:34:23

Generated On: 20 Jul 2016 22:28:45

If you agree or strongly agree, please describe : MENTHAL DOES NOT TASTE
AS STRONG

4. The device is easy to use. Agree ☒

If you disagree or strongly disagree, please describe : _____

5. Your smoking is disturbed by the device. Strongly agree ☒

If you agree or strongly agree, please describe : I'M NOT USED TO IT.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 4

Form: Questionnaire on smoking urges (QSU)

Data signed: (hfarmer1) 30 Mar 2015 13:34:24

Generated On: 20 Jul 2016 22:28:45

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

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

Date of assessment	2014 APR 08
--------------------	-------------

DD/MMM/YYYY

Time of assessment	20:01
--------------------	-------

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

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

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

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

6. I have an urge for a cigarette	Somewhat agree <input type="radio"/>
-----------------------------------	--------------------------------------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 4

Form: Questionnaire on smoking urges (QSU)

Data signed: (hfarmer1) 30 Mar 2015 13:34:24

Generated On: 20 Jul 2016 22:28:45

7. A cigarette would taste good now Strongly disagree ☐

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

9. Smoking would make me less depressed Strongly disagree ☐

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 4

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

Data signed: (hfarmer1) 30 Mar 2015 13:34:24

Generated On: 20 Jul 2016 22:28:45

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 4

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

Data signed: (hfarmer1) 30 Mar 2015 13:34:24

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112450002857
Analyte	HPMA
Sample type	URINE
Result	266
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	4
Celerion Study Number	AA99128-03
Date of Collection	2014-APR-08
Timepoint-minutes	
Urine Start Day	4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 4

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

Data signed: (hfarmer1) 30 Mar 2015 13:34:24

Generated On: 20 Jul 2016 22:28:45

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 4

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

Data signed: (hfarmer1) 30 Mar 2015 13:34:24

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112450002857
Analyte	CEMA
Sample type	URINE
Result	34.7
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	4
Celerion Study Number	AA99128-03
Date of Collection	2014-APR-08
Timepoint-minutes	
Urine Start Day	4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 4

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

Data signed: (hfarmer1) 30 Mar 2015 13:34:24

Generated On: 20 Jul 2016 22:28:45

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 4

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

Data signed: (hfarmer1) 30 Mar 2015 13:34:24

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112450002857
Analyte	HBMA
Sample type	URINE
Result	60.7
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	4
Celerion Study Number	AA99128-03
Date of Collection	2014-APR-08
Timepoint-minutes	
Urine Start Day	4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 4

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

Data signed: (hfarmer1) 30 Mar 2015 13:34:24

Generated On: 20 Jul 2016 22:28:45

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 4

Form: Biomarker-Urine (NNN, NNAL)

Data signed: (hfarmer1) 30 Mar 2015 13:34:24

Generated On: 20 Jul 2016 22:28:45

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 4

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

Data signed: (hfarmer1) 30 Mar 2015 13:34:24

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112460003428
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Analyte	NNAL
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Sample type	URINE
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Result	.
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Result Unit	PG/ML
-------------	-------

Lab Status	OK
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Sample comment	ANALYSIS NOT PERFORMED IN ERROR
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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	AA99128-04
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Date of Collection	2014-APR-08
--------------------	-------------

Timepoint-minutes	
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 4

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

Data signed: (hfarmer1) 30 Mar 2015 13:34:24

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Day 4

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

Data signed: (hfarmer1) 30 Mar 2015 13:34:24

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112460003428
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Analyte	NNN
---------	-----

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

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

Result Unit	PG/ML
-------------	-------

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

Sample comment	ANALYSIS NOT PERFORMED IN ERROR
----------------	------------------------------------

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	4
--------------	---

Celerion Study Number	AA99128-04
-----------------------	------------

Date of Collection	2014-APR-08
--------------------	-------------

Timepoint-minutes	
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 4

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

Data signed: (hfarmer1) 30 Mar 2015 13:34:24

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Day 4

Form: Biomarker-Urine (HEMA)

Data signed: (hfarmer1) 30 Mar 2015 13:34:24

Generated On: 20 Jul 2016 22:28:45

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 4

Form: Biomarker-Urine (HEMA) (1)

Data signed: (hfarmer1) 30 Mar 2015 13:34:24

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112470001712
Analyte	HEMA
Sample type	URINE
Result	0.509
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	4
Celerion Study Number	AA99128-05
Date of Collection	2014-APR-08
Timepoint-minutes	
Urine Start Day	4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 4

Form: Biomarker-Urine (HEMA) (1)

Data signed: (hfarmer1) 30 Mar 2015 13:34:24

Generated On: 20 Jul 2016 22:28:45

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 4

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

Data signed: (hfarmer1) 30 Mar 2015 13:34:25

Generated On: 20 Jul 2016 22:28:45

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 4

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

Data signed: (hfarmer1) 30 Mar 2015 13:34:25

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112480000777
Analyte	COT
Sample type	URINE
Result	1510
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	4
Celerion Study Number	AA99128-06
Date of Collection	2014-APR-09
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 4

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

Data signed: (hfarmer1) 30 Mar 2015 13:34:25

Generated On: 20 Jul 2016 22:28:45

Urine Start Day	4
<hr/>	
Urine End Day	5
<hr/>	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 4

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

Data signed: (hfarmer1) 30 Mar 2015 13:34:25

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112480000777
Analyte	COT-GLUC
Sample type	URINE
Result	5450
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	4
Celerion Study Number	AA99128-06
Date of Collection	2014-APR-09
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 4

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

Data signed: (hfarmer1) 30 Mar 2015 13:34:25

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Day 4

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

Data signed: (hfarmer1) 30 Mar 2015 13:34:25

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112480000777
Analyte	NIC
Sample type	URINE
Result	754
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	4
Celerion Study Number	AA99128-06
Date of Collection	2014-APR-09
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 4

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

Data signed: (hfarmer1) 30 Mar 2015 13:34:25

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Day 4

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

Data signed: (hfarmer1) 30 Mar 2015 13:34:25

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112480000777
Analyte	NIC-GLUC
Sample type	URINE
Result	793
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	4
Celerion Study Number	AA99128-06
Date of Collection	2014-APR-09
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 4

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

Data signed: (hfarmer1) 30 Mar 2015 13:34:25

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Day 4

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

Data signed: (hfarmer1) 30 Mar 2015 13:34:25

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112480000777
Analyte	THCOT
Sample type	URINE
Result	4250
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	4
Celerion Study Number	AA99128-06
Date of Collection	2014-APR-09
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 4

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

Data signed: (hfarmer1) 30 Mar 2015 13:34:25

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Day 4

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(6)**

Data signed: (hfarmer1) 30 Mar 2015 13:34:25

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112480000777
Analyte	THCOT-GLUC
Sample type	URINE
Result	3530
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	4
Celerion Study Number	AA99128-06
Date of Collection	2014-APR-09
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 4

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(6)**

Data signed: (hfarmer1) 30 Mar 2015 13:34:25

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Day 4

Form: Biomarker-Urine (3-OH BaP)

Data signed: (hfarmer1) 30 Mar 2015 13:34:25

Generated On: 20 Jul 2016 22:28:45

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 4

Form: Biomarker-Urine (3-OH BaP) (1)

Data signed: (hfarmer1) 30 Mar 2015 13:34:25

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112490001712
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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	OK
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Sample comment	ANALYSIS NOT PERFORMED IN ERROR
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Detection method	LC-MS/MS
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Planned time point (Hour)	0
---------------------------	---

Day of Visit	4
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Celerion Study Number	AA99128-07
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Date of Collection	2014-APR-08
--------------------	-------------

Timepoint-minutes	
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 4

Form: Biomarker-Urine (3-OH BaP) (1)

Data signed: (hfarmer1) 30 Mar 2015 13:34:25

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Day 4

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP)

Data signed: (hfarmer1) 30 Mar 2015 13:34:25

Generated On: 20 Jul 2016 22:28:45

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 4

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (1)

Data signed: (hfarmer1) 30 Mar 2015 13:34:25

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112510001734
Analyte	1-NA
Sample type	URINE
Result	2.51
Result Unit	PG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	4
Celerion Study Number	AA99128-09
Date of Collection	2014-APR-08
Timepoint-minutes	
Urine Start Day	4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 4

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (1)

Data signed: (hfarmer1) 30 Mar 2015 13:34:25

Generated On: 20 Jul 2016 22:28:45

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 4

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (2)

Data signed: (hfarmer1) 30 Mar 2015 13:34:25

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112510001734
Analyte	2-NA
Sample type	URINE
Result	BLQ<(2.50)
Result Unit	PG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	4
Celerion Study Number	AA99128-09
Date of Collection	2014-APR-08
Timepoint-minutes	
Urine Start Day	4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 4

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (2)

Data signed: (hfarmer1) 30 Mar 2015 13:34:25

Generated On: 20 Jul 2016 22:28:45

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 4

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (3)

Data signed: (hfarmer1) 30 Mar 2015 13:34:25

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112510001734
Analyte	4-ABP
Sample type	URINE
Result	2.37
Result Unit	PG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	4
Celerion Study Number	AA99128-09
Date of Collection	2014-APR-08
Timepoint-minutes	
Urine Start Day	4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 4

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (3)

Data signed: (hfarmer1) 30 Mar 2015 13:34:25

Generated On: 20 Jul 2016 22:28:45

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 4

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (4)

Data signed: (hfarmer1) 30 Mar 2015 13:34:25

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112510001734
Analyte	O-TOL
Sample type	URINE
Result	BLQ<(50.0)
Result Unit	PG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	4
Celerion Study Number	AA99128-09
Date of Collection	2014-APR-08
Timepoint-minutes	
Urine Start Day	4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 4

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (4)

Data signed: (hfarmer1) 30 Mar 2015 13:34:25

Generated On: 20 Jul 2016 22:28:45

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 4

Form: Biomarker-Urine (1-OHP)

Data signed: (hfarmer1) 30 Mar 2015 13:34:25

Generated On: 20 Jul 2016 22:28:45

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 4

Form: Biomarker-Urine (1-OHP) (1)

Data signed: (hfarmer1) 30 Mar 2015 13:34:25

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05115190003736
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Analyte	1-OHP
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Sample type	URINE
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Result	.
--------	---

Result Unit	PG/ML
-------------	-------

Lab Status	OK
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Sample comment	NOT ANALYZED IN ERROR
----------------	-----------------------

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
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Day of Visit	4
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Celerion Study Number	AA99598-03
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Date of Collection	2014-APR-08
--------------------	-------------

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: 1252**

Folder: Day 4

Form: Biomarker-Urine (1-OHP) (1)

Data signed: (hfarmer1) 30 Mar 2015 13:34:25

Generated On: 20 Jul 2016 22:28:45

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 4

Form: Biomarker-Urine (SPMA, SBMA)

Data signed: (hfarmer1) 30 Mar 2015 13:34:24

Generated On: 20 Jul 2016 22:28:45

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 4

Form: Biomarker-Urine (SPMA, SBMA) (1)

Data signed: (hfarmer1) 30 Mar 2015 13:34:24

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05115170003727
----------------	----------------

Analyte	SPMA
---------	------

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

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

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

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

Sample comment	NOT ANALYZED IN ERROR
----------------	-----------------------

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	4
--------------	---

Celerion Study Number	AA99598-01
-----------------------	------------

Date of Collection	2014-APR-08
--------------------	-------------

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

Urine Start Day	4
-----------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 4

Form: Biomarker-Urine (SPMA, SBMA) (1)

Data signed: (hfarmer1) 30 Mar 2015 13:34:24

Generated On: 20 Jul 2016 22:28:45

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 4

Form: Biomarker-Urine (SPMA, SBMA) (2)

Data signed: (hfarmer1) 30 Mar 2015 13:34:24

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05115170003736
----------------	----------------

Analyte	SBMA
---------	------

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

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

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

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

Sample comment	NOT ANALYZED IN ERROR
----------------	-----------------------

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	4
--------------	---

Celerion Study Number	AA99598-01
-----------------------	------------

Date of Collection	2014-APR-08
--------------------	-------------

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

Urine Start Day	4
-----------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 4

Form: Biomarker-Urine (SPMA, SBMA) (2)

Data signed: (hfarmer1) 30 Mar 2015 13:34:24

Generated On: 20 Jul 2016 22:28:45

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 4

Form: Biomarker-Urine (MHBMA)

Data signed: (hfarmer1) 30 Mar 2015 13:34:24

Generated On: 20 Jul 2016 22:28:45

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 4

Form: Biomarker-Urine (MHBMA) (1)

Data signed: (hfarmer1) 30 Mar 2015 13:34:24

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05115180003736
----------------	----------------

Analyte	MHBMA
---------	-------

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

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

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

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

Sample comment	NOT ANALYZED IN ERROR
----------------	-----------------------

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	4
--------------	---

Celerion Study Number	AA99598-02
-----------------------	------------

Date of Collection	2014-APR-08
--------------------	-------------

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

Urine Start Day	4
-----------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 4

Form: Biomarker-Urine (MHBMA) (1)

Data signed: (hfarmer1) 30 Mar 2015 13:34:24

Generated On: 20 Jul 2016 22:28:45

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 4

Form: Biomarker-Urine (Creatinine)

Data signed: (hfarmer1) 30 Mar 2015 13:34:25

Generated On: 20 Jul 2016 22:28:45

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 4

Form: Biomarker-Urine (Creatinine) (1)

Data signed: (hfarmer1) 30 Mar 2015 13:34:25

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05115160001712
----------------	----------------

Analyte	CREATININE
---------	------------

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

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

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

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

Sample comment	ANALYSIS NOT PERFORMED IN ERROR
----------------	------------------------------------

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

Planned time point (Hour)	0
---------------------------	---

Day of Visit	4
--------------	---

Celerion Study Number	AA99128-14
-----------------------	------------

Date of Collection	2014-APR-08
--------------------	-------------

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 4

Form: Biomarker-Urine (Creatinine) (1)

Data signed: (hfarmer1) 30 Mar 2015 13:34:25

Generated On: 20 Jul 2016 22:28:45

Urine Start Day	4
-----------------	---

Urine End Day	5
---------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 4

Form: Biomarker-Plasma (Nic, Cot, tHCot)

Data signed: (hfarmer1) 30 Mar 2015 13:34:24

Generated On: 20 Jul 2016 22:28:45

Sample type

PLASMA

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 4

Form: Biomarker-Plasma (Nic, Cot, tHCot) (1)

Data signed: (hfarmer1) 30 Mar 2015 13:34:24

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112430001810
----------------	----------------

Analyte	COT
---------	-----

Sample type	PLASMA
-------------	--------

Result	298
--------	-----

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

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

Sample comment	ANALYZED IN ERROR
----------------	-------------------

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	4
--------------	---

Celerion Study Number	AA99128-01
-----------------------	------------

Date of Collection	2014-APR-08
--------------------	-------------

Timepoint-minutes	0
-------------------	---

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 4

Form: Biomarker-Plasma (Nic, Cot, tHCot) (1)

Data signed: (hfarmer1) 30 Mar 2015 13:34:24

Generated On: 20 Jul 2016 22:28:45

Urine End Day

4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 4

Form: Biomarker-Plasma (Nic, Cot, tHCot) (2)

Data signed: (hfarmer1) 30 Mar 2015 13:34:24

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112430001810
Analyte	NIC
Sample type	PLASMA
Result	15.0
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	4
Celerion Study Number	AA99128-01
Date of Collection	2014-APR-08
Timepoint-minutes	0
Urine Start Day	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 4

Form: Biomarker-Plasma (Nic, Cot, tHCot) (2)

Data signed: (hfarmer1) 30 Mar 2015 13:34:24

Generated On: 20 Jul 2016 22:28:45

Urine End Day

4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 5

Form: Date of Visit

Data signed: (hfarmer1) 30 Mar 2015 13:34:27

Generated On: 20 Jul 2016 22:28:45

Date of Visit

09 APR 2014
DD/MMM/YYYY

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 5

Form: Vital Signs

Data signed: (hfarmer1) 30 Mar 2015 13:34:27

Generated On: 20 Jul 2016 22:28:45

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

09:21
hour:min 24-hour clock

Pulse rate

71
beats per minute

Respiratory rate

20
breaths per minute

Blood Pressure (systolic)

111
mmHg

Blood Pressure (diastolic)

66
mmHg

Vital Signs Position of Subject

Supine ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 5

Form: Plasma Nicotine Samples <Day 5> (1)

Data signed: (hfarmer1) 30 Mar 2015 13:34:28

Generated On: 20 Jul 2016 22:28:45

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	09 APR 2014
---------------------	-------------

Scheduled Time	T0 -15 min <input checked="" type="radio"/>
----------------	---

Time hour:min 24-hour clock	06:41
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 5

Form: Plasma Nicotine Samples <Day 5> (2)

Data signed: (hfarmer1) 30 Mar 2015 13:34:28

Generated On: 20 Jul 2016 22:28:45

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	09 APR 2014
---------------------	-------------

Scheduled Time	T1 <input checked="" type="radio"/>
----------------	-------------------------------------

Time hour:min 24-hour clock	08:46
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 5

Form: Plasma Nicotine Samples <Day 5> (3)

Data signed: (hfarmer1) 30 Mar 2015 13:34:28

Generated On: 20 Jul 2016 22:28:45

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	09 APR 2014
---------------------	-------------

Scheduled Time	T2 <input checked="" type="radio"/>
----------------	-------------------------------------

Time hour:min 24-hour clock	10:46
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 5

Form: Plasma Nicotine Samples <Day 5> (4)

Data signed: (hfarmer1) 30 Mar 2015 13:34:28

Generated On: 20 Jul 2016 22:28:45

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	09 APR 2014
---------------------	-------------

Scheduled Time	T3 <input checked="" type="radio"/>
----------------	-------------------------------------

Time hour:min 24-hour clock	12:46
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 5

Form: Plasma Nicotine Samples <Day 5> (5)

Data signed: (hfarmer1) 30 Mar 2015 13:34:28

Generated On: 20 Jul 2016 22:28:45

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	09 APR 2014
---------------------	-------------

Scheduled Time	T4 <input checked="" type="radio"/>
----------------	-------------------------------------

Time hour:min 24-hour clock	14:46
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 5

Form: Plasma Nicotine Samples <Day 5> (6)

Data signed: (hfarmer1) 30 Mar 2015 13:34:28

Generated On: 20 Jul 2016 22:28:45

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	09 APR 2014
---------------------	-------------

Scheduled Time	T5 <input checked="" type="radio"/>
----------------	-------------------------------------

Time hour:min 24-hour clock	16:46
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 5

Form: Plasma Nicotine Samples <Day 5> (7)

Data signed: (hfarmer1) 30 Mar 2015 13:34:28

Generated On: 20 Jul 2016 22:28:45

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	09 APR 2014
---------------------	-------------

Scheduled Time	T6 <input checked="" type="radio"/>
----------------	-------------------------------------

Time hour:min 24-hour clock	18:46
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 5

Form: Plasma Nicotine Samples <Day 5> (8)

Data signed: (hfarmer1) 30 Mar 2015 13:34:28

Generated On: 20 Jul 2016 22:28:45

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	09 APR 2014
---------------------	-------------

Scheduled Time	T7 <input checked="" type="radio"/>
----------------	-------------------------------------

Time hour:min 24-hour clock	20:46
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 5

Form: Plasma Nicotine Samples <Day 5> (9)

Data signed: (hfarmer1) 30 Mar 2015 13:34:28

Generated On: 20 Jul 2016 22:28:45

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	09 APR 2014
---------------------	-------------

Scheduled Time	T8 <input checked="" type="radio"/>
----------------	-------------------------------------

Time hour:min 24-hour clock	22:46
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 5

Form: Plasma Cotinine Samples <Day 5> (1)

Data signed: (hfarmer1) 30 Mar 2015 13:34:28

Generated On: 20 Jul 2016 22:28:45

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	09 APR 2014
---------------------	-------------

Scheduled Time	T0 -15 min <input checked="" type="radio"/>
----------------	---

Time hour:min 24-hour clock	06:41
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 5

Form: Plasma Cotinine Samples <Day 5> (2)

Data signed: (hfarmer1) 30 Mar 2015 13:34:28

Generated On: 20 Jul 2016 22:28:45

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	09 APR 2014
---------------------	-------------

Scheduled Time	T1 <input checked="" type="radio"/>
----------------	-------------------------------------

Time hour:min 24-hour clock	08:46
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 5

Form: Plasma Cotinine Samples <Day 5> (3)

Data signed: (hfarmer1) 30 Mar 2015 13:34:28

Generated On: 20 Jul 2016 22:28:45

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	09 APR 2014
---------------------	-------------

Scheduled Time	T2 <input checked="" type="radio"/>
----------------	-------------------------------------

Time hour:min 24-hour clock	10:46
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 5

Form: Plasma Cotinine Samples <Day 5> (4)

Data signed: (hfarmer1) 30 Mar 2015 13:34:28

Generated On: 20 Jul 2016 22:28:45

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	09 APR 2014
---------------------	-------------

Scheduled Time	T3 <input checked="" type="radio"/>
----------------	-------------------------------------

Time hour:min 24-hour clock	12:46
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 5

Form: Plasma Cotinine Samples <Day 5> (5)

Data signed: (hfarmer1) 30 Mar 2015 13:34:28

Generated On: 20 Jul 2016 22:28:45

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	09 APR 2014
---------------------	-------------

Scheduled Time	T4 <input checked="" type="radio"/>
----------------	-------------------------------------

Time hour:min 24-hour clock	14:46
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 5

Form: Plasma Cotinine Samples <Day 5> (6)

Data signed: (hfarmer1) 30 Mar 2015 13:34:28

Generated On: 20 Jul 2016 22:28:45

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	09 APR 2014
---------------------	-------------

Scheduled Time	T5 <input checked="" type="radio"/>
----------------	-------------------------------------

Time hour:min 24-hour clock	16:46
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 5

Form: Plasma Cotinine Samples <Day 5> (7)

Data signed: (hfarmer1) 30 Mar 2015 13:34:28

Generated On: 20 Jul 2016 22:28:45

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	09 APR 2014
---------------------	-------------

Scheduled Time	T6 <input checked="" type="radio"/>
----------------	-------------------------------------

Time hour:min 24-hour clock	18:46
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 5

Form: Plasma Cotinine Samples <Day 5> (8)

Data signed: (hfarmer1) 30 Mar 2015 13:34:28

Generated On: 20 Jul 2016 22:28:45

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	09 APR 2014
---------------------	-------------

Scheduled Time	T7 <input checked="" type="radio"/>
----------------	-------------------------------------

Time hour:min 24-hour clock	20:46
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 5

Form: Plasma Cotinine Samples <Day 5> (9)

Data signed: (hfarmer1) 30 Mar 2015 13:34:28

Generated On: 20 Jul 2016 22:28:45

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	09 APR 2014
---------------------	-------------

Scheduled Time	T8 <input checked="" type="radio"/>
----------------	-------------------------------------

Time hour:min 24-hour clock	22:46
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 5

Form: CoHb Blood Sample(CC/THS) (1)

Data signed: (hfarmer1) 30 Mar 2015 13:34:28

Generated On: 20 Jul 2016 22:28:45

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	09 APR 2014
---------------------	-------------

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

Time hour:min 24-hour clock	06:41
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 5

Form: CoHb Blood Sample(CC/THS) (2)

Data signed: (hfarmer1) 30 Mar 2015 13:34:28

Generated On: 20 Jul 2016 22:28:45

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	09 APR 2014
---------------------	-------------

Scheduled Time	12:00 - 13:30 <input checked="" type="radio"/>
----------------	--

Time hour:min 24-hour clock	12:46
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 5

Form: CoHb Blood Sample(CC/THS) (3)

Data signed: (hfarmer1) 30 Mar 2015 13:34:28

Generated On: 20 Jul 2016 22:28:45

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	09 APR 2014
---------------------	-------------

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

Time hour:min 24-hour clock	16:17
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 5

Form: CoHb Blood Sample(CC/THS) (4)

Data signed: (hfarmer1) 30 Mar 2015 13:34:28

Generated On: 20 Jul 2016 22:28:45

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	09 APR 2014
---------------------	-------------

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

Time hour:min 24-hour clock	20:46
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 5

Form: CO Breath Test (1)

Data signed: (hfarmer1) 30 Mar 2015 13:34:27

Generated On: 20 Jul 2016 22:28:45

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	06:44
---	-------

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 5

Form: CO Breath Test (2)

Data signed: (hfarmer1) 30 Mar 2015 13:34:27

Generated On: 20 Jul 2016 22:28:45

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

If Not Done, please specify the reason: _____

Scheduled Time	12:00 - 13:30 <input checked="" type="radio"/>
----------------	--

Actual Time of Assessment hour:min 24-hour clock	12:04
---	-------

Result(ppm)	2
-------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 5

Form: CO Breath Test (3)

Data signed: (hfarmer1) 30 Mar 2015 13:34:27

Generated On: 20 Jul 2016 22:28:45

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	16:20
---	-------

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 5

Form: CO Breath Test (4)

Data signed: (hfarmer1) 30 Mar 2015 13:34:27

Generated On: 20 Jul 2016 22:28:45

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

If Not Done, please specify the reason: _____

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

Actual Time of Assessment hour:min 24-hour clock	20:10
---	-------

Result(ppm)	2
-------------	---

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Day 5

Form: CYP1A2 activity Sample

Data signed: (hfarmer1) 30 Mar 2015 13:34:26

Generated On: 20 Jul 2016 22:28:45

Time of caffeine tablet intake	10:16
	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
09 APR 2014	16:17	Caffeine
09 APR 2014	16:17	Paraxanthine

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 5

Form: 24 hour urine collections

Data signed: (hfarmer1) 30 Mar 2015 13:34:27

Generated On: 20 Jul 2016 22:28:45

Start Time	06:02
	hour:min 24-hour clock

End Date	10 APR 2014
	DD/MMM/YYYY

End Time	06:21
	hour:min 24-hour clock

Volume	2802
	mL

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 5

Form: Sample Urine Collection

Data signed: (hfarmer1) 30 Mar 2015 13:34:27

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Day 5

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Data signed: (hfarmer1) 30 Mar 2015 13:34:29

Generated On: 20 Jul 2016 22:28:45

Date of Birth

(b) (6)

Date of assessment
DD/MMM/YYYY

2014 APR 09
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?

Moderate ☐

2. Anxious, nervous

How have you been feeling over the past 24 hours?

None ☐

3. Depressed Mood, sad

How have you been feeling over the past 24 hours?

Moderate ☐

4. Desire or craving to smoke

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 5

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Data signed: (hfarmer1) 30 Mar 2015 13:34:29

Generated On: 20 Jul 2016 22:28:45

How have you been feeling over the past 24 hours? None ☐

5. Difficulty concentrating

How have you been feeling over the past 24 hours? None ☐

6. Increased appetite, hungry, weight gain

How have you been feeling over the past 24 hours? None ☐

7. Insomnia, sleep problems, awakening at night

How have you been feeling over the past 24 hours? Slight ☐

8. Restless

How have you been feeling over the past 24 hours? Slight ☐

9. Impatient

How have you been feeling over the past 24 hours? None ☐

10. Constipation

How have you been feeling over the past 24 hours? None ☐

11. Dizziness

How have you been feeling over the past 24 hours? Slight ☐

12. Coughing

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 5

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Data signed: (hfarmer1) 30 Mar 2015 13:34:29

Generated On: 20 Jul 2016 22:28:45

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: 1252

Folder: Day 5

Form: Cough Assessment

Data signed: (hfarmer1) 30 Mar 2015 13:34:28

Generated On: 20 Jul 2016 22:28:45

Date of Birth

(b) (6)

Date of assessment
DD/MMM/YYYY

2014 APR 09
DD/MMM/YYYY

Time of assessment

06:05
hour:min 24-hour clock

Assessment Status

Completed ☒

Have you experienced a regular need to cough e.g.
coughing several times in the last 24 hrs?

Yes ☒

If YES, please answer the following questions:

First Question: Cough Impact Scale
How much is your cough bothering you?

50

Second Question: Cough Intensity Scale:
How intense is your cough?

Moderate ☒

Third Question: Cough Frequency Scale:
How frequently do you normally have to cough each
day?

Almost always ☒

Fourth Question: Sputum Production
To what extent do you produce sputum when coughing?

A moderate amount of
sputum ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 5

Form: Lab_BU_COHB (1)

Data signed: (hfarmer1) 30 Mar 2015 13:34:29

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05115150004504
----------------	----------------

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

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

Result	2.20
--------	------

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

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

Sample comment	.
----------------	---

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

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

Planned time point (Hour)	6
---------------------------	---

Day of Visit	5
--------------	---

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

Date of Collection	2014-APR-09
--------------------	-------------

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 5

Form: Lab_BU_COHB (1)

Data signed: (hfarmer1) 30 Mar 2015 13:34:29

Generated On: 20 Jul 2016 22:28:45

Start Day (24 hour urine only) _____

End Day (24 hour Urine Only) _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 5

Form: Lab_BU_COHB (2)

Data signed: (hfarmer1) 30 Mar 2015 13:34:29

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05115150004505
----------------	----------------

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

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

Result	2.20
--------	------

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

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

Sample comment	.
----------------	---

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

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

Planned time point (Hour)	12
---------------------------	----

Day of Visit	5
--------------	---

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

Date of Collection	2014-APR-09
--------------------	-------------

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 5

Form: Lab_BU_COHB (2)

Data signed: (hfarmer1) 30 Mar 2015 13:34:29

Generated On: 20 Jul 2016 22:28:45

Start Day (24 hour urine only)

End Day (24 hour Urine Only)

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 5

Form: Lab_BU_COHB (3)

Data signed: (hfarmer1) 30 Mar 2015 13:34:29

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05115150004506
Analyte	CARBOXYHEMOGLOBIN
Sample type	BLOOD
Result	2.40
Result Unit	%
Lab Status	OK
Sample comment	.
Detection method	SPECTROPHOTOMETRIC
Lower limit of quantification	0.500
Planned time point (Hour)	16
Day of Visit	5
Celerion Study Number	AA99128-16
Date of Collection	2014-APR-09
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 5

Form: Lab_BU_COHB (3)

Data signed: (hfarmer1) 30 Mar 2015 13:34:29

Generated On: 20 Jul 2016 22:28:45

Start Day (24 hour urine only) _____

End Day (24 hour Urine Only) _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 5

Form: Lab_BU_COHB (4)

Data signed: (hfarmer1) 30 Mar 2015 13:34:29

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05115150004507
Analyte	CARBOXYHEMOGLOBIN
Sample type	BLOOD
Result	2.30
Result Unit	%
Lab Status	OK
Sample comment	.
Detection method	SPECTROPHOTOMETRIC
Lower limit of quantification	0.500
Planned time point (Hour)	20
Day of Visit	5
Celerion Study Number	AA99128-16
Date of Collection	2014-APR-09
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 5

Form: Lab_BU_COHB (4)

Data signed: (hfarmer1) 30 Mar 2015 13:34:29

Generated On: 20 Jul 2016 22:28:45

Start Day (24 hour urine only) _____

End Day (24 hour Urine Only) _____

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Day 5

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)

Data signed: (hfarmer1) 30 Mar 2015 13:34:29

Generated On: 20 Jul 2016 22:28:45

Date of Birth

(b) (6)

Date of assessment

2014 APR 09

DD/MMM/YYYY

DD/MMM/YYYY

Time of assessment

20:03

hour:min 24-hour clock

Assessment Status

Completed

1. Was smoking satisfying?

A lot

2. Did cigarettes taste good?

Not at all

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

Not at all

4. Did smoking calm you down?

Not at all

5. Did smoking make you feel more awake?

Not at all

6. Did smoking make you feel less irritable?

Moderately

7. Did smoking help you concentrate?

Not at all

8. Did smoking reduce your hunger for food?

Very little

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 5

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)

Data signed: (hfarmer1) 30 Mar 2015 13:34:29

Generated On: 20 Jul 2016 22:28:45

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

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

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

12. Did you enjoy smoking? Moderately ☐

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 5

Form: Behavioral Risk Factor Surveillance System Questionnaire

Data signed: (hfarmer1) 30 Mar 2015 13:34:26

Generated On: 20 Jul 2016 22:28:45

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

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

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

Date of assessment	09 APR 2014 DD/MMM/YYYY
--------------------	----------------------------

Time of assessment	21:05 hour:min 24-hour clock
--------------------	---------------------------------

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

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

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

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 5

Form: Behavioral Risk Factor Surveillance System Questionnaire

Data signed: (hfarmer1) 30 Mar 2015 13:34:26

Generated On: 20 Jul 2016 22:28:45

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: 1252

Folder: Day 5

Form: Smoking Questionnaire (SQ)

Data signed: (hfarmer1) 30 Mar 2015 13:34:26

Generated On: 20 Jul 2016 22:28:45

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

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

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

Date of assessment	09 APR 2014 DD/MMM/YYYY
--------------------	----------------------------

Time of assessment	21:09 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?	21 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: 1252**

Folder: Day 5

Form: Smoking Questionnaire (SQ)

Data signed: (hfarmer1) 30 Mar 2015 13:34:26

Generated On: 20 Jul 2016 22:28:45

Months

Days

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

Years

00 Years

Months

00 Months

Days

00 Days

7. What brand of cigarettes/hand-rolled tobacco did you predominantly smoke in the last 12 months of smoking? 305'S MENTHOL

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Day 5

Form: Smoking Questionnaire (SQ) (1)

Data signed: (hfarmer1) 30 Mar 2015 13:34:26

Generated On: 20 Jul 2016 22:28:45

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

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

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

Date of assessment	09 APR 2014 DD/MMM/YYYY
--------------------	----------------------------

Time of assessment	21:09 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?	21 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: 1252

Folder: Day 5

Form: Smoking Questionnaire (SQ) (1)

Data signed: (hfarmer1) 30 Mar 2015 13:34:26

Generated On: 20 Jul 2016 22:28:45

Months

Days

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

Years

00 Years

Months

00 Months

Days

00 Days

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

Time

Currently (last 3 months) ☒

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

Manufactured Cigarettes
per day

20

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

None ☒

Hand-rolled Cigarettes
per day

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 5

Form: Smoking Questionnaire (SQ) (1)

Data signed: (hfarmer1) 30 Mar 2015 13:34:26

Generated On: 20 Jul 2016 22:28:45

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: 1252

Folder: Day 5

Form: Smoking Questionnaire (SQ) (2)

Data signed: (hfarmer1) 30 Mar 2015 13:34:26

Generated On: 20 Jul 2016 22:28:45

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

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

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

Date of assessment	09 APR 2014 DD/MMM/YYYY
--------------------	----------------------------

Time of assessment	21:09 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?	21 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: 1252

Folder: Day 5

Form: Smoking Questionnaire (SQ) (2)

Data signed: (hfarmer1) 30 Mar 2015 13:34:26

Generated On: 20 Jul 2016 22:28:45

Months

Days

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

Years

00 Years

Months

00 Months

Days

00 Days

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

Time

1 year ago ☒

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

Manufactured Cigarettes
per day

20

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

None ☒

Hand-rolled Cigarettes
per day

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 5

Form: Smoking Questionnaire (SQ) (2)

Data signed: (hfarmer1) 30 Mar 2015 13:34:26

Generated On: 20 Jul 2016 22:28:45

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: 1252

Folder: Day 5

Form: Smoking Questionnaire (SQ) (3)

Data signed: (hfarmer1) 30 Mar 2015 13:34:26

Generated On: 20 Jul 2016 22:28:45

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

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

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

Date of assessment	09 APR 2014 DD/MMM/YYYY
--------------------	----------------------------

Time of assessment	21:09 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?	21 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: 1252

Folder: Day 5

Form: Smoking Questionnaire (SQ) (3)

Data signed: (hfarmer1) 30 Mar 2015 13:34:26

Generated On: 20 Jul 2016 22:28:45

Months

Days

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

Years

00 Years

Months

00 Months

Days

00 Days

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

Time

5 years ago ☒

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

Manufactured Cigarettes
per day

20

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

None ☒

Hand-rolled Cigarettes
per day

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 5

Form: Smoking Questionnaire (SQ) (3)

Data signed: (hfarmer1) 30 Mar 2015 13:34:26

Generated On: 20 Jul 2016 22:28:45

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: 1252

Folder: Day 5

Form: Smoking Questionnaire (SQ) (4)

Data signed: (hfarmer1) 30 Mar 2015 13:34:26

Generated On: 20 Jul 2016 22:28:45

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

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

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

Date of assessment	09 APR 2014 DD/MMM/YYYY
--------------------	----------------------------

Time of assessment	21:09 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?	21 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: 1252**

Folder: Day 5

Form: Smoking Questionnaire (SQ) (4)

Data signed: (hfarmer1) 30 Mar 2015 13:34:26

Generated On: 20 Jul 2016 22:28:45

Months

Days

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

Years 00 Years

Months 00 Months

Days 00 Days

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

Time 10 years ago ☒

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

Manufactured Cigarettes 20
per day

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

Hand-rolled Cigarettes
per day

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 5

Form: Smoking Questionnaire (SQ) (4)

Data signed: (hfarmer1) 30 Mar 2015 13:34:26

Generated On: 20 Jul 2016 22:28:45

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: 1252

Folder: Day 5

Form: Smoking Questionnaire (SQ) (5)

Data signed: (hfarmer1) 30 Mar 2015 13:34:26

Generated On: 20 Jul 2016 22:28:45

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

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

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

Date of assessment	09 APR 2014 DD/MMM/YYYY
--------------------	----------------------------

Time of assessment	21:09 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?	21 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: 1252

Folder: Day 5

Form: Smoking Questionnaire (SQ) (5)

Data signed: (hfarmer1) 30 Mar 2015 13:34:26

Generated On: 20 Jul 2016 22:28:45

Months

Days

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

Years

00 Years

Months

00 Months

Days

00 Days

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

Time

15 years ago ☒

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

Manufactured Cigarettes
per day

20

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

None ☒

Hand-rolled Cigarettes
per day

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 5

Form: Smoking Questionnaire (SQ) (5)

Data signed: (hfarmer1) 30 Mar 2015 13:34:26

Generated On: 20 Jul 2016 22:28:45

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: 1252

Folder: Day 5

Form: Smoking Questionnaire (SQ) (6)

Data signed: (hfarmer1) 30 Mar 2015 13:34:26

Generated On: 20 Jul 2016 22:28:45

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

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

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

Date of assessment	09 APR 2014 DD/MMM/YYYY
--------------------	----------------------------

Time of assessment	21:09 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?	21 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: 1252**

Folder: Day 5

Form: Smoking Questionnaire (SQ) (6)

Data signed: (hfarmer1) 30 Mar 2015 13:34:26

Generated On: 20 Jul 2016 22:28:45

Months

Days

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

Years

00 Years

Months

00 Months

Days

00 Days

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

Time

20 years ago ☒

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

Manufactured Cigarettes
per day

20

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

None ☒

Hand-rolled Cigarettes
per day

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 5

Form: Smoking Questionnaire (SQ) (6)

Data signed: (hfarmer1) 30 Mar 2015 13:34:26

Generated On: 20 Jul 2016 22:28:45

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: 1252

Folder: Day 5

Form: Smoking Questionnaire (SQ) (7)

Data signed: (hfarmer1) 30 Mar 2015 13:34:26

Generated On: 20 Jul 2016 22:28:45

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

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

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

Date of assessment	09 APR 2014 DD/MMM/YYYY
--------------------	----------------------------

Time of assessment	21:09 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?	21 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: 1252**

Folder: Day 5

Form: Smoking Questionnaire (SQ) (7)

Data signed: (hfarmer1) 30 Mar 2015 13:34:26

Generated On: 20 Jul 2016 22:28:45

Months

Days

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

Years 00 Years

Months 00 Months

Days 00 Days

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

Time More than 20 years ago ☒

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

Manufactured Cigarettes 20
per day

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

Hand-rolled Cigarettes
per day

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 5

Form: Smoking Questionnaire (SQ) (7)

Data signed: (hfarmer1) 30 Mar 2015 13:34:26

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Day 5

Form: Supplemental Questions

Data signed: (hfarmer1) 30 Mar 2015 13:34:27

Generated On: 20 Jul 2016 22:28:45

Was paper questionnaire used?

Yes ☒

Reason not done

Date of Assessment

09 APR 2014
DD/MMM/YYYY

Time of assessment

21:10

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

03 minutes

Comments (open-end)

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 5

Form: Supplemental Questions (1)

Data signed: (hfarmer1) 30 Mar 2015 13:34:27

Generated On: 20 Jul 2016 22:28:45

Was paper questionnaire used? Yes ☐

Reason not done _____

Date of Assessment 09 APR 2014
DD/MMM/YYYY

Time of assessment 21:10

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

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

Answer Yes ☐

Comments (open-end) _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 5

Form: Supplemental Questions (2)

Data signed: (hfarmer1) 30 Mar 2015 13:34:27

Generated On: 20 Jul 2016 22:28:45

Was paper questionnaire used? Yes ☐

Reason not done _____

Date of Assessment 09 APR 2014
DD/MMM/YYYY

Time of assessment 21:10

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

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

Answer Yes ☐

Comments (open-end) _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 5

Form: Supplemental Questions (3)

Data signed: (hfarmer1) 30 Mar 2015 13:34:27

Generated On: 20 Jul 2016 22:28:45

Was paper questionnaire used? Yes ☐

Reason not done _____

Date of Assessment 09 APR 2014
DD/MMM/YYYY

Time of assessment 21:10

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

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

Answer Yes ☐

Comments (open-end) _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 5

Form: Supplemental Questions (4)

Data signed: (hfarmer1) 30 Mar 2015 13:34:27

Generated On: 20 Jul 2016 22:28:45

Was paper questionnaire used? Yes ☐

Reason not done _____

Date of Assessment 09 APR 2014
DD/MMM/YYYY

Time of assessment 21:10

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

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

Answer Yes ☐

Comments (open-end) _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 5

Form: Supplemental Questions (5)

Data signed: (hfarmer1) 30 Mar 2015 13:34:27

Generated On: 20 Jul 2016 22:28:45

Was paper questionnaire used? Yes ☐

Reason not done _____

Date of Assessment 09 APR 2014
DD/MMM/YYYY

Time of assessment 21:10

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

Question 6. Was the SQ self-explaining? ☐

Answer Yes ☐

Comments (open-end) _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 5

Form: Supplemental Questions (6)

Data signed: (hfarmer1) 30 Mar 2015 13:34:27

Generated On: 20 Jul 2016 22:28:45

Was paper questionnaire used? Yes ☐

Reason not done _____

Date of Assessment 09 APR 2014
DD/MMM/YYYY

Time of assessment 21:10

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

Question 7. Was the SQ easy to use? ☐

Answer Yes ☐

Comments (open-end) _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 5

Form: Questionnaire on smoking urges (QSU)

Data signed: (hfarmer1) 30 Mar 2015 13:34:29

Generated On: 20 Jul 2016 22:28:45

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

Date of Birth	(b) (6)
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Date of assessment	2014 APR 09
--------------------	-------------

DD/MMM/YYYY

Time of assessment	20:01
--------------------	-------

hour:min 24-hour clock

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

1. I have a desire for a cigarette right now	Somewhat agree <input checked="" type="radio"/>
--	---

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

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

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

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

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 5

Form: Questionnaire on smoking urges (QSU)

Data signed: (hfarmer1) 30 Mar 2015 13:34:29

Generated On: 20 Jul 2016 22:28:45

7. A cigarette would taste good now Strongly disagree ☐

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

9. Smoking would make me less depressed Strongly disagree ☐

10. I am going to smoke as soon as possible Strongly agree ☐

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 5

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

Data signed: (hfarmer1) 30 Mar 2015 13:34:31

Generated On: 20 Jul 2016 22:28:45

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 5

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

Data signed: (hfarmer1) 30 Mar 2015 13:34:31

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112450002858
Analyte	HPMA
Sample type	URINE
Result	291
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	5
Celerion Study Number	AA99128-03
Date of Collection	2014-APR-09
Timepoint-minutes	
Urine Start Day	5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 5

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

Data signed: (hfarmer1) 30 Mar 2015 13:34:31

Generated On: 20 Jul 2016 22:28:45

Urine End Day

6

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 5

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

Data signed: (hfarmer1) 30 Mar 2015 13:34:31

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112450002858
Analyte	CEMA
Sample type	URINE
Result	34.8
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	5
Celerion Study Number	AA99128-03
Date of Collection	2014-APR-09
Timepoint-minutes	
Urine Start Day	5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 5

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

Data signed: (hfarmer1) 30 Mar 2015 13:34:31

Generated On: 20 Jul 2016 22:28:45

Urine End Day

6

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 5

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

Data signed: (hfarmer1) 30 Mar 2015 13:34:31

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112450002858
Analyte	HBMA
Sample type	URINE
Result	76.7
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	5
Celerion Study Number	AA99128-03
Date of Collection	2014-APR-09
Timepoint-minutes	
Urine Start Day	5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 5

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

Data signed: (hfarmer1) 30 Mar 2015 13:34:31

Generated On: 20 Jul 2016 22:28:45

Urine End Day

6

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 5

Form: Biomarker-Urine (NNN, NNAL)

Data signed: (hfarmer1) 30 Mar 2015 13:34:29

Generated On: 20 Jul 2016 22:28:45

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 5

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

Data signed: (hfarmer1) 30 Mar 2015 13:34:29

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112460003429
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Analyte	NNAL
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Sample type	URINE
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Result	.
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Result Unit	PG/ML
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Lab Status	OK
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Sample comment	ANALYSIS NOT PERFORMED IN ERROR
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Detection method	LC-MS/MS
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Planned time point (Hour)	0
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Day of Visit	5
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Celerion Study Number	AA99128-04
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Date of Collection	2014-APR-09
--------------------	-------------

Timepoint-minutes	
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 5

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

Data signed: (hfarmer1) 30 Mar 2015 13:34:29

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Day 5

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

Data signed: (hfarmer1) 30 Mar 2015 13:34:29

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112460003429
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Analyte	NNN
---------	-----

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

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

Result Unit	PG/ML
-------------	-------

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

Sample comment	ANALYSIS NOT PERFORMED IN ERROR
----------------	------------------------------------

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	5
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Celerion Study Number	AA99128-04
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Date of Collection	2014-APR-09
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Timepoint-minutes	
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 5

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

Data signed: (hfarmer1) 30 Mar 2015 13:34:29

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Day 5

Form: Biomarker-Urine (HEMA)

Data signed: (hfarmer1) 30 Mar 2015 13:34:29

Generated On: 20 Jul 2016 22:28:45

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 5

Form: Biomarker-Urine (HEMA) (1)

Data signed: (hfarmer1) 30 Mar 2015 13:34:29

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112470001713
Analyte	HEMA
Sample type	URINE
Result	0.702
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	5
Celerion Study Number	AA99128-05
Date of Collection	2014-APR-09
Timepoint-minutes	
Urine Start Day	5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 5

Form: Biomarker-Urine (HEMA) (1)

Data signed: (hfarmer1) 30 Mar 2015 13:34:29

Generated On: 20 Jul 2016 22:28:45

Urine End Day

6

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 5

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

Data signed: (hfarmer1) 30 Mar 2015 13:34:31

Generated On: 20 Jul 2016 22:28:45

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 5

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

Data signed: (hfarmer1) 30 Mar 2015 13:34:31

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112480000778
Analyte	COT
Sample type	URINE
Result	1560
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	5
Celerion Study Number	AA99128-06
Date of Collection	2014-APR-09
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 5

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

Data signed: (hfarmer1) 30 Mar 2015 13:34:31

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Day 5

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

Data signed: (hfarmer1) 30 Mar 2015 13:34:31

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112480000778
Analyte	COT-GLUC
Sample type	URINE
Result	4830
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	5
Celerion Study Number	AA99128-06
Date of Collection	2014-APR-09
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 5

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

Data signed: (hfarmer1) 30 Mar 2015 13:34:31

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Day 5

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

Data signed: (hfarmer1) 30 Mar 2015 13:34:31

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112480000778
Analyte	NIC
Sample type	URINE
Result	1070
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	5
Celerion Study Number	AA99128-06
Date of Collection	2014-APR-09
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 5

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

Data signed: (hfarmer1) 30 Mar 2015 13:34:31

Generated On: 20 Jul 2016 22:28:45

Urine Start Day	5
-----------------	---

Urine End Day	6
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 5

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

Data signed: (hfarmer1) 30 Mar 2015 13:34:31

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112480000778
Analyte	NIC-GLUC
Sample type	URINE
Result	766
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	5
Celerion Study Number	AA99128-06
Date of Collection	2014-APR-09
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 5

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

Data signed: (hfarmer1) 30 Mar 2015 13:34:31

Generated On: 20 Jul 2016 22:28:45

Urine Start Day	5
-----------------	---

Urine End Day	6
---------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 5

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

Data signed: (hfarmer1) 30 Mar 2015 13:34:31

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112480000778
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Analyte	THCOT
---------	-------

Sample type	URINE
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Result	4000
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Result Unit	NG/ML
-------------	-------

Lab Status	OK
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Sample comment	ANALYZED IN ERROR
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Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	5
--------------	---

Celerion Study Number	AA99128-06
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Date of Collection	2014-APR-09
--------------------	-------------

Timepoint-minutes	
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 5

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

Data signed: (hfarmer1) 30 Mar 2015 13:34:31

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Day 5

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(6)**

Data signed: (hfarmer1) 30 Mar 2015 13:34:31

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112480000778
Analyte	THCOT-GLUC
Sample type	URINE
Result	2790
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	5
Celerion Study Number	AA99128-06
Date of Collection	2014-APR-09
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 5

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(6)**

Data signed: (hfarmer1) 30 Mar 2015 13:34:31

Generated On: 20 Jul 2016 22:28:45

Urine Start Day	5
-----------------	---

Urine End Day	6
---------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 5

Form: Biomarker-Urine (3-OH BaP)

Data signed: (hfarmer1) 30 Mar 2015 13:34:31

Generated On: 20 Jul 2016 22:28:45

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 5

Form: Biomarker-Urine (3-OH BaP) (1)

Data signed: (hfarmer1) 30 Mar 2015 13:34:31

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112490001713
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Analyte	3-OH BAP
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Sample type	URINE
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Result	.
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Result Unit	FG/ML
-------------	-------

Lab Status	OK
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Sample comment	ANALYSIS NOT PERFORMED IN ERROR
----------------	------------------------------------

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	5
--------------	---

Celerion Study Number	AA99128-07
-----------------------	------------

Date of Collection	2014-APR-09
--------------------	-------------

Timepoint-minutes	
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 5

Form: Biomarker-Urine (3-OH BaP) (1)

Data signed: (hfarmer1) 30 Mar 2015 13:34:31

Generated On: 20 Jul 2016 22:28:45

Urine Start Day	5
-----------------	---

Urine End Day	6
---------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 5

Form: Biomarker-Plasma (Caffeine, Paraxanthine)

Generated On: 20 Jul 2016 22:28:45

Sample type

PLASMA

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 5

Form: Biomarker-Plasma (Caffeine, Paraxanthine) (1)

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112500000467
----------------	----------------

Analyte	CAFFEINE
---------	----------

Sample type	PLASMA
-------------	--------

Result	888
--------	-----

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

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

Sample comment	ANALYZED IN ERROR
----------------	-------------------

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	6
---------------------------	---

Day of Visit	5
--------------	---

Celerion Study Number	AA99128-08
-----------------------	------------

Date of Collection	2014-APR-09
--------------------	-------------

Timepoint-minutes	0
-------------------	---

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 5

Form: Biomarker-Plasma (Caffeine, Paraxanthine) (1)

Generated On: 20 Jul 2016 22:28:45

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 5

Form: Biomarker-Plasma (Caffeine, Paraxanthine) (2)

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112500000467
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Analyte	PARAXANTHINE
---------	--------------

Sample type	PLASMA
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Result	1110
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Result Unit	NG/ML
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Lab Status	OK
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Sample comment	ANALYZED IN ERROR
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Detection method	LC-MS/MS
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Planned time point (Hour)	6
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Day of Visit	5
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Celerion Study Number	AA99128-08
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Date of Collection	2014-APR-09
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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: 1252**

Folder: Day 5

Form: Biomarker-Plasma (Caffeine, Paraxanthine) (2)

Generated On: 20 Jul 2016 22:28:45

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 5

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP)

Data signed: (hfarmer1) 30 Mar 2015 13:34:31

Generated On: 20 Jul 2016 22:28:45

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 5

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (1)

Data signed: (hfarmer1) 30 Mar 2015 13:34:31

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112510001735
Analyte	1-NA
Sample type	URINE
Result	BLQ<(2.50)
Result Unit	PG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	5
Celerion Study Number	AA99128-09
Date of Collection	2014-APR-09
Timepoint-minutes	
Urine Start Day	5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 5

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (1)

Data signed: (hfarmer1) 30 Mar 2015 13:34:31

Generated On: 20 Jul 2016 22:28:45

Urine End Day

6

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 5

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (2)

Data signed: (hfarmer1) 30 Mar 2015 13:34:31

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112510001735
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Analyte	2-NA
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Sample type	URINE
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Result	BLQ<(2.50)
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Result Unit	PG/ML
-------------	-------

Lab Status	OK
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Sample comment	ANALYZED IN ERROR
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Detection method	LC-MS/MS
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Planned time point (Hour)	0
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Day of Visit	5
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Celerion Study Number	AA99128-09
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Date of Collection	2014-APR-09
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Timepoint-minutes	
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Urine Start Day	5
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 5

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (2)

Data signed: (hfarmer1) 30 Mar 2015 13:34:31

Generated On: 20 Jul 2016 22:28:45

Urine End Day

6

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 5

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (3)

Data signed: (hfarmer1) 30 Mar 2015 13:34:31

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112510001735
Analyte	4-ABP
Sample type	URINE
Result	2.25
Result Unit	PG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	5
Celerion Study Number	AA99128-09
Date of Collection	2014-APR-09
Timepoint-minutes	
Urine Start Day	5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 5

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (3)

Data signed: (hfarmer1) 30 Mar 2015 13:34:31

Generated On: 20 Jul 2016 22:28:45

Urine End Day

6

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 5

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (4)

Data signed: (hfarmer1) 30 Mar 2015 13:34:31

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112510001735
Analyte	O-TOL
Sample type	URINE
Result	BLQ<(50.0)
Result Unit	PG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	5
Celerion Study Number	AA99128-09
Date of Collection	2014-APR-09
Timepoint-minutes	
Urine Start Day	5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 5

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (4)

Data signed: (hfarmer1) 30 Mar 2015 13:34:31

Generated On: 20 Jul 2016 22:28:45

Urine End Day

6

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 5

Form: Biomarker-Urine (11-dTXb2)

Data signed: (hfarmer1) 30 Mar 2015 13:34:30

Generated On: 20 Jul 2016 22:28:45

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 5

Form: Biomarker-Urine (11-dTXb2) (1)

Data signed: (hfarmer1) 30 Mar 2015 13:34:30

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112530000543
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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	OK
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Sample comment	ANALYSIS NOT PERFORMED IN ERROR
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Detection method	LC-MS/MS
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Planned time point (Hour)	0
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Day of Visit	5
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Celerion Study Number	AA99128-11
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Date of Collection	2014-APR-09
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Timepoint-minutes	
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 5

Form: Biomarker-Urine (11-dTXb2) (1)

Data signed: (hfarmer1) 30 Mar 2015 13:34:30

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Day 5

Form: Biomarker-Urine (iPF2a-III)

Data signed: (hfarmer1) 30 Mar 2015 13:34:30

Generated On: 20 Jul 2016 22:28:45

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 5

Form: Biomarker-Urine (iPF2a-III) (1)

Data signed: (hfarmer1) 30 Mar 2015 13:34:30

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112540000536
Analyte	IPF2A-III
Sample type	URINE
Result	230
Result Unit	PG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	5
Celerion Study Number	AA99128-12
Date of Collection	2014-APR-09
Timepoint-minutes	
Urine Start Day	5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 5

Form: Biomarker-Urine (iPF2a-III) (1)

Data signed: (hfarmer1) 30 Mar 2015 13:34:30

Generated On: 20 Jul 2016 22:28:45

Urine End Day

6

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 5

Form: Biomarker-Urine (Ames)

Data signed: (hfarmer1) 30 Mar 2015 13:34:31

Generated On: 20 Jul 2016 22:28:45

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 5

Form: Biomarker-Urine (Ames) (1)

Data signed: (hfarmer1) 30 Mar 2015 13:34:31

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05113320000233
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Analyte	AMES
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Sample type	URINE
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Result	.
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Result Unit	REV/ML
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Lab Status	OK
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Sample comment	ANALYSIS NOT PERFORMED IN ERROR
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Detection method	COUNT
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Planned time point (Hour)	0
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Day of Visit	5
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Celerion Study Number	AA99128-15
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Date of Collection	2014-APR-09
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Timepoint-minutes	
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 5

Form: Biomarker-Urine (Ames) (1)

Data signed: (hfarmer1) 30 Mar 2015 13:34:31

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Day 5

Form: Biomarker-Urine (1-OHP)

Data signed: (hfarmer1) 30 Mar 2015 13:34:32

Generated On: 20 Jul 2016 22:28:45

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 5

Form: Biomarker-Urine (1-OHP) (1)

Data signed: (hfarmer1) 30 Mar 2015 13:34:32

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05115190003737
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Analyte	1-OHP
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Sample type	URINE
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Result	.
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Result Unit	PG/ML
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Lab Status	OK
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Sample comment	NOT ANALYZED IN ERROR
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Detection method	LC-MS/MS
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Planned time point (Hour)	0
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Day of Visit	5
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Celerion Study Number	AA99598-03
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Date of Collection	2014-APR-09
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Timepoint-minutes	
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Urine Start Day	5
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 5

Form: Biomarker-Urine (1-OHP) (1)

Data signed: (hfarmer1) 30 Mar 2015 13:34:32

Generated On: 20 Jul 2016 22:28:45

Urine End Day

6

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 5

Form: Biomarker-Urine (SPMA, SBMA)

Data signed: (hfarmer1) 30 Mar 2015 13:34:30

Generated On: 20 Jul 2016 22:28:45

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 5

Form: Biomarker-Urine (SPMA, SBMA) (1)

Data signed: (hfarmer1) 30 Mar 2015 13:34:30

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05115170003728
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Analyte	SPMA
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Sample type	URINE
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Result	.
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Result Unit	NG/ML
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Lab Status	OK
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Sample comment	NOT ANALYZED IN ERROR
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Detection method	LC-MS/MS
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Planned time point (Hour)	0
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Day of Visit	5
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Celerion Study Number	AA99598-01
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Date of Collection	2014-APR-09
--------------------	-------------

Timepoint-minutes	
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Urine Start Day	5
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 5

Form: Biomarker-Urine (SPMA, SBMA) (1)

Data signed: (hfarmer1) 30 Mar 2015 13:34:30

Generated On: 20 Jul 2016 22:28:45

Urine End Day

6

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 5

Form: Biomarker-Urine (SPMA, SBMA) (2)

Data signed: (hfarmer1) 30 Mar 2015 13:34:30

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05115170003737
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Analyte	SBMA
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Sample type	URINE
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Result	.
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Result Unit	NG/ML
-------------	-------

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

Sample comment	NOT ANALYZED IN ERROR
----------------	-----------------------

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
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Day of Visit	5
--------------	---

Celerion Study Number	AA99598-01
-----------------------	------------

Date of Collection	2014-APR-09
--------------------	-------------

Timepoint-minutes	
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Urine Start Day	5
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 5

Form: Biomarker-Urine (SPMA, SBMA) (2)

Data signed: (hfarmer1) 30 Mar 2015 13:34:30

Generated On: 20 Jul 2016 22:28:45

Urine End Day

6

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 5

Form: Biomarker-Urine (MHBMA)

Data signed: (hfarmer1) 30 Mar 2015 13:34:30

Generated On: 20 Jul 2016 22:28:45

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 5

Form: Biomarker-Urine (MHBMA) (1)

Data signed: (hfarmer1) 30 Mar 2015 13:34:30

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05115180003737
Analyte	MHBMA
Sample type	URINE
Result	.
Result Unit	NG/ML
Lab Status	OK
Sample comment	NOT ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	5
Celerion Study Number	AA99598-02
Date of Collection	2014-APR-09
Timepoint-minutes	
Urine Start Day	5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 5

Form: Biomarker-Urine (MHBMA) (1)

Data signed: (hfarmer1) 30 Mar 2015 13:34:30

Generated On: 20 Jul 2016 22:28:45

Urine End Day

6

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 5

Form: Biomarker-Urine (Creatinine)

Data signed: (hfarmer1) 30 Mar 2015 13:34:31

Generated On: 20 Jul 2016 22:28:45

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 5

Form: Biomarker-Urine (Creatinine) (1)

Data signed: (hfarmer1) 30 Mar 2015 13:34:31

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05115160001713
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Analyte	CREATININE
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Sample type	URINE
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Result	.
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Result Unit	MG/DL
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Lab Status	OK
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Sample comment	ANALYSIS NOT PERFORMED IN ERROR
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Detection method	SPECTROPHOTOMETRIC
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Planned time point (Hour)	0
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Day of Visit	5
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Celerion Study Number	AA99128-14
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Date of Collection	2014-APR-09
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Timepoint-minutes	
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 5

Form: Biomarker-Urine (Creatinine) (1)

Data signed: (hfarmer1) 30 Mar 2015 13:34:31

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot)

Data signed: (hfarmer1) 30 Mar 2015 13:34:30

Generated On: 20 Jul 2016 22:28:45

Sample type

PLASMA

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (1)

Data signed: (hfarmer1) 30 Mar 2015 13:34:30

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112430001811
Analyte	COT
Sample type	PLASMA
Result	263
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	5
Celerion Study Number	AA99128-01
Date of Collection	2014-APR-09
Timepoint-minutes	-15
Urine Start Day	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (1)

Data signed: (hfarmer1) 30 Mar 2015 13:34:30

Generated On: 20 Jul 2016 22:28:45

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (2)

Data signed: (hfarmer1) 30 Mar 2015 13:34:30

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112430001811
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Analyte	NIC
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Sample type	PLASMA
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Result	1.88
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Result Unit	NG/ML
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Lab Status	OK
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Sample comment	ANALYZED IN ERROR
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Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	5
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Celerion Study Number	AA99128-01
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Date of Collection	2014-APR-09
--------------------	-------------

Timepoint-minutes	-15
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Urine Start Day	
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (2)

Data signed: (hfarmer1) 30 Mar 2015 13:34:30

Generated On: 20 Jul 2016 22:28:45

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (3)

Data signed: (hfarmer1) 30 Mar 2015 13:34:30

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112430001812
Analyte	COT
Sample type	PLASMA
Result	247
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	2
Day of Visit	5
Celerion Study Number	AA99128-01
Date of Collection	2014-APR-09
Timepoint-minutes	0
Urine Start Day	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (3)

Data signed: (hfarmer1) 30 Mar 2015 13:34:30

Generated On: 20 Jul 2016 22:28:45

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (4)

Data signed: (hfarmer1) 30 Mar 2015 13:34:30

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112430001812
Analyte	NIC
Sample type	PLASMA
Result	12.6
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	2
Day of Visit	5
Celerion Study Number	AA99128-01
Date of Collection	2014-APR-09
Timepoint-minutes	0
Urine Start Day	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (4)

Data signed: (hfarmer1) 30 Mar 2015 13:34:30

Generated On: 20 Jul 2016 22:28:45

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (5)

Data signed: (hfarmer1) 30 Mar 2015 13:34:30

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112430001813
Analyte	COT
Sample type	PLASMA
Result	267
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	4
Day of Visit	5
Celerion Study Number	AA99128-01
Date of Collection	2014-APR-09
Timepoint-minutes	0
Urine Start Day	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (5)

Data signed: (hfarmer1) 30 Mar 2015 13:34:30

Generated On: 20 Jul 2016 22:28:45

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (6)

Data signed: (hfarmer1) 30 Mar 2015 13:34:30

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112430001813
Analyte	NIC
Sample type	PLASMA
Result	12.1
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	4
Day of Visit	5
Celerion Study Number	AA99128-01
Date of Collection	2014-APR-09
Timepoint-minutes	0
Urine Start Day	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (6)

Data signed: (hfarmer1) 30 Mar 2015 13:34:30

Generated On: 20 Jul 2016 22:28:45

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (7)

Data signed: (hfarmer1) 30 Mar 2015 13:34:30

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112430001814
Analyte	COT
Sample type	PLASMA
Result	275
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	6
Day of Visit	5
Celerion Study Number	AA99128-01
Date of Collection	2014-APR-09
Timepoint-minutes	0
Urine Start Day	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (7)

Data signed: (hfarmer1) 30 Mar 2015 13:34:30

Generated On: 20 Jul 2016 22:28:45

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (8)

Data signed: (hfarmer1) 30 Mar 2015 13:34:30

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112430001814
Analyte	NIC
Sample type	PLASMA
Result	17.5
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	6
Day of Visit	5
Celerion Study Number	AA99128-01
Date of Collection	2014-APR-09
Timepoint-minutes	0
Urine Start Day	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (8)

Data signed: (hfarmer1) 30 Mar 2015 13:34:30

Generated On: 20 Jul 2016 22:28:45

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (9)

Data signed: (hfarmer1) 30 Mar 2015 13:34:30

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112430001815
Analyte	COT
Sample type	PLASMA
Result	282
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	8
Day of Visit	5
Celerion Study Number	AA99128-01
Date of Collection	2014-APR-09
Timepoint-minutes	0
Urine Start Day	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (9)

Data signed: (hfarmer1) 30 Mar 2015 13:34:30

Generated On: 20 Jul 2016 22:28:45

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (10)

Data signed: (hfarmer1) 30 Mar 2015 13:34:30

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112430001815
Analyte	NIC
Sample type	PLASMA
Result	18.8
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	8
Day of Visit	5
Celerion Study Number	AA99128-01
Date of Collection	2014-APR-09
Timepoint-minutes	0
Urine Start Day	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (10)

Data signed: (hfarmer1) 30 Mar 2015 13:34:30

Generated On: 20 Jul 2016 22:28:45

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (11)

Data signed: (hfarmer1) 30 Mar 2015 13:34:30

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112430001816
Analyte	COT
Sample type	PLASMA
Result	276
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	10
Day of Visit	5
Celerion Study Number	AA99128-01
Date of Collection	2014-APR-09
Timepoint-minutes	0
Urine Start Day	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (11)

Data signed: (hfarmer1) 30 Mar 2015 13:34:30

Generated On: 20 Jul 2016 22:28:45

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (12)

Data signed: (hfarmer1) 30 Mar 2015 13:34:30

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112430001816
Analyte	NIC
Sample type	PLASMA
Result	17.0
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	10
Day of Visit	5
Celerion Study Number	AA99128-01
Date of Collection	2014-APR-09
Timepoint-minutes	0
Urine Start Day	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (12)

Data signed: (hfarmer1) 30 Mar 2015 13:34:30

Generated On: 20 Jul 2016 22:28:45

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (13)

Data signed: (hfarmer1) 30 Mar 2015 13:34:30

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112430001817
Analyte	COT
Sample type	PLASMA
Result	301
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	12
Day of Visit	5
Celerion Study Number	AA99128-01
Date of Collection	2014-APR-09
Timepoint-minutes	0
Urine Start Day	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (13)

Data signed: (hfarmer1) 30 Mar 2015 13:34:30

Generated On: 20 Jul 2016 22:28:45

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (14)

Data signed: (hfarmer1) 30 Mar 2015 13:34:30

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112430001817
Analyte	NIC
Sample type	PLASMA
Result	28.5
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	12
Day of Visit	5
Celerion Study Number	AA99128-01
Date of Collection	2014-APR-09
Timepoint-minutes	0
Urine Start Day	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (14)

Data signed: (hfarmer1) 30 Mar 2015 13:34:30

Generated On: 20 Jul 2016 22:28:45

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (15)

Data signed: (hfarmer1) 30 Mar 2015 13:34:30

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112430001818
Analyte	COT
Sample type	PLASMA
Result	320
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	14
Day of Visit	5
Celerion Study Number	AA99128-01
Date of Collection	2014-APR-09
Timepoint-minutes	0
Urine Start Day	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (15)

Data signed: (hfarmer1) 30 Mar 2015 13:34:30

Generated On: 20 Jul 2016 22:28:45

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (16)

Data signed: (hfarmer1) 30 Mar 2015 13:34:30

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112430001818
Analyte	NIC
Sample type	PLASMA
Result	25.2
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	14
Day of Visit	5
Celerion Study Number	AA99128-01
Date of Collection	2014-APR-09
Timepoint-minutes	0
Urine Start Day	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (16)

Data signed: (hfarmer1) 30 Mar 2015 13:34:30

Generated On: 20 Jul 2016 22:28:45

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (17)

Data signed: (hfarmer1) 30 Mar 2015 13:34:30

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112430001819
Analyte	COT
Sample type	PLASMA
Result	337
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	16
Day of Visit	5
Celerion Study Number	AA99128-01
Date of Collection	2014-APR-09
Timepoint-minutes	0
Urine Start Day	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (17)

Data signed: (hfarmer1) 30 Mar 2015 13:34:30

Generated On: 20 Jul 2016 22:28:45

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (18)

Data signed: (hfarmer1) 30 Mar 2015 13:34:30

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112430001819
Analyte	NIC
Sample type	PLASMA
Result	27.0
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	16
Day of Visit	5
Celerion Study Number	AA99128-01
Date of Collection	2014-APR-09
Timepoint-minutes	0
Urine Start Day	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (18)

Data signed: (hfarmer1) 30 Mar 2015 13:34:30

Generated On: 20 Jul 2016 22:28:45

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 6

Form: Date of Visit

Data signed: (hfarmer1) 30 Mar 2015 13:34:32

Generated On: 20 Jul 2016 22:28:45

Date of Visit

10 APR 2014
DD/MMM/YYYY

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 6

Form: Plasma Nicotine Samples <Day 6> (1)

Data signed: (hfarmer1) 30 Mar 2015 13:34:32

Generated On: 20 Jul 2016 22:28:45

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	10 APR 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: 1252**

Folder: Day 6

Form: Plasma Nicotine Samples <Day 6> (2)

Data signed: (hfarmer1) 30 Mar 2015 13:34:32

Generated On: 20 Jul 2016 22:28:45

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	10 APR 2014
---------------------	-------------

Scheduled Time	T0 + 24H <input checked="" type="radio"/>
----------------	---

Time hour:min 24-hour clock	06:54
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 6

Form: Plasma Cotinine Samples <Day 6> (1)

Data signed: (hfarmer1) 30 Mar 2015 13:34:32

Generated On: 20 Jul 2016 22:28:45

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	10 APR 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: 1252**

Folder: Day 6

Form: Plasma Cotinine Samples <Day 6> (2)

Data signed: (hfarmer1) 30 Mar 2015 13:34:32

Generated On: 20 Jul 2016 22:28:45

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	10 APR 2014
---------------------	-------------

Scheduled Time	T0 + 24H <input checked="" type="radio"/>
----------------	---

Time hour:min 24-hour clock	06:54
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 6

Form: CoHb Blood Sample <prior to gas transfer and product>

Data signed: (hfarmer1) 30 Mar 2015 13:34:32

Generated On: 20 Jul 2016 22:28:45

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	10 APR 2014
---------------------	-------------

Timepoint	Prior to gas transfer assessment and prior to product use <input checked="" type="radio"/>
-----------	--

Time hour:min 24-hour clock	06:54
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 6

Form: Oxysterols

Data signed: (hfarmer1) 30 Mar 2015 13:34:32

Generated On: 20 Jul 2016 22:28:45

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	10 APR 2014
---------------------	-------------

Time hour:min 24-hour clock	06:54
--------------------------------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Day 6

Form: CYP2A6 activity Sample

Data signed: (hfarmer1) 30 Mar 2015 13:34:32

Generated On: 20 Jul 2016 22:28:45

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

10 APR 2014

06:54

trans-3'-hydroxyc
otinine

10 APR 2014

06:54

cotinine

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 6

Form: Risk Marker: sICAM-1

Data signed: (hfarmer1) 30 Mar 2015 13:34:32

Generated On: 20 Jul 2016 22:28:45

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	10 APR 2014
---------------------	-------------

Time hour:min 24-hour clock	06:54
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 6

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Data signed: (hfarmer1) 30 Mar 2015 13:34:33

Generated On: 20 Jul 2016 22:28:45

Date of Birth

(b) (6)

Date of assessment
DD/MMM/YYYY

2014 APR 10
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?

None ☐

1. Angry, irritable, frustrated

How have you been feeling over the past 24 hours?

Moderate ☐

2. Anxious, nervous

How have you been feeling over the past 24 hours?

None ☐

3. Depressed Mood, sad

How have you been feeling over the past 24 hours?

Moderate ☐

4. Desire or craving to smoke

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 6

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Data signed: (hfarmer1) 30 Mar 2015 13:34:33

Generated On: 20 Jul 2016 22:28:45

How have you been feeling over the past 24 hours? None ☐

5. Difficulty concentrating

How have you been feeling over the past 24 hours? None ☐

6. Increased appetite, hungry, weight gain

How have you been feeling over the past 24 hours? None ☐

7. Insomnia, sleep problems, awakening at night

How have you been feeling over the past 24 hours? Moderate ☐

8. Restless

How have you been feeling over the past 24 hours? Moderate ☐

9. Impatient

How have you been feeling over the past 24 hours? 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: 1252**

Folder: Day 6

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Data signed: (hfarmer1) 30 Mar 2015 13:34:33

Generated On: 20 Jul 2016 22:28:45

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: 1252

Folder: Day 6

Form: Cough Assessment

Data signed: (hfarmer1) 30 Mar 2015 13:34:33

Generated On: 20 Jul 2016 22:28:45

Date of Birth

(b) (6)

Date of assessment
DD/MMM/YYYY

2014 APR 10
DD/MMM/YYYY

Time of assessment

06:02
hour:min 24-hour clock

Assessment Status

Completed ☒

Have you experienced a regular need to cough e.g.
coughing several times in the last 24 hrs?

Yes ☒

If YES, please answer the following questions:

First Question: Cough Impact Scale
How much is your cough bothering you?

50

Second Question: Cough Intensity Scale:
How intense is your cough?

Mild ☒

Third Question: Cough Frequency Scale:
How frequently do you normally have to cough each
day?

Sometimes ☒

Fourth Question: Sputum Production
To what extent do you produce sputum when coughing?

A moderate amount of
sputum ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 6

Form: Bio-banking (Transcriptomics)

Data signed: (hfarmer1) 30 Mar 2015 13:34:33

Generated On: 20 Jul 2016 22:28:45

Was a Bio-banking sample for transcriptomics taken?

Yes ☒

Time of Sample Collection

06:54
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: 1252**

Folder: Day 6

Form: Bio-banking (Biomarkers of exposure and risk markers)

Data signed: (hfarmer1) 30 Mar 2015 13:34:33

Generated On: 20 Jul 2016 22:28:45

Was a Bio-banking sample for biomarkers of exposure
and risk markers taken?

Yes ☒

Time of Sample Collection

06:54
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: 1252**

Folder: Day 6

Form: Bio-banking (nasal epithelial collection/buccal collection)

Data signed: (hfarmer1) 30 Mar 2015 13:34:33

Generated On: 20 Jul 2016 22:28:45

Was a Bio-banking sample for nasal epithelial collection/buccal collection taken?	Yes <input checked="" type="radio"/>
---	--------------------------------------

Time of Buccal Collection	10:37
	hour:min 24-hour clock

Time of Nasal Epithelial Collection	10:33
	hour:min 24-hour clock

Was the subject fasting for at least 30 minutes at time of sample collection?	Yes <input checked="" type="radio"/>
---	--------------------------------------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 6

Form: Oxysterol results (1)

Generated On: 20 Jul 2016 22:28:45

Sample Accession number	3281678015
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Analyte	22(R)-HYDROXYCHOLESTERO L
---------	------------------------------

Analyte code	22RHCRL
--------------	---------

Result	
--------	--

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

Comment	NOT ANALYSED, INCOMPLETE SAMPLE SET
---------	--

Lower limit of quantification	9.46
-------------------------------	------

Date of Collection DD MMM YYYY	
-----------------------------------	--

Collection time hh:mm 24 hour clock	
--	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 6

Form: Oxysterol results (2)

Generated On: 20 Jul 2016 22:28:45

Sample Accession number	3281678015
-------------------------	------------

Analyte	24(R)-HYDROXYCHOLESTERO L
---------	------------------------------

Analyte code	24RHCRL
--------------	---------

Result	
--------	--

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

Comment	NOT ANALYSED, INCOMPLETE SAMPLE SET
---------	--

Lower limit of quantification	6.56
-------------------------------	------

Date of Collection DD MMM YYYY	
-----------------------------------	--

Collection time hh:mm 24 hour clock	
--	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 6

Form: Oxysterol results (3)

Generated On: 20 Jul 2016 22:28:45

Sample Accession number	3281678015
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Analyte	25-HYDROXYCHOLESTEROL
---------	-----------------------

Analyte code	25HCRL
--------------	--------

Result	
--------	--

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

Comment	NOT ANALYSED, INCOMPLETE SAMPLE SET
---------	--

Lower limit of quantification	4.70
-------------------------------	------

Date of Collection DD MMM YYYY	
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Collection time hh:mm 24 hour clock	
--	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 6

Form: Oxysterol results (4)

Generated On: 20 Jul 2016 22:28:45

Sample Accession number	3281678015
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Analyte	27-HYDROXYCHOLESTEROL
---------	-----------------------

Analyte code	27HCRL
--------------	--------

Result	
--------	--

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

Comment	NOT ANALYSED, INCOMPLETE SAMPLE SET
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Lower limit of quantification	11.60
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Date of Collection DD MMM YYYY	
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Collection time hh:mm 24 hour clock	
--	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 6

Form: Oxysterol results (5)

Generated On: 20 Jul 2016 22:28:45

Sample Accession number	3281678015
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Analyte	4B-HYDROXYCHOLESTEROL
---------	-----------------------

Analyte code	4BHCRL
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Result	
--------	--

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

Comment	NOT ANALYSED, INCOMPLETE SAMPLE SET
---------	--

Lower limit of quantification	10.66
-------------------------------	-------

Date of Collection DD MMM YYYY	
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Collection time hh:mm 24 hour clock	
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 6

Form: Oxysterol results (6)

Generated On: 20 Jul 2016 22:28:45

Sample Accession number	3281678015
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Analyte	5A,6A-EPOXYCHOLESTANOL
---------	------------------------

Analyte code	5A6AECNL
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Result	
--------	--

Result Unit	NG/ML
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Comment	NOT ANALYSED, INCOMPLETE SAMPLE SET
---------	--

Lower limit of quantification	12.46
-------------------------------	-------

Date of Collection DD MMM YYYY	
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Collection time hh:mm 24 hour clock	
--	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 6

Form: Oxysterol results (7)

Generated On: 20 Jul 2016 22:28:45

Sample Accession number	3281678015
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Analyte	5B,6B-EPOXYCHOLESTANOL
---------	------------------------

Analyte code	5B6BECNL
--------------	----------

Result	
--------	--

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

Comment	NOT ANALYSED, INCOMPLETE SAMPLE SET
---------	--

Lower limit of quantification	26.83
-------------------------------	-------

Date of Collection DD MMM YYYY	
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Collection time hh:mm 24 hour clock	
--	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 6

Form: Oxysterol results (8)

Generated On: 20 Jul 2016 22:28:45

Sample Accession number	3281678015
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Analyte	6A-HYDROXY-5A-CHOLESTAN OL
---------	-------------------------------

Analyte code	6AH5ACNL
--------------	----------

Result	
--------	--

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

Comment	NOT ANALYSED, INCOMPLETE SAMPLE SET
---------	--

Lower limit of quantification	13.70
-------------------------------	-------

Date of Collection DD MMM YYYY	
-----------------------------------	--

Collection time hh:mm 24 hour clock	
--	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 6

Form: Oxysterol results (9)

Generated On: 20 Jul 2016 22:28:45

Sample Accession number	3281678015
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Analyte	7-KETOCHOLESTEROL
---------	-------------------

Analyte code	7KCRL
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Result	
--------	--

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

Comment	NOT ANALYSED, INCOMPLETE SAMPLE SET
---------	--

Lower limit of quantification	15.43
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Date of Collection DD MMM YYYY	
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Collection time hh:mm 24 hour clock	
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 6

Form: Oxysterol results (10)

Generated On: 20 Jul 2016 22:28:45

Sample Accession number	3281678015
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Analyte	7A-HYDROXYCHOLESTEROL
---------	-----------------------

Analyte code	7AHCRL
--------------	--------

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

Comment	NOT ANALYSED, INCOMPLETE SAMPLE SET
---------	--

Lower limit of quantification	13.46
-------------------------------	-------

Date of Collection DD MMM YYYY	
-----------------------------------	--

Collection time hh:mm 24 hour clock	
--	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 6

Form: Oxysterol results (11)

Generated On: 20 Jul 2016 22:28:45

Sample Accession number	3281678015
-------------------------	------------

Analyte	7B-HYDROXYCHOLESTEROL
---------	-----------------------

Analyte code	7BHCRL
--------------	--------

Result	
--------	--

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

Comment	NOT ANALYSED, INCOMPLETE SAMPLE SET
---------	--

Lower limit of quantification	12.86
-------------------------------	-------

Date of Collection DD MMM YYYY	
-----------------------------------	--

Collection time hh:mm 24 hour clock	
--	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 6

Form: Oxysterol results (12)

Generated On: 20 Jul 2016 22:28:45

Sample Accession number	3281678015
-------------------------	------------

Analyte	CHOLESTEROL
---------	-------------

Analyte code	CHOL
--------------	------

Result	
--------	--

Result Unit	MG/ML
-------------	-------

Comment	NOT ANALYSED, INCOMPLETE SAMPLE SET
---------	--

Lower limit of quantification	0.50
-------------------------------	------

Date of Collection DD MMM YYYY	
-----------------------------------	--

Collection time hh:mm 24 hour clock	
--	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 6

Form: Lab_BU_COHB (1)

Data signed: (hfarmer1) 30 Mar 2015 13:34:34

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05115150004508
Analyte	CARBOXYHEMOGLOBIN
Sample type	BLOOD
Result	2.40
Result Unit	%
Lab Status	OK
Sample comment	.
Detection method	SPECTROPHOTOMETRIC
Lower limit of quantification	0.500
Planned time point (Hour)	6
Day of Visit	6
Celerion Study Number	AA99128-16
Date of Collection	2014-APR-10
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 6

Form: Lab_BU_COHB (1)

Data signed: (hfarmer1) 30 Mar 2015 13:34:34

Generated On: 20 Jul 2016 22:28:45

Start Day (24 hour urine only) _____

End Day (24 hour Urine Only) _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 6

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)

Data signed: (hfarmer1) 30 Mar 2015 13:34:33

Generated On: 20 Jul 2016 22:28:45

Date of Birth	(b) (6)
Date of assessment DD/MMM/YYYY	2014 APR 10 DD/MMM/YYYY
Time of assessment	06:05 hour:min 24-hour clock
Assessment Status	Completed <input type="radio"/>
1. Was smoking satisfying?	Moderately <input type="radio"/>
2. Did cigarettes taste good?	Not at all <input type="radio"/>
3. Did you enjoy the sensation in your throat and chest?	Not at all <input type="radio"/>
4. Did smoking calm you down?	Not at all <input type="radio"/>
5. Did smoking make you feel more awake?	Not at all <input type="radio"/>
6. Did smoking make you feel less irritable?	Not at all <input type="radio"/>
7. Did smoking help you concentrate?	Not at all <input type="radio"/>
8. Did smoking reduce your hunger for food?	Not at all <input type="radio"/>

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 6

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)

Data signed: (hfarmer1) 30 Mar 2015 13:34:33

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Day 6

Form: Questionnaire on smoking urges (QSU)

Data signed: (hfarmer1) 30 Mar 2015 13:34:33

Generated On: 20 Jul 2016 22:28:45

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

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

Date of assessment	2014 APR 10
--------------------	-------------

DD/MMM/YYYY

Time of assessment	06:06
--------------------	-------

hour:min 24-hour clock

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

1. I have a desire for a cigarette right now	Strongly agree <input type="radio"/>
--	--------------------------------------

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

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

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

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

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 6

Form: Questionnaire on smoking urges (QSU)

Data signed: (hfarmer1) 30 Mar 2015 13:34:33

Generated On: 20 Jul 2016 22:28:45

7. A cigarette would taste good now Strongly disagree ☐

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

9. Smoking would make me less depressed Strongly disagree ☐

10. I am going to smoke as soon as possible Strongly agree ☐

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 6

Form: Risk Markers(CCLS) (1)

Data signed: (hfarmer1) 30 Mar 2015 13:34:33

Generated On: 20 Jul 2016 22:28:45

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	1252
----------------------	------

Subject Sex	M
-------------	---

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

Visit Name	DAY6
------------	------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	W816780
--------------	---------

Actual Collection Date	2014 04 10
------------------------	------------

Actual Collection Time	06:54
------------------------	-------

Specimen Condition	
--------------------	--

Battery ID	IM2293
------------	--------

Battery Name	SICAM-1
--------------	---------

Lab Test ID	IMT1768
-------------	---------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 6

Form: Risk Markers(CCLS) (1)

Data signed: (hfarmer1) 30 Mar 2015 13:34:33

Generated On: 20 Jul 2016 22:28:45

Lab Test Name	SICAM-1-RUO
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	244.4
Reported Numeric Result	244.4
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: 1252**

Folder: Day 6

Form: Risk Markers(CCLS) (1)

Data signed: (hfarmer1) 30 Mar 2015 13:34:33

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Day 6

Form: Biomarker-Plasma (Nic, Cot, tHCot)

Generated On: 20 Jul 2016 22:28:45

Sample type

PLASMA

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 6

Form: Biomarker-Plasma (Nic, Cot, tHCot) (1)

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112430001820
----------------	----------------

Analyte	COT
---------	-----

Sample type	PLASMA
-------------	--------

Result	325
--------	-----

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

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

Sample comment	ANALYZED IN ERROR
----------------	-------------------

Detection method	LC-MS/MS
------------------	----------

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

Day of Visit	6
--------------	---

Celerion Study Number	AA99128-01
-----------------------	------------

Date of Collection	2014-APR-10
--------------------	-------------

Timepoint-minutes	0
-------------------	---

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 6

Form: Biomarker-Plasma (Nic, Cot, tHCot) (1)

Generated On: 20 Jul 2016 22:28:45

Urine End Day	5
---------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 6

Form: Biomarker-Plasma (Nic, Cot, tHCot) (2)

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112430001820
----------------	----------------

Analyte	NIC
---------	-----

Sample type	PLASMA
-------------	--------

Result	9.25
--------	------

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

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

Sample comment	ANALYZED IN ERROR
----------------	-------------------

Detection method	LC-MS/MS
------------------	----------

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

Day of Visit	6
--------------	---

Celerion Study Number	AA99128-01
-----------------------	------------

Date of Collection	2014-APR-10
--------------------	-------------

Timepoint-minutes	0
-------------------	---

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 6

Form: Biomarker-Plasma (Nic, Cot, tHCot) (2)

Generated On: 20 Jul 2016 22:28:45

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 6

Form: Biomarker-Plasma (Nic, Cot, tHCot) (3)

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112430001821
----------------	----------------

Analyte	COT
---------	-----

Sample type	PLASMA
-------------	--------

Result	270
--------	-----

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

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

Sample comment	ANALYZED IN ERROR
----------------	-------------------

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	24
---------------------------	----

Day of Visit	6
--------------	---

Celerion Study Number	AA99128-01
-----------------------	------------

Date of Collection	2014-APR-10
--------------------	-------------

Timepoint-minutes	0
-------------------	---

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 6

Form: Biomarker-Plasma (Nic, Cot, tHCot) (3)

Generated On: 20 Jul 2016 22:28:45

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 6

Form: Biomarker-Plasma (Nic, Cot, tHCot) (4)

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112430001821
----------------	----------------

Analyte	NIC
---------	-----

Sample type	PLASMA
-------------	--------

Result	1.95
--------	------

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

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

Sample comment	ANALYZED IN ERROR
----------------	-------------------

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	24
---------------------------	----

Day of Visit	6
--------------	---

Celerion Study Number	AA99128-01
-----------------------	------------

Date of Collection	2014-APR-10
--------------------	-------------

Timepoint-minutes	0
-------------------	---

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 6

Form: Biomarker-Plasma (Nic, Cot, tHCot) (4)

Generated On: 20 Jul 2016 22:28:45

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 6

Form: Biomarker-Plasma (Nic, Cot, tHCot) (5)

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112520000467
----------------	----------------

Analyte	COT
---------	-----

Sample type	PLASMA
-------------	--------

Result	260
--------	-----

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

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

Sample comment	ANALYZED IN ERROR
----------------	-------------------

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	6
--------------	---

Celerion Study Number	AA99128-10
-----------------------	------------

Date of Collection	2014-APR-10
--------------------	-------------

Timepoint-minutes	0
-------------------	---

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 6

Form: Biomarker-Plasma (Nic, Cot, tHCot) (5)

Generated On: 20 Jul 2016 22:28:45

Urine End Day

6

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 6

Form: Biomarker-Plasma (Nic, Cot, tHCot) (6)

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112520000467
----------------	----------------

Analyte	THCOT
---------	-------

Sample type	PLASMA
-------------	--------

Result	135
--------	-----

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

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

Sample comment	ANALYZED IN ERROR
----------------	-------------------

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	6
--------------	---

Celerion Study Number	AA99128-10
-----------------------	------------

Date of Collection	2014-APR-10
--------------------	-------------

Timepoint-minutes	0
-------------------	---

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 6

Form: Biomarker-Plasma (Nic, Cot, tHCot) (6)

Generated On: 20 Jul 2016 22:28:45

Urine End Day

6

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Discharge (Confinement)

Form: Date of Discharge

Data signed: (hfarmer1) 30 Mar 2015 13:34:36

Generated On: 20 Jul 2016 22:28:45

Date of Visit

10 APR 2014
DD/MMM/YYYY

Discharge Time

11:55
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: 1252**

Folder: Discharge (Confinement)

Form: Vital Signs

Data signed: (hfarmer1) 30 Mar 2015 13:34:36

Generated On: 20 Jul 2016 22:28:45

Were Vitals Signs assessed? Yes ☒

If No, please specify the reason: _____

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

Time of assessment 08:46
hour:min 24-hour clock

Pulse rate 53
beats per minute

Respiratory rate 20
breaths per minute

Blood Pressure (systolic) 124
mmHg

Blood Pressure (diastolic) 83
mmHg

Vital Signs Position of Subject Supine ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Discharge (Confinement)

Form: Advice on the risk of smoking and debriefing

Data signed: (hfarmer1) 30 Mar 2015 13:34:36

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Discharge (Confinement)

Form: Physical Examination

Data signed: (hfarmer1) 30 Mar 2015 13:34:34

Generated On: 20 Jul 2016 22:28:45

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Discharge (Confinement)

Form: Physical Examination (1)

Data signed: (hfarmer1) 30 Mar 2015 13:34:34

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Discharge (Confinement)

Form: Physical Examination (2)

Data signed: (hfarmer1) 30 Mar 2015 13:34:34

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Discharge (Confinement)

Form: Physical Examination (3)

Data signed: (hfarmer1) 30 Mar 2015 13:34:34

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Discharge (Confinement)

Form: Physical Examination (4)

Data signed: (hfarmer1) 30 Mar 2015 13:34:34

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Discharge (Confinement)

Form: Physical Examination (5)

Data signed: (hfarmer1) 30 Mar 2015 13:34:34

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Discharge (Confinement)

Form: Physical Examination (6)

Data signed: (hfarmer1) 30 Mar 2015 13:34:34

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Discharge (Confinement)

Form: Physical Examination (7)

Data signed: (hfarmer1) 30 Mar 2015 13:34:34

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Discharge (Confinement)

Form: Physical Examination (8)

Data signed: (hfarmer1) 30 Mar 2015 13:34:34

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Discharge (Confinement)

Form: Physical Examination (9)

Data signed: (hfarmer1) 30 Mar 2015 13:34:34

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Discharge (Confinement)

Form: Physical Examination (10)

Data signed: (hfarmer1) 30 Mar 2015 13:34:34

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Discharge (Confinement)

Form: Physical Examination (11)

Data signed: (hfarmer1) 30 Mar 2015 13:34:34

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Discharge (Confinement)

Form: Physical Examination (12)

Data signed: (hfarmer1) 30 Mar 2015 13:34:34

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Discharge (Confinement)

Form: Physical Examination (13)

Data signed: (hfarmer1) 30 Mar 2015 13:34:34

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Discharge (Confinement)

Form: Physical Examination (14)

Data signed: (hfarmer1) 30 Mar 2015 13:34:34

Generated On: 20 Jul 2016 22:28:45

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

System Dentition ☒

Outcome Abnormal ☒

Abnormal, please specify MISSING AND DECAYED
TEETH

Clinically significant No ☒

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Discharge (Confinement)

Form: Physical Examination (15)

Data signed: (hfarmer1) 30 Mar 2015 13:34:34

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Discharge (Confinement)

Form: Physical Examination (16)

Data signed: (hfarmer1) 30 Mar 2015 13:34:34

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Discharge (Confinement)

Form: Physical Examination (17)

Data signed: (hfarmer1) 30 Mar 2015 13:34:34

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Discharge (Confinement)

Form: Physical Examination (18)

Data signed: (hfarmer1) 30 Mar 2015 13:34:34

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Discharge (Confinement)

Form: Physical Examination (19)

Data signed: (hfarmer1) 30 Mar 2015 13:34:34

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Discharge (Confinement)

Form: Weight

Data signed: (hfarmer1) 30 Mar 2015 13:34:36

Generated On: 20 Jul 2016 22:28:45

Measurement(s) assessed?

Yes ☒

If No, please specify the reason: _____

Date of Assessment

10 APR 2014
DD/MMM/YYYY

Time of assessment

11:10
hour:min 24-hour clock

Weight

86.2
kg

BMI

27.7

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Discharge (Confinement)

Form: ECG (12-Lead Standard)

Data signed: (hfarmer1) 30 Mar 2015 13:34:34

Generated On: 20 Jul 2016 22:28:45

Was the ECG performed? Yes ☒

If No, please specify the reason: _____

Position Supine ☒

Heart Rate 52
beats per minute

QRS Interval 97
msec

QT Interval 451
msec

QTcB Interval 421
msec

PR Interval 170
msec

QTcF Interval 430
msec

Interpretation Normal ☒

If Abnormal, Clinical Significance _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Discharge (Confinement)

Form: ECG (12-Lead Standard)

Data signed: (hfarmer1) 30 Mar 2015 13:34:34

Generated On: 20 Jul 2016 22:28:45

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

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Discharge (Confinement)

Form: Gas Transfer

Data signed: (hfarmer1) 30 Mar 2015 13:34:35

Generated On: 20 Jul 2016 22:28:45

Was the Gas Transfer performed?

Yes ☒

If No, please specify the reason: _____

Category _____

Position

SITTING

Date of assessment
DD/MMM/YYYY

10 APR 2014

Time of assessment

07:48

DLCO value

32.78
ml/min/mmHg

KCO value

1.19
mmol/min/kPa/L

DLCO/VA value

3.56
mL/min/mmHg/L

Interpretation

Normal ☒

If Abnormal, Clinical Significance _____

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

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Discharge (Confinement)

Form: Lung Volume Measurements

Data signed: (hfarmer1) 30 Mar 2015 13:34:35

Generated On: 20 Jul 2016 22:28:45

Were the Lung Volume Measurements performed? Yes ☒

If No, please specify the reason: _____

Category _____

Position SITTING

Date of assessment DD/MMM/YYYY 10 APR 2014

Time of assessment 08:03

VC value 5.60
L

TLC value 7.73
L

IC value 4.70
L

FRC value 3.03
L

Interpretation Normal ☒

If Abnormal, Clinical Significance _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Discharge (Confinement)

Form: Lung Volume Measurements

Data signed: (hfarmer1) 30 Mar 2015 13:34:35

Generated On: 20 Jul 2016 22:28:45

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

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Discharge (Confinement)

Form: Spirometry with a short-acting bronchodilator

Data signed: (hfarmer1) 30 Mar 2015 13:34:36

Generated On: 20 Jul 2016 22:28:45

Was the Spirometry with a short-acting bronchodilator performed?

Yes ☒

If No, please specify the reason: _____

Category

With short-acting
bronchodilator ☒

Position

SITTING

Date of assessment
DD/MMM/YYYY

10 APR 2014

Time of assessment

08:33

Name of bronchodilator

ALBUTEROL SULFATE

Dose

180 MCG

Predicted FVC value

4.99
L

Best measured FVC value

4.90
L

Percent of predicted FVC value

98
%

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Discharge (Confinement)

Form: Spirometry with a short-acting bronchodilator

Data signed: (hfarmer1) 30 Mar 2015 13:34:36

Generated On: 20 Jul 2016 22:28:45

Best measured FEV1 value	3.71 L
--------------------------	-----------

Predicted FEV1 value	3.90 L
----------------------	-----------

Percent of predicted FEV1 value	95 %
---------------------------------	---------

Calculated ratio between FEV1/FVC	_____
-----------------------------------	-------

MEF 25/75 value	2.88 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: 1252**

Folder: Discharge (Confinement)

Form: Haematology

Data signed: (hfarmer1) 30 Mar 2015 13:34:34

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Discharge (Confinement)

Form: Clinical Chemistry

Data signed: (hfarmer1) 30 Mar 2015 13:34:34

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Discharge (Confinement)

Form: Urine analysis

Data signed: (hfarmer1) 30 Mar 2015 13:34:34

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Discharge (Confinement)

Form: CO Breath Test

Data signed: (hfarmer1) 30 Mar 2015 13:34:34

Generated On: 20 Jul 2016 22:28:45

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

If Not Done, please specify the reason: _____

Actual Time of Assessment	08:48
	hour:min 24-hour clock

Result	10
	ppm

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (1)

Data signed: (hfarmer1) 30 Mar 2015 13:34:36

Generated On: 20 Jul 2016 22:28:45

Transmission Type Cumulative ☒

Subject ID or Number

Subject Sex M

Subject Date of Birth (b) (6) 

Visit Name

Visit Type Scheduled ☒

Accession ID W816780

Actual Collection Date 2014 04 10

Actual Collection Time 06:54

Specimen Condition

Battery ID RC1029

Battery Name TRIGLYCERIDES

Lab Test ID RCT19

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (1)

Data signed: (hfarmer1) 30 Mar 2015 13:34:36

Generated On: 20 Jul 2016 22:28:45

Lab Test Name	TRIGLYCERIDES (GPO)
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	281
Reported Numeric Result	281
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: 1252**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (1)

Data signed: (hfarmer1) 30 Mar 2015 13:34:36

Generated On: 20 Jul 2016 22:28:45

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (2)

Data signed: (hfarmer1) 30 Mar 2015 13:34:36

Generated On: 20 Jul 2016 22:28:45

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6)

Visit Name _____

Visit Type Scheduled ☒

Accession ID W816780

Actual Collection Date 2014 04 10

Actual Collection Time 06:54

Specimen Condition _____

Battery ID RC1092

Battery Name FASTING GLUCOSE

Lab Test ID RCT142

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (2)

Data signed: (hfarmer1) 30 Mar 2015 13:34:36

Generated On: 20 Jul 2016 22:28:45

Lab Test Name	FASTING GLUCOSE
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	98
Reported Numeric Result	98
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: 1252**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (2)

Data signed: (hfarmer1) 30 Mar 2015 13:34:36

Generated On: 20 Jul 2016 22:28:45

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (3)

Data signed: (hfarmer1) 30 Mar 2015 13:34:36

Generated On: 20 Jul 2016 22:28:45

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6) ☒

Visit Name _____

Visit Type Scheduled ☒

Accession ID W816780

Actual Collection Date 2014 04 10

Actual Collection Time 06:54

Specimen Condition _____

Battery ID RC272

Battery Name TOTAL CHOLESTEROL

Lab Test ID RCT20

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (3)

Data signed: (hfarmer1) 30 Mar 2015 13:34:36

Generated On: 20 Jul 2016 22:28:45

Lab Test Name	CHOLESTEROL (HIGH PERFORMANCE)
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	241
Reported Numeric Result	241
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: 1252**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (3)

Data signed: (hfarmer1) 30 Mar 2015 13:34:36

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (4)

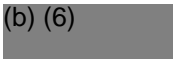
Data signed: (hfarmer1) 30 Mar 2015 13:34:36

Generated On: 20 Jul 2016 22:28:45

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6) 

Visit Name _____

Visit Type Scheduled ☒

Accession ID W816780

Actual Collection Date 2014 04 10

Actual Collection Time 06:54

Specimen Condition _____

Battery ID RC9255

Battery Name CHEMISTRY PANEL

Lab Test ID RCT1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (4)

Data signed: (hfarmer1) 30 Mar 2015 13:34:36

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (4)

Data signed: (hfarmer1) 30 Mar 2015 13:34:36

Generated On: 20 Jul 2016 22:28:45

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (5)

Data signed: (hfarmer1) 30 Mar 2015 13:34:36

Generated On: 20 Jul 2016 22:28:45

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6)

Visit Name _____

Visit Type Scheduled ☒

Accession ID W816780

Actual Collection Date 2014 04 10

Actual Collection Time 06:54

Specimen Condition _____

Battery ID RC9255

Battery Name CHEMISTRY PANEL

Lab Test ID RCT12

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (5)

Data signed: (hfarmer1) 30 Mar 2015 13:34:36

Generated On: 20 Jul 2016 22:28:45

Lab Test Name	TOTAL PROTEIN
Test ID	
Test Status	Done <input type="checkbox"/>
Reported Text Result	7.7
Reported Numeric Result	7.7
Reference Range low	6.1
Reference Range high	8.4
Range Units	G/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (5)

Data signed: (hfarmer1) 30 Mar 2015 13:34:36

Generated On: 20 Jul 2016 22:28:45

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (6)

Data signed: (hfarmer1) 30 Mar 2015 13:34:36

Generated On: 20 Jul 2016 22:28:45

Transmission Type Cumulative ☒

Subject ID or Number

Subject Sex M

Subject Date of Birth (b) (6) 

Visit Name

Visit Type Scheduled ☒

Accession ID W816780

Actual Collection Date 2014 04 10

Actual Collection Time 06:54

Specimen Condition

Battery ID RC9255

Battery Name CHEMISTRY PANEL

Lab Test ID RCT13

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (6)

Data signed: (hfarmer1) 30 Mar 2015 13:34:36

Generated On: 20 Jul 2016 22:28:45

Lab Test Name	ALBUMIN
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	4.5
Reported Numeric Result	4.5
Reference Range low	3.3
Reference Range high	4.9
Range Units	G/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (6)

Data signed: (hfarmer1) 30 Mar 2015 13:34:36

Generated On: 20 Jul 2016 22:28:45

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (7)

Data signed: (hfarmer1) 30 Mar 2015 13:34:36

Generated On: 20 Jul 2016 22:28:45

Transmission Type Cumulative ☐

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6) 

Visit Name _____

Visit Type Scheduled ☐

Accession ID W816780

Actual Collection Date 2014 04 10

Actual Collection Time 06:54

Specimen Condition _____

Battery ID RC9255

Battery Name CHEMISTRY PANEL

Lab Test ID RCT1407

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (7)

Data signed: (hfarmer1) 30 Mar 2015 13:34:36

Generated On: 20 Jul 2016 22:28:45

Lab Test Name	ALKALINE PHOSPHATASE
Test ID	
Test Status	Done <input type="checkbox"/>
Reported Text Result	59
Reported Numeric Result	59
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: 1252**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (7)

Data signed: (hfarmer1) 30 Mar 2015 13:34:36

Generated On: 20 Jul 2016 22:28:45

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (8)

Data signed: (hfarmer1) 30 Mar 2015 13:34:36

Generated On: 20 Jul 2016 22:28:45

Transmission Type Cumulative ☒

Subject ID or Number

Subject Sex M

Subject Date of Birth (b) (6) 

Visit Name

Visit Type Scheduled ☒

Accession ID W816780

Actual Collection Date 2014 04 10

Actual Collection Time 06:54

Specimen Condition

Battery ID RC9255

Battery Name CHEMISTRY PANEL

Lab Test ID RCT1408

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (8)

Data signed: (hfarmer1) 30 Mar 2015 13:34:36

Generated On: 20 Jul 2016 22:28:45

Lab Test Name	LDH
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	127
Reported Numeric Result	127
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: 1252**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (8)

Data signed: (hfarmer1) 30 Mar 2015 13:34:36

Generated On: 20 Jul 2016 22:28:45

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (9)

Data signed: (hfarmer1) 30 Mar 2015 13:34:36

Generated On: 20 Jul 2016 22:28:45

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6)

Visit Name _____

Visit Type Scheduled ☒

Accession ID W816780

Actual Collection Date 2014 04 10

Actual Collection Time 06:54

Specimen Condition _____

Battery ID RC9255

Battery Name CHEMISTRY PANEL

Lab Test ID RCT15

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (9)

Data signed: (hfarmer1) 30 Mar 2015 13:34:36

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (9)

Data signed: (hfarmer1) 30 Mar 2015 13:34:36

Generated On: 20 Jul 2016 22:28:45

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (10)

Data signed: (hfarmer1) 30 Mar 2015 13:34:36

Generated On: 20 Jul 2016 22:28:45

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6)

Visit Name _____

Visit Type Scheduled ☒

Accession ID W816780

Actual Collection Date 2014 04 10

Actual Collection Time 06:54

Specimen Condition _____

Battery ID RC9255

Battery Name CHEMISTRY PANEL

Lab Test ID RCT16

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (10)

Data signed: (hfarmer1) 30 Mar 2015 13:34:36

Generated On: 20 Jul 2016 22:28:45

Lab Test Name	SERUM POTASSIUM
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	4.2
Reported Numeric Result	4.2
Reference Range low	3.4
Reference Range high	5.4
Range Units	MEQ/L
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (10)

Data signed: (hfarmer1) 30 Mar 2015 13:34:36

Generated On: 20 Jul 2016 22:28:45

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (11)

Data signed: (hfarmer1) 30 Mar 2015 13:34:36

Generated On: 20 Jul 2016 22:28:45

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6)

Visit Name _____

Visit Type Scheduled ☒

Accession ID W816780

Actual Collection Date 2014 04 10

Actual Collection Time 06:54

Specimen Condition _____

Battery ID RC9255

Battery Name CHEMISTRY PANEL

Lab Test ID RCT29

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (11)

Data signed: (hfarmer1) 30 Mar 2015 13:34:36

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (11)

Data signed: (hfarmer1) 30 Mar 2015 13:34:36

Generated On: 20 Jul 2016 22:28:45

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (12)

Data signed: (hfarmer1) 30 Mar 2015 13:34:36

Generated On: 20 Jul 2016 22:28:45

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6)

Visit Name _____

Visit Type Scheduled ☒

Accession ID W816780

Actual Collection Date 2014 04 10

Actual Collection Time 06:54

Specimen Condition _____

Battery ID RC9255

Battery Name CHEMISTRY PANEL

Lab Test ID RCT3

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (12)

Data signed: (hfarmer1) 30 Mar 2015 13:34:36

Generated On: 20 Jul 2016 22:28:45

Lab Test Name	GGT
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	34
Reported Numeric Result	34
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: 1252**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (12)

Data signed: (hfarmer1) 30 Mar 2015 13:34:36

Generated On: 20 Jul 2016 22:28:45

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (13)

Data signed: (hfarmer1) 30 Mar 2015 13:34:36

Generated On: 20 Jul 2016 22:28:45

Transmission Type Cumulative ☐

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6) 

Visit Name _____

Visit Type Scheduled ☐

Accession ID W816780

Actual Collection Date 2014 04 10

Actual Collection Time 06:54

Specimen Condition _____

Battery ID RC9255

Battery Name CHEMISTRY PANEL

Lab Test ID RCT392

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (13)

Data signed: (hfarmer1) 30 Mar 2015 13:34:36

Generated On: 20 Jul 2016 22:28:45

Lab Test Name	CREATININE (RATE BLANKED)
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Test ID	<hr/>
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Test Status	Done <input checked="" type="radio"/>
-------------	---------------------------------------

Reported Text Result	0.9
----------------------	-----

Reported Numeric Result	0.9
-------------------------	-----

Reference Range low	0.5
---------------------	-----

Reference Range high	1.2
----------------------	-----

Range Units	MG/DL
-------------	-------

Conventional Text Result	<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: 1252**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (13)

Data signed: (hfarmer1) 30 Mar 2015 13:34:36

Generated On: 20 Jul 2016 22:28:45

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (14)

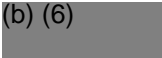
Data signed: (hfarmer1) 30 Mar 2015 13:34:36

Generated On: 20 Jul 2016 22:28:45

Transmission Type Cumulative ☒

Subject ID or Number

Subject Sex M

Subject Date of Birth (b) (6) 

Visit Name

Visit Type Scheduled ☒

Accession ID W816780

Actual Collection Date 2014 04 10

Actual Collection Time 06:54

Specimen Condition

Battery ID RC9255

Battery Name CHEMISTRY PANEL

Lab Test ID RCT4

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (14)

Data signed: (hfarmer1) 30 Mar 2015 13:34:36

Generated On: 20 Jul 2016 22:28:45

Lab Test Name	ALT (SGPT)
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	36
Reported Numeric Result	36
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: 1252**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (14)

Data signed: (hfarmer1) 30 Mar 2015 13:34:36

Generated On: 20 Jul 2016 22:28:45

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (15)

Data signed: (hfarmer1) 30 Mar 2015 13:34:36

Generated On: 20 Jul 2016 22:28:45

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6) 

Visit Name _____

Visit Type Scheduled ☒

Accession ID W816780

Actual Collection Date 2014 04 10

Actual Collection Time 06:54

Specimen Condition _____

Battery ID RC9255

Battery Name CHEMISTRY PANEL

Lab Test ID RCT5

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (15)

Data signed: (hfarmer1) 30 Mar 2015 13:34:36

Generated On: 20 Jul 2016 22:28:45

Lab Test Name	AST (SGOT)
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	24
Reported Numeric Result	24
Reference Range low	11
Reference Range high	36
Range Units	U/L
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (15)

Data signed: (hfarmer1) 30 Mar 2015 13:34:36

Generated On: 20 Jul 2016 22:28:45

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (16)

Data signed: (hfarmer1) 30 Mar 2015 13:34:36

Generated On: 20 Jul 2016 22:28:45

Transmission Type Cumulative ☐

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6)

Visit Name _____

Visit Type Scheduled ☐

Accession ID W816780

Actual Collection Date 2014 04 10

Actual Collection Time 06:54

Specimen Condition _____

Battery ID RC9255

Battery Name CHEMISTRY PANEL

Lab Test ID RCT6

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (16)

Data signed: (hfarmer1) 30 Mar 2015 13:34:36

Generated On: 20 Jul 2016 22:28:45

Lab Test Name	UREA NITROGEN
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	17
Reported Numeric Result	17
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: 1252**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (16)

Data signed: (hfarmer1) 30 Mar 2015 13:34:36

Generated On: 20 Jul 2016 22:28:45

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (17)

Data signed: (hfarmer1) 30 Mar 2015 13:34:36

Generated On: 20 Jul 2016 22:28:45

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	W816780
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Actual Collection Date	2014 04 10
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Actual Collection Time	06:54
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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: 1252

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (17)

Data signed: (hfarmer1) 30 Mar 2015 13:34:36

Generated On: 20 Jul 2016 22:28:45

Lab Test Name	MONOCYTES
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	0.42
Reported Numeric Result	0.42
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: 1252**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (17)

Data signed: (hfarmer1) 30 Mar 2015 13:34:36

Generated On: 20 Jul 2016 22:28:45

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (18)

Data signed: (hfarmer1) 30 Mar 2015 13:34:36

Generated On: 20 Jul 2016 22:28:45

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6)

Visit Name _____

Visit Type Scheduled ☒

Accession ID W816780

Actual Collection Date 2014 04 10

Actual Collection Time 06:54

Specimen Condition _____

Battery ID HM1604

Battery Name HEMATOLOGY
&DIFFERENTIAL PANEL

Lab Test ID HMT100

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (18)

Data signed: (hfarmer1) 30 Mar 2015 13:34:36

Generated On: 20 Jul 2016 22:28:45

Lab Test Name	MCH
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	34
Reported Numeric Result	34
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: 1252**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (18)

Data signed: (hfarmer1) 30 Mar 2015 13:34:36

Generated On: 20 Jul 2016 22:28:45

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (19)

Data signed: (hfarmer1) 30 Mar 2015 13:34:36

Generated On: 20 Jul 2016 22:28:45

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6) 

Visit Name _____

Visit Type Scheduled ☒

Accession ID W816780

Actual Collection Date 2014 04 10

Actual Collection Time 06:54

Specimen Condition _____

Battery ID HM1604

Battery Name HEMATOLOGY
&DIFFERENTIAL PANEL

Lab Test ID HMT102

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (19)

Data signed: (hfarmer1) 30 Mar 2015 13:34:36

Generated On: 20 Jul 2016 22:28:45

Lab Test Name	MCHC
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	33
Reported Numeric Result	33
Reference Range low	31
Reference Range high	38
Range Units	G/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (19)

Data signed: (hfarmer1) 30 Mar 2015 13:34:36

Generated On: 20 Jul 2016 22:28:45

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (20)

Data signed: (hfarmer1) 30 Mar 2015 13:34:36

Generated On: 20 Jul 2016 22:28:45

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	W816780
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Actual Collection Date	2014 04 10
------------------------	------------

Actual Collection Time	06:54
------------------------	-------

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: 1252

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (20)

Data signed: (hfarmer1) 30 Mar 2015 13:34:36

Generated On: 20 Jul 2016 22:28:45

Lab Test Name	EOSINOPHILS
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	0.17
Reported Numeric Result	0.17
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: 1252**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (20)

Data signed: (hfarmer1) 30 Mar 2015 13:34:36

Generated On: 20 Jul 2016 22:28:45

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (21)

Data signed: (hfarmer1) 30 Mar 2015 13:34:36

Generated On: 20 Jul 2016 22:28:45

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6)

Visit Name _____

Visit Type Scheduled ☒

Accession ID W816780

Actual Collection Date 2014 04 10

Actual Collection Time 06:54

Specimen Condition _____

Battery ID HM1604

Battery Name HEMATOLOGY
&DIFFERENTIAL PANEL

Lab Test ID HMT12

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (21)

Data signed: (hfarmer1) 30 Mar 2015 13:34:36

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (21)

Data signed: (hfarmer1) 30 Mar 2015 13:34:36

Generated On: 20 Jul 2016 22:28:45

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (22)

Data signed: (hfarmer1) 30 Mar 2015 13:34:36

Generated On: 20 Jul 2016 22:28:45

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6)

Visit Name _____

Visit Type Scheduled ☒

Accession ID W816780

Actual Collection Date 2014 04 10

Actual Collection Time 06:54

Specimen Condition _____

Battery ID HM1604

Battery Name HEMATOLOGY
&DIFFERENTIAL PANEL

Lab Test ID HMT13

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (22)

Data signed: (hfarmer1) 30 Mar 2015 13:34:36

Generated On: 20 Jul 2016 22:28:45

Lab Test Name	PLATELETS
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	267
Reported Numeric Result	267
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: 1252**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (22)

Data signed: (hfarmer1) 30 Mar 2015 13:34:36

Generated On: 20 Jul 2016 22:28:45

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (23)

Data signed: (hfarmer1) 30 Mar 2015 13:34:36

Generated On: 20 Jul 2016 22:28:45

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6) ☒

Visit Name _____

Visit Type Scheduled ☒

Accession ID W816780

Actual Collection Date 2014 04 10

Actual Collection Time 06:54

Specimen Condition _____

Battery ID HM1604

Battery Name HEMATOLOGY
&DIFFERENTIAL PANEL

Lab Test ID HMT15

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (23)

Data signed: (hfarmer1) 30 Mar 2015 13:34:36

Generated On: 20 Jul 2016 22:28:45

Lab Test Name	NEUTROPHILS (%)
Test ID	
Test Status	Done <input checked="" type="checkbox"/>
Reported Text Result	65.7
Reported Numeric Result	65.7
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: 1252**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (23)

Data signed: (hfarmer1) 30 Mar 2015 13:34:36

Generated On: 20 Jul 2016 22:28:45

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (24)

Data signed: (hfarmer1) 30 Mar 2015 13:34:36

Generated On: 20 Jul 2016 22:28:45

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	W816780
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Actual Collection Date	2014 04 10
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Actual Collection Time	06:54
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Specimen Condition	<hr/>
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Battery ID	HM1604
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Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
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Lab Test ID	HMT16
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (24)

Data signed: (hfarmer1) 30 Mar 2015 13:34:36

Generated On: 20 Jul 2016 22:28:45

Lab Test Name	LYMPHOCYTES (%)
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	24.4
Reported Numeric Result	24.4
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: 1252**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (24)

Data signed: (hfarmer1) 30 Mar 2015 13:34:36

Generated On: 20 Jul 2016 22:28:45

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (25)

Data signed: (hfarmer1) 30 Mar 2015 13:34:36

Generated On: 20 Jul 2016 22:28:45

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	W816780
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Actual Collection Date	2014 04 10
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Actual Collection Time	06:54
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Specimen Condition	<hr/>
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Battery ID	HM1604
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Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
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Lab Test ID	HMT17
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (25)

Data signed: (hfarmer1) 30 Mar 2015 13:34:36

Generated On: 20 Jul 2016 22:28:45

Lab Test Name	MONOCYTES (%)
Test ID	
Test Status	Done <input type="checkbox"/>
Reported Text Result	6.6
Reported Numeric Result	6.6
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: 1252**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (25)

Data signed: (hfarmer1) 30 Mar 2015 13:34:36

Generated On: 20 Jul 2016 22:28:45

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (26)

Data signed: (hfarmer1) 30 Mar 2015 13:34:36

Generated On: 20 Jul 2016 22:28:45

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6)

Visit Name _____

Visit Type Scheduled ☒

Accession ID W816780

Actual Collection Date 2014 04 10

Actual Collection Time 06:54

Specimen Condition _____

Battery ID HM1604

Battery Name HEMATOLOGY
&DIFFERENTIAL PANEL

Lab Test ID HMT18

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (26)

Data signed: (hfarmer1) 30 Mar 2015 13:34:36

Generated On: 20 Jul 2016 22:28:45

Lab Test Name	EOSINOPHILS (%)
Test ID	
Test Status	Done <input checked="" type="checkbox"/>
Reported Text Result	2.6
Reported Numeric Result	2.6
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: 1252**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (26)

Data signed: (hfarmer1) 30 Mar 2015 13:34:36

Generated On: 20 Jul 2016 22:28:45

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (27)

Data signed: (hfarmer1) 30 Mar 2015 13:34:36

Generated On: 20 Jul 2016 22:28:45

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6) 

Visit Name _____

Visit Type Scheduled ☒

Accession ID W816780

Actual Collection Date 2014 04 10

Actual Collection Time 06:54

Specimen Condition _____

Battery ID HM1604

Battery Name HEMATOLOGY
&DIFFERENTIAL PANEL

Lab Test ID HMT19

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (27)

Data signed: (hfarmer1) 30 Mar 2015 13:34:36

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (27)

Data signed: (hfarmer1) 30 Mar 2015 13:34:36

Generated On: 20 Jul 2016 22:28:45

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (28)

Data signed: (hfarmer1) 30 Mar 2015 13:34:36

Generated On: 20 Jul 2016 22:28:45

Transmission Type Cumulative ☐

Subject ID or Number

Subject Sex M

Subject Date of Birth (b) (6) 

Visit Name

Visit Type Scheduled ☐

Accession ID W816780

Actual Collection Date 2014 04 10

Actual Collection Time 06:54

Specimen Condition

Battery ID HM1604

Battery Name HEMATOLOGY
&DIFFERENTIAL PANEL

Lab Test ID HMT2

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (28)

Data signed: (hfarmer1) 30 Mar 2015 13:34:36

Generated On: 20 Jul 2016 22:28:45

Lab Test Name	HEMATOCRIT
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	45
Reported Numeric Result	45
Reference Range low	39
Reference Range high	54
Range Units	%
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (28)

Data signed: (hfarmer1) 30 Mar 2015 13:34:36

Generated On: 20 Jul 2016 22:28:45

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (29)

Data signed: (hfarmer1) 30 Mar 2015 13:34:36

Generated On: 20 Jul 2016 22:28:45

Transmission Type Cumulative ☒

Subject ID or Number

Subject Sex M

Subject Date of Birth (b) (6)

Visit Name

Visit Type Scheduled ☒

Accession ID W816780

Actual Collection Date 2014 04 10

Actual Collection Time 06:54

Specimen Condition

Battery ID HM1604

Battery Name HEMATOLOGY
&DIFFERENTIAL PANEL

Lab Test ID HMT3

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (29)

Data signed: (hfarmer1) 30 Mar 2015 13:34:36

Generated On: 20 Jul 2016 22:28:45

Lab Test Name	RBC
Test ID	
Test Status	Done <input checked="" type="checkbox"/>
Reported Text Result	4.4
Reported Numeric Result	4.4
Reference Range low	4.5
Reference Range high	6.4
Range Units	X10^6/UL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (29)

Data signed: (hfarmer1) 30 Mar 2015 13:34:36

Generated On: 20 Jul 2016 22:28:45

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: 1252

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (30)

Data signed: (hfarmer1) 30 Mar 2015 13:34:36

Generated On: 20 Jul 2016 22:28:45

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6)

Visit Name _____

Visit Type Scheduled ☒

Accession ID W816780

Actual Collection Date 2014 04 10

Actual Collection Time 06:54

Specimen Condition _____

Battery ID HM1604

Battery Name HEMATOLOGY
&DIFFERENTIAL PANEL

Lab Test ID HMT4

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (30)

Data signed: (hfarmer1) 30 Mar 2015 13:34:36

Generated On: 20 Jul 2016 22:28:45

Lab Test Name	MCV
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	102
Reported Numeric Result	102
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: 1252**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (30)

Data signed: (hfarmer1) 30 Mar 2015 13:34:36

Generated On: 20 Jul 2016 22:28:45

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: 1252

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (31)

Data signed: (hfarmer1) 30 Mar 2015 13:34:36

Generated On: 20 Jul 2016 22:28:45

Transmission Type Cumulative ☐

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6)

Visit Name _____

Visit Type Scheduled ☐

Accession ID W816780

Actual Collection Date 2014 04 10

Actual Collection Time 06:54

Specimen Condition _____

Battery ID HM1604

Battery Name HEMATOLOGY
&DIFFERENTIAL PANEL

Lab Test ID HMT40

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (31)

Data signed: (hfarmer1) 30 Mar 2015 13:34:36

Generated On: 20 Jul 2016 22:28:45

Lab Test Name	HEMOGLOBIN
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	15.1
Reported Numeric Result	15.1
Reference Range low	12.7
Reference Range high	18.1
Range Units	G/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (31)

Data signed: (hfarmer1) 30 Mar 2015 13:34:36

Generated On: 20 Jul 2016 22:28:45

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (32)

Data signed: (hfarmer1) 30 Mar 2015 13:34:36

Generated On: 20 Jul 2016 22:28:45

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	M
-------------	---

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

Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	W816780
--------------	---------

Actual Collection Date	2014 04 10
------------------------	------------

Actual Collection Time	06:54
------------------------	-------

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: 1252**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (32)

Data signed: (hfarmer1) 30 Mar 2015 13:34:36

Generated On: 20 Jul 2016 22:28:45

Lab Test Name	WBC
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	6.40
Reported Numeric Result	6.40
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: 1252**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (32)

Data signed: (hfarmer1) 30 Mar 2015 13:34:36

Generated On: 20 Jul 2016 22:28:45

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (33)

Data signed: (hfarmer1) 30 Mar 2015 13:34:36

Generated On: 20 Jul 2016 22:28:45

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6) 

Visit Name _____

Visit Type Scheduled ☒

Accession ID W816780

Actual Collection Date 2014 04 10

Actual Collection Time 06:54

Specimen Condition _____

Battery ID HM1604

Battery Name HEMATOLOGY
&DIFFERENTIAL PANEL

Lab Test ID HMT71

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (33)

Data signed: (hfarmer1) 30 Mar 2015 13:34:36


Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (33)

Data signed: (hfarmer1) 30 Mar 2015 13:34:36

Generated On: 20 Jul 2016 22:28:45

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (34)

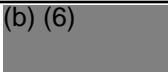
Data signed: (hfarmer1) 30 Mar 2015 13:34:36

Generated On: 20 Jul 2016 22:28:45

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6) 

Visit Name _____

Visit Type Scheduled ☒

Accession ID W816780

Actual Collection Date 2014 04 10

Actual Collection Time 06:54

Specimen Condition _____

Battery ID HM1604

Battery Name HEMATOLOGY
&DIFFERENTIAL PANEL

Lab Test ID HMT8

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (34)

Data signed: (hfarmer1) 30 Mar 2015 13:34:36

Generated On: 20 Jul 2016 22:28:45

Lab Test Name	NEUTROPHILS
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	4.20
Reported Numeric Result	4.20
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: 1252**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (34)

Data signed: (hfarmer1) 30 Mar 2015 13:34:36

Generated On: 20 Jul 2016 22:28:45

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (35)

Data signed: (hfarmer1) 30 Mar 2015 13:34:36

Generated On: 20 Jul 2016 22:28:45

Transmission Type Cumulative ☐

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6) 

Visit Name _____

Visit Type Scheduled ☐

Accession ID W816780

Actual Collection Date 2014 04 10

Actual Collection Time 06:54

Specimen Condition _____

Battery ID HM1604

Battery Name HEMATOLOGY
&DIFFERENTIAL PANEL

Lab Test ID HMT9

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (35)

Data signed: (hfarmer1) 30 Mar 2015 13:34:36

Generated On: 20 Jul 2016 22:28:45

Lab Test Name	LYMPHOCYTES
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	1.57
Reported Numeric Result	1.57
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: 1252**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (35)

Data signed: (hfarmer1) 30 Mar 2015 13:34:36

Generated On: 20 Jul 2016 22:28:45

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (36)

Data signed: (hfarmer1) 30 Mar 2015 13:34:36

Generated On: 20 Jul 2016 22:28:45

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6) 

Visit Name _____

Visit Type Scheduled ☒

Accession ID W816780

Actual Collection Date 2014 04 10

Actual Collection Time 06:54

Specimen Condition _____

Battery ID UA1538

Battery Name URINE MACRO PANEL

Lab Test ID UAT10

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (36)

Data signed: (hfarmer1) 30 Mar 2015 13:34:36


Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (36)

Data signed: (hfarmer1) 30 Mar 2015 13:34:36

Generated On: 20 Jul 2016 22:28:45

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (37)

Data signed: (hfarmer1) 30 Mar 2015 13:34:36

Generated On: 20 Jul 2016 22:28:45

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6) 

Visit Name _____

Visit Type Scheduled ☒

Accession ID W816780

Actual Collection Date 2014 04 10

Actual Collection Time 06:54

Specimen Condition _____

Battery ID UA1538

Battery Name URINE MACRO PANEL

Lab Test ID UAT2

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (37)

Data signed: (hfarmer1) 30 Mar 2015 13:34:36

Generated On: 20 Jul 2016 22:28:45

Lab Test Name	UR SPECIFIC GRAVITY
Test ID	
Test Status	Done <input type="checkbox"/>
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: 1252**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (37)

Data signed: (hfarmer1) 30 Mar 2015 13:34:36

Generated On: 20 Jul 2016 22:28:45

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (38)

Data signed: (hfarmer1) 30 Mar 2015 13:34:36

Generated On: 20 Jul 2016 22:28:45

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6) 

Visit Name _____

Visit Type Scheduled ☒

Accession ID W816780

Actual Collection Date 2014 04 10

Actual Collection Time 06:54

Specimen Condition _____

Battery ID UA1538

Battery Name URINE MACRO PANEL

Lab Test ID UAT3

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (38)

Data signed: (hfarmer1) 30 Mar 2015 13:34:36

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (38)

Data signed: (hfarmer1) 30 Mar 2015 13:34:36

Generated On: 20 Jul 2016 22:28:45

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (39)

Data signed: (hfarmer1) 30 Mar 2015 13:34:36

Generated On: 20 Jul 2016 22:28:45

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6)

Visit Name _____

Visit Type Scheduled ☒

Accession ID W816780

Actual Collection Date 2014 04 10

Actual Collection Time 06:54

Specimen Condition _____

Battery ID UA1538

Battery Name URINE MACRO PANEL

Lab Test ID UAT43

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (39)

Data signed: (hfarmer1) 30 Mar 2015 13:34:36


Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (39)

Data signed: (hfarmer1) 30 Mar 2015 13:34:36

Generated On: 20 Jul 2016 22:28:45

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (40)

Data signed: (hfarmer1) 30 Mar 2015 13:34:36

Generated On: 20 Jul 2016 22:28:45

Transmission Type Cumulative ☒

Subject ID or Number

Subject Sex M

Subject Date of Birth (b) (6) 

Visit Name

Visit Type Scheduled ☒

Accession ID W816780

Actual Collection Date 2014 04 10

Actual Collection Time 06:54

Specimen Condition

Battery ID UA1538

Battery Name URINE MACRO PANEL

Lab Test ID UAT49

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (40)

Data signed: (hfarmer1) 30 Mar 2015 13:34:36


Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (40)

Data signed: (hfarmer1) 30 Mar 2015 13:34:36

Generated On: 20 Jul 2016 22:28:45

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (41)

Data signed: (hfarmer1) 30 Mar 2015 13:34:36

Generated On: 20 Jul 2016 22:28:45

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6) 

Visit Name _____

Visit Type Scheduled ☒

Accession ID W816780

Actual Collection Date 2014 04 10

Actual Collection Time 06:54

Specimen Condition _____

Battery ID UA1538

Battery Name URINE MACRO PANEL

Lab Test ID UAT5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (41)

Data signed: (hfarmer1) 30 Mar 2015 13:34:36


Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (41)

Data signed: (hfarmer1) 30 Mar 2015 13:34:36

Generated On: 20 Jul 2016 22:28:45

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (42)

Data signed: (hfarmer1) 30 Mar 2015 13:34:36

Generated On: 20 Jul 2016 22:28:45

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6) 

Visit Name _____

Visit Type Scheduled ☒

Accession ID W816780

Actual Collection Date 2014 04 10

Actual Collection Time 06:54

Specimen Condition _____

Battery ID UA1538

Battery Name URINE MACRO PANEL

Lab Test ID UAT7

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (42)

Data signed: (hfarmer1) 30 Mar 2015 13:34:36


Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (42)

Data signed: (hfarmer1) 30 Mar 2015 13:34:36

Generated On: 20 Jul 2016 22:28:45

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

Form: Date of Visit

Data signed: (hfarmer1) 30 Mar 2015 13:34:55

Generated On: 20 Jul 2016 22:28:45

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

If Not Done, Specify Reason	<hr/>
-----------------------------	-------

Date of Visit	04 MAY 2014 DD/MMM/YYYY
---------------	----------------------------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

Form: Vital Signs

Data signed: (hcoleman1) 18 Jun 2015 21:27:19

Generated On: 20 Jul 2016 22:28:45

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

04 MAY 2014
DD/MMM/YYYY

Time of assessment

14:58
hour:min 24-hour clock

Pulse rate

73
beats per minute

Respiratory rate

16
breaths per minute

Blood Pressure (systolic)

137
mmHg

Blood Pressure (diastolic)

88
mmHg

Vital Signs Position of Subject

Supine ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

Form: Advice on the risk of smoking and debriefing

Data signed: (hfarmer1) 30 Mar 2015 13:34:55

Generated On: 20 Jul 2016 22:28:45

Date	05 MAY 2014 DD/MMM/YYYY
------	----------------------------

Has the subject received advices on the risks of smoking?	Yes <input type="radio"/>
---	---------------------------

Has a debriefing been performed about THS 2.2?	Yes <input type="radio"/>
--	---------------------------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

Form: Physical Examination

Data signed: (hfarmer1) 30 Mar 2015 13:34:53

Generated On: 20 Jul 2016 22:28:45

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of Assessment

04 MAY 2014
DD/MMM/YYYY

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

Form: Physical Examination (1)

Data signed: (hfarmer1) 30 Mar 2015 13:34:53

Generated On: 20 Jul 2016 22:28:45

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of Assessment 04 MAY 2014
DD/MMM/YYYY

System General Appearance ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

Form: Physical Examination (2)

Data signed: (hfarmer1) 30 Mar 2015 13:34:53

Generated On: 20 Jul 2016 22:28:45

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of Assessment

04 MAY 2014
DD/MMM/YYYY

System

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

Outcome

Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done

False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

Form: Physical Examination (3)

Data signed: (hfarmer1) 30 Mar 2015 13:34:53

Generated On: 20 Jul 2016 22:28:45

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of Assessment 04 MAY 2014
DD/MMM/YYYY

System Thyroid Gland ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

Form: Physical Examination (4)

Data signed: (hfarmer1) 30 Mar 2015 13:34:53

Generated On: 20 Jul 2016 22:28:45

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of Assessment

04 MAY 2014
DD/MMM/YYYY

System

Heart ☒

Outcome

Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done

False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

Form: Physical Examination (5)

Data signed: (hfarmer1) 30 Mar 2015 13:34:53

Generated On: 20 Jul 2016 22:28:45

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of Assessment 04 MAY 2014
DD/MMM/YYYY

System Chest ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

Form: Physical Examination (6)

Data signed: (hfarmer1) 30 Mar 2015 13:34:53

Generated On: 20 Jul 2016 22:28:45

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of Assessment 04 MAY 2014
DD/MMM/YYYY

System Lungs ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

Form: Physical Examination (7)

Data signed: (hfarmer1) 30 Mar 2015 13:34:53

Generated On: 20 Jul 2016 22:28:45

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of Assessment 04 MAY 2014
DD/MMM/YYYY

System Gastrointestinal ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

Form: Physical Examination (8)

Data signed: (hfarmer1) 30 Mar 2015 13:34:53

Generated On: 20 Jul 2016 22:28:45

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of Assessment 04 MAY 2014
DD/MMM/YYYY

System Cardiovascular System ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

Form: Physical Examination (9)

Data signed: (hfarmer1) 30 Mar 2015 13:34:53

Generated On: 20 Jul 2016 22:28:45

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of Assessment 04 MAY 2014
DD/MMM/YYYY

System Neurologic ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

Form: Physical Examination (10)

Data signed: (hfarmer1) 30 Mar 2015 13:34:53

Generated On: 20 Jul 2016 22:28:45

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of Assessment 04 MAY 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: 1252**

Folder: Day 30

Form: Physical Examination (11)

Data signed: (hfarmer1) 30 Mar 2015 13:34:53

Generated On: 20 Jul 2016 22:28:45

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of Assessment

04 MAY 2014
DD/MMM/YYYY

System

Back ☒

Outcome

Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done

False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

Form: Physical Examination (12)

Data signed: (hfarmer1) 30 Mar 2015 13:34:53

Generated On: 20 Jul 2016 22:28:45

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of Assessment

04 MAY 2014
DD/MMM/YYYY

System

Musculoskeletal ☒

Outcome

Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done

False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

Form: Physical Examination (13)

Data signed: (hfarmer1) 30 Mar 2015 13:34:53

Generated On: 20 Jul 2016 22:28:45

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of Assessment 04 MAY 2014
DD/MMM/YYYY

System Abdomen ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

Form: Physical Examination (14)

Data signed: (hfarmer1) 30 Mar 2015 13:34:53

Generated On: 20 Jul 2016 22:28:45

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of Assessment 04 MAY 2014
DD/MMM/YYYY

System Dentition ☒

Outcome Abnormal ☒

Abnormal, please specify DECAyed AND MISSING
TEETH

Clinically significant No ☒

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

Form: Physical Examination (15)

Data signed: (hfarmer1) 30 Mar 2015 13:34:53

Generated On: 20 Jul 2016 22:28:45

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of Assessment

04 MAY 2014
DD/MMM/YYYY

System

Other ☒

Other, Specify _____

Outcome _____

Abnormal, please specify _____

Clinically significant _____

Not Done

True

Not Done; please specify the reason: _____

NOT EXAMINED

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

Form: Physical Examination (16)

Data signed: (hfarmer1) 30 Mar 2015 13:34:53

Generated On: 20 Jul 2016 22:28:45

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of Assessment

04 MAY 2014
DD/MMM/YYYY

System

Other ☒

Other, Specify _____

Outcome _____

Abnormal, please specify _____

Clinically significant _____

Not Done

True

Not Done; please specify the reason: _____

NOT EXAMINED

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

Form: Physical Examination (17)

Data signed: (hfarmer1) 30 Mar 2015 13:34:53

Generated On: 20 Jul 2016 22:28:45

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of Assessment

04 MAY 2014
DD/MMM/YYYY

System

Other ☒

Other, Specify _____

Outcome _____

Abnormal, please specify _____

Clinically significant _____

Not Done

True

Not Done; please specify the reason: _____

NOT EXAMINED

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

Form: Physical Examination (18)

Data signed: (hfarmer1) 30 Mar 2015 13:34:53

Generated On: 20 Jul 2016 22:28:45

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of Assessment

04 MAY 2014
DD/MMM/YYYY

System

Other ☒

Other, Specify _____

Outcome _____

Abnormal, please specify _____

Clinically significant _____

Not Done

True

Not Done; please specify the reason: _____

NOT EXAMINED

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

Form: Physical Examination (19)

Data signed: (hfarmer1) 30 Mar 2015 13:34:53

Generated On: 20 Jul 2016 22:28:45

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of Assessment

04 MAY 2014
DD/MMM/YYYY

System

Other ☒

Other, Specify _____

Outcome _____

Abnormal, please specify _____

Clinically significant _____

Not Done

True

Not Done; please specify the reason: _____

NOT EXAMINED

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

Form: Weight

Data signed: (hfarmer1) 30 Mar 2015 13:34:56

Generated On: 20 Jul 2016 22:28:45

Measurement(s) assessed?

Yes ☒

If No, please specify the reason: _____

Date of Assessment

04 MAY 2014
DD/MMM/YYYY

Time of assessment

15:06
hour:min 24-hour clock

Weight

86.8
kg

BMI

27.9

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

Form: ECG (12-Lead Standard)

Data signed: (hfarmer1) 30 Mar 2015 13:34:52

Generated On: 20 Jul 2016 22:28:45

Was the ECG performed?

Yes ☒

If No, please specify the reason: _____

Date of Assessment

04 MAY 2014
DD/MMM/YYYY

Position

Supine ☒

Heart Rate

68
beats per minute

QRS Interval

92
msec

QT Interval

445
msec

QTcB Interval

475
msec

PR Interval

155
msec

QTcF Interval

464
msec

Interpretation

Abnormal ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

Form: ECG (12-Lead Standard)

Data signed: (hfarmer1) 30 Mar 2015 13:34:52

Generated On: 20 Jul 2016 22:28:45

If Abnormal, Clinical Significance

Not clinically significant ☒

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

SINUS RHYTHM QTC
PROLONGATION OF 464

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

Form: Haematology

Data signed: (hfarmer1) 30 Mar 2015 13:34:53

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Day 30

Form: Clinical Chemistry

Data signed: (hfarmer1) 30 Mar 2015 13:34:53

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Day 30

Form: Urine analysis

Data signed: (hfarmer1) 30 Mar 2015 13:34:53

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Day 30

Form: Plasma Nicotine Sample

Data signed: (hfarmer1) 30 Mar 2015 13:34:53

Generated On: 20 Jul 2016 22:28:45

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	04 MAY 2014
---------------------	-------------

Time hour:min 24-hour clock	10:16
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

Form: Plasma Cotinine Sample

Data signed: (hfarmer1) 30 Mar 2015 13:34:53

Generated On: 20 Jul 2016 22:28:45

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	04 MAY 2014
---------------------	-------------

Time hour:min 24-hour clock	10:16
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

Form: CoHb Blood Sample <D30_D60>

Data signed: (hfarmer1) 30 Mar 2015 13:34:53

Generated On: 20 Jul 2016 22:28:45

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	04 MAY 2014
---------------------	-------------

Timepoint	10:00 - 11:30 <input checked="" type="radio"/>
-----------	--

Time hour:min 24-hour clock	10:16
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

Form: CO Breath Test

Data signed: (hfarmer1) 30 Mar 2015 13:34:52

Generated On: 20 Jul 2016 22:28:45

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

If Not Done, please specify the reason: _____

Actual Date of Assessment	04 MAY 2014 DD/MMM/YYYY
---------------------------	----------------------------

Actual Time of Assessment	10:20 hour:min 24-hour clock
---------------------------	---------------------------------

Result	12 ppm
--------	-----------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

Form: Risk markers: hs-CRP, fibrinogen, homocysteine, LDL, HDL, sICAM-1

Data signed: (hfarmer1) 30 Mar 2015 13:34:53

Generated On: 20 Jul 2016 22:28:45

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	05 MAY 2014
---------------------	-------------

Time hour:min 24-hour clock	06:27
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

Form: 24 hour urine collections

Data signed: (hfarmer1) 30 Mar 2015 13:34:55

Generated On: 20 Jul 2016 22:28:45

Start Date	04 MAY 2014 DD/MMM/YYYY
------------	----------------------------

Start Time	09:26 hour:min 24-hour clock
------------	---------------------------------

End Date	05 MAY 2014 DD/MMM/YYYY
----------	----------------------------

End Time	09:11 hour:min 24-hour clock
----------	---------------------------------

Volume	1086 mL
--------	------------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

Form: Sample Urine Collection

Data signed: (hfarmer1) 30 Mar 2015 13:34:55

Generated On: 20 Jul 2016 22:28:45

Were samples for 24h collected?

Yes ☒

If No, please specify the reason: _____

How many primary tubes were collected?

13

How many back up tubes were collected?

13

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

Form: Lab_BU_CCLS (1)

Data signed: (hfarmer1) 30 Mar 2015 13:34:59

Generated On: 20 Jul 2016 22:28:45

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	X312806
--------------	---------

Actual Collection Date	2014 05 05
------------------------	------------

Actual Collection Time	06:27
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	RC1029
------------	--------

Battery Name	TRIGLYCERIDES
--------------	---------------

Lab Test ID	RCT19
-------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

Form: Lab_BU_CCLS (1)

Data signed: (hfarmer1) 30 Mar 2015 13:34:59

Generated On: 20 Jul 2016 22:28:45

Lab Test Name	TRIGLYCERIDES (GPO)
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	177
Reported Numeric Result	177
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: 1252**

Folder: Day 30

Form: Lab_BU_CCLS (1)

Data signed: (hfarmer1) 30 Mar 2015 13:34:59

Generated On: 20 Jul 2016 22:28:45

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

Form: Lab_BU_CCLS (2)

Data signed: (hfarmer1) 30 Mar 2015 13:34:59

Generated On: 20 Jul 2016 22:28:45

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6) 

Visit Name _____

Visit Type Scheduled ☒

Accession ID X312806

Actual Collection Date 2014 05 05

Actual Collection Time 06:27

Specimen Condition _____

Battery ID RC1092

Battery Name FASTING GLUCOSE

Lab Test ID RCT142

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

Form: Lab_BU_CCLS (2)

Data signed: (hfarmer1) 30 Mar 2015 13:34:59

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Day 30

Form: Lab_BU_CCLS (2)

Data signed: (hfarmer1) 30 Mar 2015 13:34:59

Generated On: 20 Jul 2016 22:28:45

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

Form: Lab_BU_CCLS (3)

Data signed: (hfarmer1) 30 Mar 2015 13:34:59

Generated On: 20 Jul 2016 22:28:45

Transmission Type Cumulative ☐

Subject ID or Number

Subject Sex M

Subject Date of Birth (b) (6) 

Visit Name

Visit Type Scheduled ☐

Accession ID X312806

Actual Collection Date 2014 05 05

Actual Collection Time 06:27

Specimen Condition

Battery ID RC272

Battery Name TOTAL CHOLESTEROL

Lab Test ID RCT20

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

Form: Lab_BU_CCLS (3)

Data signed: (hfarmer1) 30 Mar 2015 13:34:59

Generated On: 20 Jul 2016 22:28:45

Lab Test Name	CHOLESTEROL (HIGH PERFORMANCE)
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	286
Reported Numeric Result	286
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: 1252**

Folder: Day 30

Form: Lab_BU_CCLS (3)

Data signed: (hfarmer1) 30 Mar 2015 13:34:59

Generated On: 20 Jul 2016 22:28:45

SI Text Result

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: 1252**

Folder: Day 30

Form: Lab_BU_CCLS (4)

Data signed: (hfarmer1) 30 Mar 2015 13:34:59

Generated On: 20 Jul 2016 22:28:45

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6)

Visit Name _____

Visit Type Scheduled ☒

Accession ID X312806

Actual Collection Date 2014 05 05

Actual Collection Time 06:27

Specimen Condition _____

Battery ID RC9255

Battery Name CHEMISTRY PANEL

Lab Test ID RCT1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

Form: Lab_BU_CCLS (4)

Data signed: (hfarmer1) 30 Mar 2015 13:34:59

Generated On: 20 Jul 2016 22:28:45

Lab Test Name	TOTAL BILIRUBIN
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	0.7
Reported Numeric Result	0.7
Reference Range low	0.2
Reference Range high	1.2
Range Units	MG/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

Form: Lab_BU_CCLS (4)

Data signed: (hfarmer1) 30 Mar 2015 13:34:59

Generated On: 20 Jul 2016 22:28:45

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

Form: Lab_BU_CCLS (5)

Data signed: (hfarmer1) 30 Mar 2015 13:34:59

Generated On: 20 Jul 2016 22:28:45

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6) 

Visit Name _____

Visit Type Scheduled ☒

Accession ID X312806

Actual Collection Date 2014 05 05

Actual Collection Time 06:27

Specimen Condition _____

Battery ID RC9255

Battery Name CHEMISTRY PANEL

Lab Test ID RCT12

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

Form: Lab_BU_CCLS (5)

Data signed: (hfarmer1) 30 Mar 2015 13:34:59

Generated On: 20 Jul 2016 22:28:45

Lab Test Name	TOTAL PROTEIN
Test ID	
Test Status	Done <input type="checkbox"/>
Reported Text Result	7.3
Reported Numeric Result	7.3
Reference Range low	6.1
Reference Range high	8.4
Range Units	G/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

Form: Lab_BU_CCLS (5)

Data signed: (hfarmer1) 30 Mar 2015 13:34:59

Generated On: 20 Jul 2016 22:28:45

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

Form: Lab_BU_CCLS (6)


Data signed: (hfarmer1) 30 Mar 2015 13:34:59

Generated On: 20 Jul 2016 22:28:45

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6) 

Visit Name _____

Visit Type Scheduled ☒

Accession ID X312806

Actual Collection Date 2014 05 05

Actual Collection Time 06:27

Specimen Condition _____

Battery ID RC9255

Battery Name CHEMISTRY PANEL

Lab Test ID RCT13

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

Form: Lab_BU_CCLS (6)

Data signed: (hfarmer1) 30 Mar 2015 13:34:59

Generated On: 20 Jul 2016 22:28:45

Lab Test Name	ALBUMIN
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	4.1
Reported Numeric Result	4.1
Reference Range low	3.3
Reference Range high	4.9
Range Units	G/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

Form: Lab_BU_CCLS (6)

Data signed: (hfarmer1) 30 Mar 2015 13:34:59

Generated On: 20 Jul 2016 22:28:45

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

Form: Lab_BU_CCLS (7)

Data signed: (hfarmer1) 30 Mar 2015 13:34:59

Generated On: 20 Jul 2016 22:28:45

Transmission Type Cumulative ☒

Subject ID or Number

Subject Sex M

Subject Date of Birth (b) (6) 

Visit Name

Visit Type Scheduled ☒

Accession ID X312806

Actual Collection Date 2014 05 05

Actual Collection Time 06:27

Specimen Condition

Battery ID RC9255

Battery Name CHEMISTRY PANEL

Lab Test ID RCT1407

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

Form: Lab_BU_CCLS (7)

Data signed: (hfarmer1) 30 Mar 2015 13:34:59

Generated On: 20 Jul 2016 22:28:45

Lab Test Name	ALKALINE PHOSPHATASE
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	68
Reported Numeric Result	68
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: 1252**

Folder: Day 30

Form: Lab_BU_CCLS (7)

Data signed: (hfarmer1) 30 Mar 2015 13:34:59

Generated On: 20 Jul 2016 22:28:45

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

Form: Lab_BU_CCLS (8)

Data signed: (hfarmer1) 30 Mar 2015 13:34:59

Generated On: 20 Jul 2016 22:28:45

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6)

Visit Name _____

Visit Type Scheduled ☒

Accession ID X312806

Actual Collection Date 2014 05 05

Actual Collection Time 06:27

Specimen Condition _____

Battery ID RC9255

Battery Name CHEMISTRY PANEL

Lab Test ID RCT1408

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

Form: Lab_BU_CCLS (8)

Data signed: (hfarmer1) 30 Mar 2015 13:34:59

Generated On: 20 Jul 2016 22:28:45

Lab Test Name	LDH
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	211
Reported Numeric Result	211
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: 1252**

Folder: Day 30

Form: Lab_BU_CCLS (8)

Data signed: (hfarmer1) 30 Mar 2015 13:34:59

Generated On: 20 Jul 2016 22:28:45

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

Form: Lab_BU_CCLS (9)

Data signed: (hfarmer1) 30 Mar 2015 13:34:59

Generated On: 20 Jul 2016 22:28:45

Transmission Type Cumulative ☐

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6) 

Visit Name _____

Visit Type Scheduled ☐

Accession ID X312806

Actual Collection Date 2014 05 05

Actual Collection Time 06:27

Specimen Condition _____

Battery ID RC9255

Battery Name CHEMISTRY PANEL

Lab Test ID RCT15

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

Form: Lab_BU_CCLS (9)

Data signed: (hfarmer1) 30 Mar 2015 13:34:59

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Day 30

Form: Lab_BU_CCLS (9)

Data signed: (hfarmer1) 30 Mar 2015 13:34:59

Generated On: 20 Jul 2016 22:28:45

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

Form: Lab_BU_CCLS (10)

Data signed: (hfarmer1) 30 Mar 2015 13:34:59

Generated On: 20 Jul 2016 22:28:45

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6) 

Visit Name _____

Visit Type Scheduled ☒

Accession ID X312806

Actual Collection Date 2014 05 05

Actual Collection Time 06:27

Specimen Condition _____

Battery ID RC9255

Battery Name CHEMISTRY PANEL

Lab Test ID RCT16

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

Form: Lab_BU_CCLS (10)

Data signed: (hfarmer1) 30 Mar 2015 13:34:59

Generated On: 20 Jul 2016 22:28:45

Lab Test Name	SERUM POTASSIUM
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	4.4
Reported Numeric Result	4.4
Reference Range low	3.4
Reference Range high	5.4
Range Units	MEQ/L
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

Form: Lab_BU_CCLS (10)

Data signed: (hfarmer1) 30 Mar 2015 13:34:59

Generated On: 20 Jul 2016 22:28:45

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

Form: Lab_BU_CCLS (11)

Data signed: (hfarmer1) 30 Mar 2015 13:34:59

Generated On: 20 Jul 2016 22:28:45

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	X312806
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Actual Collection Date	2014 05 05
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Actual Collection Time	06:27
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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: 1252**

Folder: Day 30

Form: Lab_BU_CCLS (11)

Data signed: (hfarmer1) 30 Mar 2015 13:34:59

Generated On: 20 Jul 2016 22:28:45

Lab Test Name	DIRECT BILIRUBIN
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	0.2
Reported Numeric Result	0.2
Reference Range low	0.0
Reference Range high	0.4
Range Units	MG/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

Form: Lab_BU_CCLS (11)

Data signed: (hfarmer1) 30 Mar 2015 13:34:59

Generated On: 20 Jul 2016 22:28:45

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

Form: Lab_BU_CCLS (12)

Data signed: (hfarmer1) 30 Mar 2015 13:34:59

Generated On: 20 Jul 2016 22:28:45

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6) 

Visit Name _____

Visit Type Scheduled ☒

Accession ID X312806

Actual Collection Date 2014 05 05

Actual Collection Time 06:27

Specimen Condition _____

Battery ID RC9255

Battery Name CHEMISTRY PANEL

Lab Test ID RCT3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

Form: Lab_BU_CCLS (12)

Data signed: (hfarmer1) 30 Mar 2015 13:34:59

Generated On: 20 Jul 2016 22:28:45

Lab Test Name	GGT
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	53
Reported Numeric Result	53
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: 1252**

Folder: Day 30

Form: Lab_BU_CCLS (12)

Data signed: (hfarmer1) 30 Mar 2015 13:34:59

Generated On: 20 Jul 2016 22:28:45

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

Form: Lab_BU_CCLS (13)

Data signed: (hfarmer1) 30 Mar 2015 13:34:59

Generated On: 20 Jul 2016 22:28:45

Transmission Type Cumulative ☐

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6) 

Visit Name _____

Visit Type Scheduled ☐

Accession ID X312806

Actual Collection Date 2014 05 05

Actual Collection Time 06:27

Specimen Condition _____

Battery ID RC9255

Battery Name CHEMISTRY PANEL

Lab Test ID RCT392

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

Form: Lab_BU_CCLS (13)

Data signed: (hfarmer1) 30 Mar 2015 13:34:59

Generated On: 20 Jul 2016 22:28:45

Lab Test Name	CREATININE (RATE BLANKED)
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Test ID	<hr/>
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Test Status	Done <input checked="" type="radio"/>
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Reported Text Result	0.9
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Reported Numeric Result	0.9
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Reference Range low	0.5
---------------------	-----

Reference Range high	1.2
----------------------	-----

Range Units	MG/DL
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Conventional Text Result	<hr/>
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Conventional Numeric Result	<hr/>
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Conventional Reference Range Low	<hr/>
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Conventional Reference Range High	<hr/>
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Conventional Units	<hr/>
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SI Text Result	<hr/>
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

Form: Lab_BU_CCLS (13)

Data signed: (hfarmer1) 30 Mar 2015 13:34:59

Generated On: 20 Jul 2016 22:28:45

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

Form: Lab_BU_CCLS (14)

Data signed: (hfarmer1) 30 Mar 2015 13:34:59

Generated On: 20 Jul 2016 22:28:45

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	X312806
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Actual Collection Date	2014 05 05
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Actual Collection Time	06:27
------------------------	-------

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: 1252**

Folder: Day 30

Form: Lab_BU_CCLS (14)

Data signed: (hfarmer1) 30 Mar 2015 13:34:59

Generated On: 20 Jul 2016 22:28:45

Lab Test Name	ALT (SGPT)
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	30
Reported Numeric Result	30
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: 1252**

Folder: Day 30

Form: Lab_BU_CCLS (14)

Data signed: (hfarmer1) 30 Mar 2015 13:34:59

Generated On: 20 Jul 2016 22:28:45

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

Form: Lab_BU_CCLS (15)

Data signed: (hfarmer1) 30 Mar 2015 13:34:59

Generated On: 20 Jul 2016 22:28:45

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	X312806
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Actual Collection Date	2014 05 05
------------------------	------------

Actual Collection Time	06:27
------------------------	-------

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: 1252**

Folder: Day 30

Form: Lab_BU_CCLS (15)

Data signed: (hfarmer1) 30 Mar 2015 13:34:59

Generated On: 20 Jul 2016 22:28:45

Lab Test Name	AST (SGOT)
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	38
Reported Numeric Result	38
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: 1252**

Folder: Day 30

Form: Lab_BU_CCLS (15)

Data signed: (hfarmer1) 30 Mar 2015 13:34:59

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Day 30

Form: Lab_BU_CCLS (16)

Data signed: (hfarmer1) 30 Mar 2015 13:34:59

Generated On: 20 Jul 2016 22:28:45

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	X312806
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Actual Collection Date	2014 05 05
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Actual Collection Time	06:27
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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: 1252**

Folder: Day 30

Form: Lab_BU_CCLS (16)

Data signed: (hfarmer1) 30 Mar 2015 13:34:59

Generated On: 20 Jul 2016 22:28:45

Lab Test Name	UREA NITROGEN
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	13
Reported Numeric Result	13
Reference Range low	4
Reference Range high	24
Range Units	MG/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

Form: Lab_BU_CCLS (16)

Data signed: (hfarmer1) 30 Mar 2015 13:34:59

Generated On: 20 Jul 2016 22:28:45

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

Form: Lab_BU_CCLS (17)

Data signed: (hfarmer1) 30 Mar 2015 13:34:59

Generated On: 20 Jul 2016 22:28:45

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	X312806
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Actual Collection Date	2014 05 05
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Actual Collection Time	06:27
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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: 1252**

Folder: Day 30

Form: Lab_BU_CCLS (17)

Data signed: (hfarmer1) 30 Mar 2015 13:34:59

Generated On: 20 Jul 2016 22:28:45

Lab Test Name	MONOCYTES
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	0.47
Reported Numeric Result	0.47
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: 1252**

Folder: Day 30

Form: Lab_BU_CCLS (17)

Data signed: (hfarmer1) 30 Mar 2015 13:34:59

Generated On: 20 Jul 2016 22:28:45

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

Form: Lab_BU_CCLS (18)

Data signed: (hfarmer1) 30 Mar 2015 13:34:59

Generated On: 20 Jul 2016 22:28:45

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	X312806
--------------	---------

Actual Collection Date	2014 05 05
------------------------	------------

Actual Collection Time	06:27
------------------------	-------

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: 1252**

Folder: Day 30

Form: Lab_BU_CCLS (18)

Data signed: (hfarmer1) 30 Mar 2015 13:34:59

Generated On: 20 Jul 2016 22:28:45

Lab Test Name	MCH
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	34
Reported Numeric Result	34
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: 1252**

Folder: Day 30

Form: Lab_BU_CCLS (18)

Data signed: (hfarmer1) 30 Mar 2015 13:34:59

Generated On: 20 Jul 2016 22:28:45

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

Form: Lab_BU_CCLS (19)

Data signed: (hfarmer1) 30 Mar 2015 13:34:59

Generated On: 20 Jul 2016 22:28:45

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) <div></div>
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	X312806
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Actual Collection Date	2014 05 05
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Actual Collection Time	06:27
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Specimen Condition	<hr/>
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Battery ID	HM1604
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Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
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Lab Test ID	HMT102
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

Form: Lab_BU_CCLS (19)

Data signed: (hfarmer1) 30 Mar 2015 13:34:59

Generated On: 20 Jul 2016 22:28:45

Lab Test Name	MCHC
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	33
Reported Numeric Result	33
Reference Range low	31
Reference Range high	38
Range Units	G/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

Form: Lab_BU_CCLS (19)

Data signed: (hfarmer1) 30 Mar 2015 13:34:59

Generated On: 20 Jul 2016 22:28:45

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

Form: Lab_BU_CCLS (20)

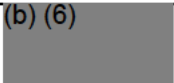
Data signed: (hfarmer1) 30 Mar 2015 13:34:59

Generated On: 20 Jul 2016 22:28:45

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	X312806
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Actual Collection Date	2014 05 05
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Actual Collection Time	06:27
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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	HMT11
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

Form: Lab_BU_CCLS (20)

Data signed: (hfarmer1) 30 Mar 2015 13:34:59

Generated On: 20 Jul 2016 22:28:45

Lab Test Name	EOSINOPHILS
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	0.17
Reported Numeric Result	0.17
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: 1252**

Folder: Day 30

Form: Lab_BU_CCLS (20)

Data signed: (hfarmer1) 30 Mar 2015 13:34:59

Generated On: 20 Jul 2016 22:28:45

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

Form: Lab_BU_CCLS (21)

Data signed: (hfarmer1) 30 Mar 2015 13:34:59

Generated On: 20 Jul 2016 22:28:45

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	X312806
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Actual Collection Date	2014 05 05
------------------------	------------

Actual Collection Time	06:27
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Specimen Condition	<hr/>
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Battery ID	HM1604
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Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
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Lab Test ID	HMT12
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

Form: Lab_BU_CCLS (21)

Data signed: (hfarmer1) 30 Mar 2015 13:34:59

Generated On: 20 Jul 2016 22:28:45

Lab Test Name	BASOPHILS
Test ID	
Test Status	Done <input type="checkbox"/>
Reported Text Result	0.07
Reported Numeric Result	0.07
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: 1252**

Folder: Day 30

Form: Lab_BU_CCLS (21)

Data signed: (hfarmer1) 30 Mar 2015 13:34:59

Generated On: 20 Jul 2016 22:28:45

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

Form: Lab_BU_CCLS (22)

Data signed: (hfarmer1) 30 Mar 2015 13:34:59

Generated On: 20 Jul 2016 22:28:45

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) <div></div>
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	X312806
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Actual Collection Date	2014 05 05
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Actual Collection Time	06:27
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Specimen Condition	<hr/>
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Battery ID	HM1604
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Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
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Lab Test ID	HMT13
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

Form: Lab_BU_CCLS (22)

Data signed: (hfarmer1) 30 Mar 2015 13:34:59

Generated On: 20 Jul 2016 22:28:45

Lab Test Name	PLATELETS
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	271
Reported Numeric Result	271
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: 1252**

Folder: Day 30

Form: Lab_BU_CCLS (22)

Data signed: (hfarmer1) 30 Mar 2015 13:34:59

Generated On: 20 Jul 2016 22:28:45

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

Form: Lab_BU_CCLS (23)

Data signed: (hfarmer1) 30 Mar 2015 13:34:59

Generated On: 20 Jul 2016 22:28:45

Transmission Type Cumulative ☐

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6) 

Visit Name _____

Visit Type Scheduled ☐

Accession ID X312806

Actual Collection Date 2014 05 05

Actual Collection Time 06:27

Specimen Condition _____

Battery ID HM1604

Battery Name HEMATOLOGY
&DIFFERENTIAL PANEL

Lab Test ID HMT15

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

Form: Lab_BU_CCLS (23)

Data signed: (hfarmer1) 30 Mar 2015 13:34:59

Generated On: 20 Jul 2016 22:28:45

Lab Test Name	NEUTROPHILS (%)
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	68.4
Reported Numeric Result	68.4
Reference Range low	40.5
Reference Range high	75.0
Range Units	%
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

Form: Lab_BU_CCLS (23)

Data signed: (hfarmer1) 30 Mar 2015 13:34:59

Generated On: 20 Jul 2016 22:28:45

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

Form: Lab_BU_CCLS (24)

Data signed: (hfarmer1) 30 Mar 2015 13:34:59

Generated On: 20 Jul 2016 22:28:45

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) <div></div>
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	X312806
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Actual Collection Date	2014 05 05
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Actual Collection Time	06:27
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Specimen Condition	<hr/>
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Battery ID	HM1604
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Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
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Lab Test ID	HMT16
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

Form: Lab_BU_CCLS (24)

Data signed: (hfarmer1) 30 Mar 2015 13:34:59

Generated On: 20 Jul 2016 22:28:45

Lab Test Name	LYMPHOCYTES (%)
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	20.2
Reported Numeric Result	20.2
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: 1252**

Folder: Day 30

Form: Lab_BU_CCLS (24)

Data signed: (hfarmer1) 30 Mar 2015 13:34:59

Generated On: 20 Jul 2016 22:28:45

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

Form: Lab_BU_CCLS (25)

Data signed: (hfarmer1) 30 Mar 2015 13:34:59

Generated On: 20 Jul 2016 22:28:45

Transmission Type Cumulative ☒

Subject ID or Number

Subject Sex M

Subject Date of Birth (b) (6) 

Visit Name

Visit Type Scheduled ☒

Accession ID X312806

Actual Collection Date 2014 05 05

Actual Collection Time 06:27

Specimen Condition

Battery ID HM1604

Battery Name HEMATOLOGY
&DIFFERENTIAL PANEL

Lab Test ID HMT17

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

Form: Lab_BU_CCLS (25)

Data signed: (hfarmer1) 30 Mar 2015 13:34:59

Generated On: 20 Jul 2016 22:28:45

Lab Test Name	MONOCYTES (%)
Test ID	
Test Status	Done <input checked="" type="checkbox"/>
Reported Text Result	7.4
Reported Numeric Result	7.4
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: 1252**

Folder: Day 30

Form: Lab_BU_CCLS (25)

Data signed: (hfarmer1) 30 Mar 2015 13:34:59

Generated On: 20 Jul 2016 22:28:45

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

Form: Lab_BU_CCLS (26)

Data signed: (hfarmer1) 30 Mar 2015 13:34:59

Generated On: 20 Jul 2016 22:28:45

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	X312806
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Actual Collection Date	2014 05 05
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Actual Collection Time	06:27
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Specimen Condition	<hr/>
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Battery ID	HM1604
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Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
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Lab Test ID	HMT18
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

Form: Lab_BU_CCLS (26)

Data signed: (hfarmer1) 30 Mar 2015 13:34:59

Generated On: 20 Jul 2016 22:28:45

Lab Test Name	EOSINOPHILS (%)
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	2.7
Reported Numeric Result	2.7
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: 1252**

Folder: Day 30

Form: Lab_BU_CCLS (26)

Data signed: (hfarmer1) 30 Mar 2015 13:34:59

Generated On: 20 Jul 2016 22:28:45

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

Form: Lab_BU_CCLS (27)

Data signed: (hfarmer1) 30 Mar 2015 13:34:59

Generated On: 20 Jul 2016 22:28:45

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	X312806
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Actual Collection Date	2014 05 05
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Actual Collection Time	06:27
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Specimen Condition	<hr/>
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Battery ID	HM1604
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Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
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Lab Test ID	HMT19
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

Form: Lab_BU_CCLS (27)

Data signed: (hfarmer1) 30 Mar 2015 13:34:59

Generated On: 20 Jul 2016 22:28:45

Lab Test Name	BASOPHILS (%)
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	1.1
Reported Numeric Result	1.1
Reference Range low	0.0
Reference Range high	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: 1252**

Folder: Day 30

Form: Lab_BU_CCLS (27)

Data signed: (hfarmer1) 30 Mar 2015 13:34:59

Generated On: 20 Jul 2016 22:28:45

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

Form: Lab_BU_CCLS (28)

Data signed: (hfarmer1) 30 Mar 2015 13:34:59

Generated On: 20 Jul 2016 22:28:45

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	X312806
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Actual Collection Date	2014 05 05
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Actual Collection Time	06:27
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Specimen Condition	<hr/>
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Battery ID	HM1604
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Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
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Lab Test ID	HMT2
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Day 30

Form: Lab_BU_CCLS (28)

Data signed: (hfarmer1) 30 Mar 2015 13:34:59

Generated On: 20 Jul 2016 22:28:45

Lab Test Name	HEMATOCRIT
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	45
Reported Numeric Result	45
Reference Range low	39
Reference Range high	54
Range Units	%
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

Form: Lab_BU_CCLS (28)

Data signed: (hfarmer1) 30 Mar 2015 13:34:59

Generated On: 20 Jul 2016 22:28:45

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

Form: Lab_BU_CCLS (29)

Data signed: (hfarmer1) 30 Mar 2015 13:34:59

Generated On: 20 Jul 2016 22:28:45

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	X312806
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Actual Collection Date	2014 05 05
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Actual Collection Time	06:27
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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: 1252**

Folder: Day 30

Form: Lab_BU_CCLS (29)

Data signed: (hfarmer1) 30 Mar 2015 13:34:59

Generated On: 20 Jul 2016 22:28:45

Lab Test Name	RBC
Test ID	
Test Status	Done <input checked="" type="checkbox"/>
Reported Text Result	4.4
Reported Numeric Result	4.4
Reference Range low	4.5
Reference Range high	6.4
Range Units	X10^6/UL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

Form: Lab_BU_CCLS (29)

Data signed: (hfarmer1) 30 Mar 2015 13:34:59

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Day 30

Form: Lab_BU_CCLS (30)

Data signed: (hfarmer1) 30 Mar 2015 13:34:59

Generated On: 20 Jul 2016 22:28:45

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6) 

Visit Name _____

Visit Type Scheduled ☒

Accession ID X312806

Actual Collection Date 2014 05 05

Actual Collection Time 06:27

Specimen Condition _____

Battery ID HM1604

Battery Name HEMATOLOGY
&DIFFERENTIAL PANEL

Lab Test ID HMT4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

Form: Lab_BU_CCLS (30)

Data signed: (hfarmer1) 30 Mar 2015 13:34:59

Generated On: 20 Jul 2016 22:28:45

Lab Test Name	MCV
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	102
Reported Numeric Result	102
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: 1252**

Folder: Day 30

Form: Lab_BU_CCLS (30)

Data signed: (hfarmer1) 30 Mar 2015 13:34:59

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Day 30

Form: Lab_BU_CCLS (31)

Data signed: (hfarmer1) 30 Mar 2015 13:34:59

Generated On: 20 Jul 2016 22:28:45

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) <div></div>
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	X312806
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Actual Collection Date	2014 05 05
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Actual Collection Time	06:27
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Specimen Condition	<hr/>
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Battery ID	HM1604
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Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
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Lab Test ID	HMT40
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

Form: Lab_BU_CCLS (31)

Data signed: (hfarmer1) 30 Mar 2015 13:34:59

Generated On: 20 Jul 2016 22:28:45

Lab Test Name	HEMOGLOBIN
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	15.0
Reported Numeric Result	15.0
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: 1252**

Folder: Day 30

Form: Lab_BU_CCLS (31)

Data signed: (hfarmer1) 30 Mar 2015 13:34:59

Generated On: 20 Jul 2016 22:28:45

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

Form: Lab_BU_CCLS (32)

Data signed: (hfarmer1) 30 Mar 2015 13:34:59

Generated On: 20 Jul 2016 22:28:45

Transmission Type Cumulative ☐

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6) 

Visit Name _____

Visit Type Scheduled ☐

Accession ID X312806

Actual Collection Date 2014 05 05

Actual Collection Time 06:27

Specimen Condition _____

Battery ID HM1604

Battery Name HEMATOLOGY
&DIFFERENTIAL PANEL

Lab Test ID HMT7

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

Form: Lab_BU_CCLS (32)

Data signed: (hfarmer1) 30 Mar 2015 13:34:59

Generated On: 20 Jul 2016 22:28:45

Lab Test Name	WBC
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	6.29
Reported Numeric Result	6.29
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: 1252**

Folder: Day 30

Form: Lab_BU_CCLS (32)

Data signed: (hfarmer1) 30 Mar 2015 13:34:59

Generated On: 20 Jul 2016 22:28:45

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

Form: Lab_BU_CCLS (33)

Data signed: (hfarmer1) 30 Mar 2015 13:34:59

Generated On: 20 Jul 2016 22:28:45

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	X312806
--------------	---------

Actual Collection Date	2014 05 05
------------------------	------------

Actual Collection Time	06:27
------------------------	-------

Specimen Condition	<hr/>
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Battery ID	HM1604
------------	--------

Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
--------------	-----------------------------------

Lab Test ID	HMT71
-------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

Form: Lab_BU_CCLS (33)

Data signed: (hfarmer1) 30 Mar 2015 13:34:59


Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Day 30

Form: Lab_BU_CCLS (33)

Data signed: (hfarmer1) 30 Mar 2015 13:34:59

Generated On: 20 Jul 2016 22:28:45

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

Form: Lab_BU_CCLS (34)

Data signed: (hfarmer1) 30 Mar 2015 13:34:59

Generated On: 20 Jul 2016 22:28:45

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	X312806
--------------	---------

Actual Collection Date	2014 05 05
------------------------	------------

Actual Collection Time	06:27
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	HM1604
------------	--------

Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
--------------	-----------------------------------

Lab Test ID	HMT8
-------------	------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

Form: Lab_BU_CCLS (34)

Data signed: (hfarmer1) 30 Mar 2015 13:34:59

Generated On: 20 Jul 2016 22:28:45

Lab Test Name	NEUTROPHILS
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	4.31
Reported Numeric Result	4.31
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: 1252**

Folder: Day 30

Form: Lab_BU_CCLS (34)

Data signed: (hfarmer1) 30 Mar 2015 13:34:59

Generated On: 20 Jul 2016 22:28:45

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

Form: Lab_BU_CCLS (35)

Data signed: (hfarmer1) 30 Mar 2015 13:34:59

Generated On: 20 Jul 2016 22:28:45

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	X312806
--------------	---------

Actual Collection Date	2014 05 05
------------------------	------------

Actual Collection Time	06:27
------------------------	-------

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: 1252**

Folder: Day 30

Form: Lab_BU_CCLS (35)

Data signed: (hfarmer1) 30 Mar 2015 13:34:59

Generated On: 20 Jul 2016 22:28:45

Lab Test Name	LYMPHOCYTES
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	1.27
Reported Numeric Result	1.27
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: 1252**

Folder: Day 30

Form: Lab_BU_CCLS (35)

Data signed: (hfarmer1) 30 Mar 2015 13:34:59

Generated On: 20 Jul 2016 22:28:45

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

Form: Lab_BU_CCLS (36)

Data signed: (hfarmer1) 30 Mar 2015 13:34:59

Generated On: 20 Jul 2016 22:28:45

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6) 

Visit Name _____

Visit Type Scheduled ☒

Accession ID X312806

Actual Collection Date 2014 05 05

Actual Collection Time 06:27

Specimen Condition _____

Battery ID UA1538

Battery Name URINE MACRO PANEL

Lab Test ID UAT10

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

Form: Lab_BU_CCLS (36)

Data signed: (hfarmer1) 30 Mar 2015 13:34:59


Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Day 30

Form: Lab_BU_CCLS (36)

Data signed: (hfarmer1) 30 Mar 2015 13:34:59

Generated On: 20 Jul 2016 22:28:45

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

Form: Lab_BU_CCLS (37)

Data signed: (hfarmer1) 30 Mar 2015 13:34:59

Generated On: 20 Jul 2016 22:28:45

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6) _____

Visit Name _____

Visit Type Scheduled ☒

Accession ID X312806

Actual Collection Date 2014 05 05

Actual Collection Time 06:27

Specimen Condition _____

Battery ID UA1538

Battery Name URINE MACRO PANEL

Lab Test ID UAT2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

Form: Lab_BU_CCLS (37)

Data signed: (hfarmer1) 30 Mar 2015 13:34:59

Generated On: 20 Jul 2016 22:28:45

Lab Test Name	UR SPECIFIC GRAVITY
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	1.017
Reported Numeric Result	1.017
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: 1252**

Folder: Day 30

Form: Lab_BU_CCLS (37)

Data signed: (hfarmer1) 30 Mar 2015 13:34:59

Generated On: 20 Jul 2016 22:28:45

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

Form: Lab_BU_CCLS (38)

Data signed: (hfarmer1) 30 Mar 2015 13:34:59

Generated On: 20 Jul 2016 22:28:45

Transmission Type Cumulative ☐

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6)

Visit Name _____

Visit Type Scheduled ☐

Accession ID X312806

Actual Collection Date 2014 05 05

Actual Collection Time 06:27

Specimen Condition _____

Battery ID UA1538

Battery Name URINE MACRO PANEL

Lab Test ID UAT3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

Form: Lab_BU_CCLS (38)

Data signed: (hfarmer1) 30 Mar 2015 13:34:59

Generated On: 20 Jul 2016 22:28:45

Lab Test Name	UR PH
Test ID	
Test Status	Done <input type="checkbox"/>
Reported Text Result	7.0
Reported Numeric Result	7.0
Reference Range low	5.0
Reference Range high	8.0
Range Units	
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

Form: Lab_BU_CCLS (38)

Data signed: (hfarmer1) 30 Mar 2015 13:34:59

Generated On: 20 Jul 2016 22:28:45

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

Form: Lab_BU_CCLS (39)

Data signed: (hfarmer1) 30 Mar 2015 13:34:59

Generated On: 20 Jul 2016 22:28:45

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6) 

Visit Name _____

Visit Type Scheduled ☒

Accession ID X312806

Actual Collection Date 2014 05 05

Actual Collection Time 06:27

Specimen Condition _____

Battery ID UA1538

Battery Name URINE MACRO PANEL

Lab Test ID UAT43

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

Form: Lab_BU_CCLS (39)

Data signed: (hfarmer1) 30 Mar 2015 13:34:59


Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Day 30

Form: Lab_BU_CCLS (39)

Data signed: (hfarmer1) 30 Mar 2015 13:34:59

Generated On: 20 Jul 2016 22:28:45

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

Form: Lab_BU_CCLS (40)

Data signed: (hfarmer1) 30 Mar 2015 13:34:59

Generated On: 20 Jul 2016 22:28:45

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6) 

Visit Name _____

Visit Type Scheduled ☒

Accession ID X312806

Actual Collection Date 2014 05 05

Actual Collection Time 06:27

Specimen Condition _____

Battery ID UA1538

Battery Name URINE MACRO PANEL

Lab Test ID UAT49

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

Form: Lab_BU_CCLS (40)

Data signed: (hfarmer1) 30 Mar 2015 13:34:59


Generated On: 20 Jul 2016 22:28:45

Lab Test Name

UR PROTEIN

Test ID

Test Status

Done 

Reported Text Result

TRACE

Reported Numeric Result

Reference Range low

Reference Range high

Range Units

Conventional Text Result

Conventional Numeric Result

Conventional Reference Range Low

Conventional Reference Range High

Conventional Units

SI Text Result

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

Form: Lab_BU_CCLS (40)

Data signed: (hfarmer1) 30 Mar 2015 13:34:59

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Day 30

Form: Lab_BU_CCLS (41)

Data signed: (hfarmer1) 30 Mar 2015 13:34:59

Generated On: 20 Jul 2016 22:28:45

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6) 

Visit Name _____

Visit Type Scheduled ☒

Accession ID X312806

Actual Collection Date 2014 05 05

Actual Collection Time 06:27

Specimen Condition _____

Battery ID UA1538

Battery Name URINE MACRO PANEL

Lab Test ID UAT5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

Form: Lab_BU_CCLS (41)

Data signed: (hfarmer1) 30 Mar 2015 13:34:59


Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Day 30

Form: Lab_BU_CCLS (41)

Data signed: (hfarmer1) 30 Mar 2015 13:34:59

Generated On: 20 Jul 2016 22:28:45

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

Form: Lab_BU_CCLS (42)

Data signed: (hfarmer1) 30 Mar 2015 13:34:59

Generated On: 20 Jul 2016 22:28:45

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6)

Visit Name _____

Visit Type Scheduled ☒

Accession ID X312806

Actual Collection Date 2014 05 05

Actual Collection Time 06:27

Specimen Condition _____

Battery ID UA1538

Battery Name URINE MACRO PANEL

Lab Test ID UAT7

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

Form: Lab_BU_CCLS (42)

Data signed: (hfarmer1) 30 Mar 2015 13:34:59


Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Day 30

Form: Lab_BU_CCLS (42)

Data signed: (hfarmer1) 30 Mar 2015 13:34:59

Generated On: 20 Jul 2016 22:28:45

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

Form: Lab_BU_COHB (1)

Data signed: (hfarmer1) 30 Mar 2015 13:35:18

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05115150004509
Analyte	CARBOXYHEMOGLOBIN
Sample type	BLOOD
Result	5.90
Result Unit	%
Lab Status	OK
Sample comment	.
Detection method	SPECTROPHOTOMETRIC
Lower limit of quantification	0.500
Planned time point (Hour)	10
Day of Visit	30
Celerion Study Number	AA99128-16
Date of Collection	2014-MAY-04
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

Form: Lab_BU_COHB (1)

Data signed: (hfarmer1) 30 Mar 2015 13:35:18

Generated On: 20 Jul 2016 22:28:45

Start Day (24 hour urine only)

End Day (24 hour Urine Only)

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

Form: Cough Assessment (Paper)

Data signed: (hfarmer1) 30 Mar 2015 13:34:54

Generated On: 20 Jul 2016 22:28:45

Was paper questionnaire used? Yes ☐

Reason not done _____

Date of assessment 05 MAY 2014
DD/MMM/YYYY DD/MMM/YYYY

Time of assessment 06:31
hour:min 24-hour clock

Have you experienced a regular need to cough e.g. coughing several times in the last 24 hrs? No ☐

If YES, please answer the following questions:

First Question: Cough Impact Scale
How much is your cough bothering you? _____

Second Question: Cough Intensity Scale:
How intense is your cough? _____

Third Question: Cough Frequency Scale:
How frequently do you normally have to cough each day? _____

Fourth Question: Sputum Production
To what extent do you produce sputum when coughing? _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

Form: Cough Assessment (Paper)

Data signed: (hfarmer1) 30 Mar 2015 13:34:54

Generated On: 20 Jul 2016 22:28:45

Are there any other important observations that you
would like to share with us about you coughing? (open
question)

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Day 30

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS) (Paper)

Data signed: (hfarmer1) 30 Mar 2015 13:34:55

Generated On: 20 Jul 2016 22:28:45

Was paper questionnaire used?

Yes ☒

Reason not done

Date of assessment
DD/MMM/YYYY

05 MAY 2014
DD/MMM/YYYY

Time of assessment

06:31
hour:min 24-hour clock

Please indicate for each of the items below, how you have been feeling over the past 24 hours

Result

1. Angry, irritable, frustrated

None

2. Anxious, tense

Mild

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Day 30

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS) (Paper) (3)

Data signed: (hfarmer1) 30 Mar 2015 13:34:55

Generated On: 20 Jul 2016 22:28:45

	Result
3. Depressed Mood, sad	Moderate
4. Desire or craving to smoke	None
5. Difficulty concentrating	Mild
6. Increased appetite, hungry, weight gain	None
7. Insomnia, sleep problems, awakening at night	None
8. Restless	Mild
9. Impatient	None

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Day 30

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS) (Paper) (10)

Data signed: (hfarmer1) 30 Mar 2015 13:34:55

Generated On: 20 Jul 2016 22:28:45

	Result
10. Constipation	None
11. Dizziness	None
12. Coughing	None
13. Dreaming or nightmares	None
14. Nausea	None
15. Sore throat	None

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

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

Data signed: (hfarmer1) 30 Mar 2015 13:34:55

Generated On: 20 Jul 2016 22:28:45

Was paper questionnaire used? Yes ☒

Reason not done _____

Type PROCHASKA STAGE OF
CHANGE QUESTIONNAIRE:
INTENTION TO QUIT
SMOKING

Date of assessment 04 MAY 2014
DD/MMM/YYYY

Time of assessment 20:36
hour:min 24-hour clock

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

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

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

Form: Human Smoking Topography Questionnaire

Data signed: (hfarmer1) 30 Mar 2015 13:34:56

Generated On: 20 Jul 2016 22:28:45

Type	HUMAN SMOKING TOPOGRAPHY QUESTIONNAIRE
------	--

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

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

Date of assessment	04 MAY 2014 DD/MMM/YYYY
--------------------	----------------------------

Time of assessment	20:34 hour:min 24-hour clock
--------------------	---------------------------------

How do you agree with the following sentences/affirmations :

1. The smoking of the conventional cigarettes/products is different with the device.	Strongly agree <input type="radio"/>
--	--------------------------------------

If you agree or strongly agree, please describe :	<hr/>
---	-------

2. You enjoy smoking with the device as much as without it.	Strongly agree <input type="radio"/>
---	--------------------------------------

If you disagree or strongly disagree, please describe :	<hr/>
---	-------

3. The taste of the conventional cigarettes/products is different with the device.	Strongly disagree <input type="radio"/>
--	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

Form: Human Smoking Topography Questionnaire

Data signed: (hfarmer1) 30 Mar 2015 13:34:56

Generated On: 20 Jul 2016 22:28:45

If you agree or strongly agree, please describe : _____

4. The device is easy to use.

Strongly agree ☒

If you disagree or strongly disagree, please describe : _____

5. Your smoking is disturbed by the device.

Strongly disagree ☒

If you agree or strongly agree, please describe : _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

Form: Questionnaire on smoking urges (QSU) (Paper)

Data signed: (hfarmer1) 30 Mar 2015 13:34:55

Generated On: 20 Jul 2016 22:28:45

Type	QUESTIONNAIRE ON SMOKING URGES
------	-----------------------------------

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

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

Date of assessment	04 MAY 2014
--------------------	-------------

DD/MMM/YYYY

Time of assessment	20:36
--------------------	-------

hour:min 24-hour clock

1. I have a desire for a cigarette right now	Strongly agree <input type="radio"/>
--	--------------------------------------

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

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

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

5. All I want right now is a cigarette	Strongly disagree <input type="radio"/>
--	---

6. I have an urge for a cigarette	Strongly agree <input type="radio"/>
-----------------------------------	--------------------------------------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

Form: Questionnaire on smoking urges (QSU) (Paper)

Data signed: (hfarmer1) 30 Mar 2015 13:34:55

Generated On: 20 Jul 2016 22:28:45

7. A cigarette would taste good now Strongly agree ☐

8. I would do almost anything for a cigarette now Strongly disagree ☐

9. Smoking would make me less depressed Strongly disagree ☐

10. I am going to smoke as soon as possible Strongly agree ☐

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper)

Data signed: (hfarmer1) 30 Mar 2015 13:34:54

Generated On: 20 Jul 2016 22:28:45

Was paper questionnaire used?

Yes ☒

Reason not done

Date of assessment

04 MAY 2014

DD/MMM/YYYY

DD/MMM/YYYY

Time of assessment

20:30

hour:min 24-hour clock

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper) (1)

Data signed: (hfarmer1) 30 Mar 2015 13:34:54

Generated On: 20 Jul 2016 22:28:45

Was paper questionnaire used? Yes ☒

Reason not done _____

Date of assessment 04 MAY 2014
DD/MMM/YYYY

Time of assessment 20:30
hour:min 24-hour clock

If you have smoked since you last completed this questionnaire,
please mark what best represents how smoking made you feel

Was smoking satisfying? ☒

Response Extremely ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper) (2)

Data signed: (hfarmer1) 30 Mar 2015 13:34:54

Generated On: 20 Jul 2016 22:28:45

Was paper questionnaire used? Yes ☒

Reason not done _____

Date of assessment 04 MAY 2014
DD/MMM/YYYY

Time of assessment 20:30
hour:min 24-hour clock

If you have smoked since you last completed this questionnaire,
please mark what best represents how smoking made you feel

Did cigarettes taste good? ☒

Response Moderately ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper) (3)

Data signed: (hfarmer1) 30 Mar 2015 13:34:54

Generated On: 20 Jul 2016 22:28:45

Was paper questionnaire used? Yes ☒

Reason not done _____

Date of assessment 04 MAY 2014
DD/MMM/YYYY

Time of assessment 20:30
hour:min 24-hour clock

If you have smoked since you last completed this questionnaire,
please mark what best represents how smoking made you feel

Did you enjoy the sensation in your throat and chest? ☒

Response Moderately ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper) (4)

Data signed: (hfarmer1) 30 Mar 2015 13:34:54

Generated On: 20 Jul 2016 22:28:45

Was paper questionnaire used? Yes ☒

Reason not done _____

Date of assessment 04 MAY 2014
DD/MMM/YYYY

Time of assessment 20:30
hour:min 24-hour clock

If you have smoked since you last completed this questionnaire,
please mark what best represents how smoking made you feel

Did smoking calm you down? ☒

Response Moderately ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper) (5)

Data signed: (hfarmer1) 30 Mar 2015 13:34:54

Generated On: 20 Jul 2016 22:28:45

Was paper questionnaire used? Yes ☒

Reason not done _____

Date of assessment 04 MAY 2014
DD/MMM/YYYY

Time of assessment 20:30
hour:min 24-hour clock

If you have smoked since you last completed this questionnaire,
please mark what best represents how smoking made you feel

Did smoking make you feel more awake? ☒

Response Moderately ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper) (6)

Data signed: (hfarmer1) 30 Mar 2015 13:34:54

Generated On: 20 Jul 2016 22:28:45

Was paper questionnaire used? Yes ☒

Reason not done _____

Date of assessment 04 MAY 2014
DD/MMM/YYYY

Time of assessment 20:30
hour:min 24-hour clock

If you have smoked since you last completed this questionnaire,
please mark what best represents how smoking made you feel

Did smoking make you feel less irritable? ☒

Response Moderately ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper) (7)

Data signed: (hfarmer1) 30 Mar 2015 13:34:54

Generated On: 20 Jul 2016 22:28:45

Was paper questionnaire used? Yes ☒

Reason not done _____

Date of assessment 04 MAY 2014
DD/MMM/YYYY

Time of assessment 20:30
hour:min 24-hour clock

If you have smoked since you last completed this questionnaire,
please mark what best represents how smoking made you feel

Did smoking help you concentrate? ☒

Response Not at all ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper) (8)

Data signed: (hfarmer1) 30 Mar 2015 13:34:54

Generated On: 20 Jul 2016 22:28:45

Was paper questionnaire used? Yes ☒

Reason not done _____

Date of assessment 04 MAY 2014
DD/MMM/YYYY

Time of assessment 20:30
hour:min 24-hour clock

If you have smoked since you last completed this questionnaire,
please mark what best represents how smoking made you feel

Did smoking reduce your hunger for food? ☒

Response Moderately ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper) (9)

Data signed: (hfarmer1) 30 Mar 2015 13:34:54

Generated On: 20 Jul 2016 22:28:45

Was paper questionnaire used? Yes ☐

Reason not done _____

Date of assessment 04 MAY 2014
DD/MMM/YYYY

Time of assessment 20:30
hour:min 24-hour clock

If you have smoked since you last completed this questionnaire,
please mark what best represents how smoking made you feel Did smoking make you dizzy? ☐

Response Not at all ☐

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper) (10)

Data signed: (hfarmer1) 30 Mar 2015 13:34:54

Generated On: 20 Jul 2016 22:28:45

Was paper questionnaire used? Yes ☒

Reason not done _____

Date of assessment 04 MAY 2014
DD/MMM/YYYY

Time of assessment 20:30
hour:min 24-hour clock

If you have smoked since you last completed this questionnaire,
please mark what best represents how smoking made you feel

Did smoking make you
nauseous? ☒

Response Not at all ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper) (11)

Data signed: (hfarmer1) 30 Mar 2015 13:34:54

Generated On: 20 Jul 2016 22:28:45

Was paper questionnaire used? Yes ☒

Reason not done _____

Date of assessment 04 MAY 2014
DD/MMM/YYYY

Time of assessment 20:30
hour:min 24-hour clock

If you have smoked since you last completed this questionnaire,
please mark what best represents how smoking made you feel

Did smoking immediately relieve your craving for a cigarette? ☒

Response Extremely ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper) (12)

Data signed: (hfarmer1) 30 Mar 2015 13:34:54

Generated On: 20 Jul 2016 22:28:45

Was paper questionnaire used? Yes ☒

Reason not done _____

Date of assessment 04 MAY 2014
DD/MMM/YYYY

Time of assessment 20:30
hour:min 24-hour clock

If you have smoked since you last completed this questionnaire,
please mark what best represents how smoking made you feel

Did you enjoy smoking? ☒

Response Moderately ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

Form: Risk Markers(CCLS) (1)

Data signed: (hfarmer1) 30 Mar 2015 13:34:56

Generated On: 20 Jul 2016 22:28:45

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	1252
----------------------	------

Subject Sex	M
-------------	---

Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	DAY30
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	X312806
--------------	---------

Actual Collection Date	2014 05 05
------------------------	------------

Actual Collection Time	06:27
------------------------	-------

Specimen Condition	
--------------------	--

Battery ID	RC6871
------------	--------

Battery Name	HDL
--------------	-----

Lab Test ID	RCT1684
-------------	---------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

Form: Risk Markers(CCLS) (1)

Data signed: (hfarmer1) 30 Mar 2015 13:34:56


Generated On: 20 Jul 2016 22:28:45

Lab Test Name

DIRECT HDL-C 3RD
GENERATION

Test ID

Test Status

Done 

Reported Text Result

80

Reported Numeric Result

80

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: 1252**

Folder: Day 30

Form: Risk Markers(CCLS) (1)

Data signed: (hfarmer1) 30 Mar 2015 13:34:56

Generated On: 20 Jul 2016 22:28:45

SI Text Result

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

High ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

Form: Risk Markers(CCLS) (2)

Data signed: (hfarmer1) 30 Mar 2015 13:34:56

Generated On: 20 Jul 2016 22:28:45

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	1252
----------------------	------

Subject Sex	M
-------------	---

Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	DAY30
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	X312806
--------------	---------

Actual Collection Date	2014 05 05
------------------------	------------

Actual Collection Time	06:27
------------------------	-------

Specimen Condition	
--------------------	--

Battery ID	SC3249
------------	--------

Battery Name	HS-CRP
--------------	--------

Lab Test ID	SCT1528
-------------	---------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

Form: Risk Markers(CCLS) (2)

Data signed: (hfarmer1) 30 Mar 2015 13:34:56

Generated On: 20 Jul 2016 22:28:45

Lab Test Name	C-REACTIVE PROTEIN (NHS)-QT
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	0.175
Reported Numeric Result	0.175
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: 1252**

Folder: Day 30

Form: Risk Markers(CCLS) (2)

Data signed: (hfarmer1) 30 Mar 2015 13:34:56

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Day 30

Form: Risk Markers(CCLS) (3)

Data signed: (hfarmer1) 30 Mar 2015 13:34:56

Generated On: 20 Jul 2016 22:28:45

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	1252
----------------------	------

Subject Sex	M
-------------	---

Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	DAY30
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	X312806
--------------	---------

Actual Collection Date	2014 05 05
------------------------	------------

Actual Collection Time	06:27
------------------------	-------

Specimen Condition	
--------------------	--

Battery ID	CG267
------------	-------

Battery Name	FIBRINOGEN
--------------	------------

Lab Test ID	CGT285
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

Form: Risk Markers(CCLS) (3)

Data signed: (hfarmer1) 30 Mar 2015 13:34:56

Generated On: 20 Jul 2016 22:28:45

Lab Test Name	FIBRINOGEN
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	281
Reported Numeric Result	281
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: 1252**

Folder: Day 30

Form: Risk Markers(CCLS) (3)

Data signed: (hfarmer1) 30 Mar 2015 13:34:56

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Day 30

Form: Risk Markers(CCLS) (4)

Data signed: (hfarmer1) 30 Mar 2015 13:34:56

Generated On: 20 Jul 2016 22:28:45

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	1252
----------------------	------

Subject Sex	M
-------------	---

Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	DAY30
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	X312806
--------------	---------

Actual Collection Date	2014 05 05
------------------------	------------

Actual Collection Time	06:27
------------------------	-------

Specimen Condition	
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Battery ID	CN236
------------	-------

Battery Name	HOMOCYSTEINE
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Lab Test ID	CNT145
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

Form: Risk Markers(CCLS) (4)

Data signed: (hfarmer1) 30 Mar 2015 13:34:56

Generated On: 20 Jul 2016 22:28:45

Lab Test Name	HOMOCYSTEINE, EDTAPL
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	15.03
Reported Numeric Result	15.03
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: 1252**

Folder: Day 30

Form: Risk Markers(CCLS) (4)

Data signed: (hfarmer1) 30 Mar 2015 13:34:56

Generated On: 20 Jul 2016 22:28:45

SI Numeric Result


SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

High 

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

Form: Risk Markers(CCLS) (5)

Data signed: (hfarmer1) 30 Mar 2015 13:34:56

Generated On: 20 Jul 2016 22:28:45

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	1252
----------------------	------

Subject Sex	M
-------------	---

Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	DAY30
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	X312806
--------------	---------

Actual Collection Date	2014 05 05
------------------------	------------

Actual Collection Time	06:27
------------------------	-------

Specimen Condition	
--------------------	--

Battery ID	IM2293
------------	--------

Battery Name	SICAM-1
--------------	---------

Lab Test ID	IMT1768
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

Form: Risk Markers(CCLS) (5)

Data signed: (hfarmer1) 30 Mar 2015 13:34:56

Generated On: 20 Jul 2016 22:28:45

Lab Test Name	SICAM-1-RUO
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	216.1
Reported Numeric Result	216.1
Reference Range low	98.8
Reference Range high	320.0
Range Units	NG/ML
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

Form: Risk Markers(CCLS) (5)

Data signed: (hfarmer1) 30 Mar 2015 13:34:56

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Day 30

Form: Risk Markers(CCLS) (6)

Data signed: (hfarmer1) 30 Mar 2015 13:34:56

Generated On: 20 Jul 2016 22:28:45

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	1252
----------------------	------

Subject Sex	M
-------------	---

Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	DAY30
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Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	X312806
--------------	---------

Actual Collection Date	2014 05 05
------------------------	------------

Actual Collection Time	06:27
------------------------	-------

Specimen Condition	
--------------------	--

Battery ID	RC9267
------------	--------

Battery Name	LDL
--------------	-----

Lab Test ID	RCT2394
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

Form: Risk Markers(CCLS) (6)

Data signed: (hfarmer1) 30 Mar 2015 13:34:56

Generated On: 20 Jul 2016 22:28:45

Lab Test Name	DIRECT LDL-C 2ND GEN (-70)
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Test ID	<hr/>
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Test Status	Done 
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Reported Text Result	180
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Reported Numeric Result	180
-------------------------	-----

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/>
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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: 1252**

Folder: Day 30

Form: Risk Markers(CCLS) (6)

Data signed: (hfarmer1) 30 Mar 2015 13:34:56

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Day 30

Form: Biomarker-Urine (CEMA, HPMA, HBMA)

Data signed: (hfarmer1) 30 Mar 2015 13:35:19

Generated On: 20 Jul 2016 22:28:45

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (1)

Data signed: (hfarmer1) 30 Mar 2015 13:35:19

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112450002859
Analyte	HPMA
Sample type	URINE
Result	1550
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	30
Celerion Study Number	AA99128-03
Date of Collection	2014-MAY-04
Timepoint-minutes	
Urine Start Day	30

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (1)

Data signed: (hfarmer1) 30 Mar 2015 13:35:19

Generated On: 20 Jul 2016 22:28:45

Urine End Day

31

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

Form: Biomarker-Urine (CEMA, HPMa, HBMA) (2)

Data signed: (hfarmer1) 30 Mar 2015 13:35:19

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112450002859
Analyte	CEMA
Sample type	URINE
Result	305
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	30
Celerion Study Number	AA99128-03
Date of Collection	2014-MAY-04
Timepoint-minutes	
Urine Start Day	30

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

Form: Biomarker-Urine (CEMA, HPMa, HBMA) (2)

Data signed: (hfarmer1) 30 Mar 2015 13:35:19

Generated On: 20 Jul 2016 22:28:45

Urine End Day

31

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (3)

Data signed: (hfarmer1) 30 Mar 2015 13:35:19

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112450002859
Analyte	HBMA
Sample type	URINE
Result	496
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	30
Celerion Study Number	AA99128-03
Date of Collection	2014-MAY-04
Timepoint-minutes	
Urine Start Day	30

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (3)

Data signed: (hfarmer1) 30 Mar 2015 13:35:19

Generated On: 20 Jul 2016 22:28:45

Urine End Day

31

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

Form: Biomarker-Urine (NNN, NNAL)

Data signed: (hfarmer1) 30 Mar 2015 13:35:18

Generated On: 20 Jul 2016 22:28:45

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

Form: Biomarker-Urine (NNN, NNAL) (1)

Data signed: (hfarmer1) 30 Mar 2015 13:35:18

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112460003430
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Analyte	NNAL
---------	------

Sample type	URINE
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Result	.
--------	---

Result Unit	PG/ML
-------------	-------

Lab Status	OK
------------	----

Sample comment	ANALYSIS NOT PERFORMED IN ERROR
----------------	------------------------------------

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	30
--------------	----

Celerion Study Number	AA99128-04
-----------------------	------------

Date of Collection	2014-MAY-04
--------------------	-------------

Timepoint-minutes	
-------------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

Form: Biomarker-Urine (NNN, NNAL) (1)

Data signed: (hfarmer1) 30 Mar 2015 13:35:18

Generated On: 20 Jul 2016 22:28:45

Urine Start Day	30
-----------------	----

Urine End Day	31
---------------	----

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

Form: Biomarker-Urine (NNN, NNAL) (2)

Data signed: (hfarmer1) 30 Mar 2015 13:35:18

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112460003430
----------------	----------------

Analyte	NNN
---------	-----

Sample type	URINE
-------------	-------

Result	.
--------	---

Result Unit	PG/ML
-------------	-------

Lab Status	OK
------------	----

Sample comment	ANALYSIS NOT PERFORMED IN ERROR
----------------	------------------------------------

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	30
--------------	----

Celerion Study Number	AA99128-04
-----------------------	------------

Date of Collection	2014-MAY-04
--------------------	-------------

Timepoint-minutes	
-------------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

Form: Biomarker-Urine (NNN, NNAL) (2)

Data signed: (hfarmer1) 30 Mar 2015 13:35:18

Generated On: 20 Jul 2016 22:28:45

Urine Start Day	30
-----------------	----

Urine End Day	31
---------------	----

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

Form: Biomarker-Urine (HEMA)

Data signed: (hfarmer1) 30 Mar 2015 13:35:19

Generated On: 20 Jul 2016 22:28:45

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

Form: Biomarker-Urine (HEMA) (1)

Data signed: (hfarmer1) 30 Mar 2015 13:35:19

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112470001714
Analyte	HEMA
Sample type	URINE
Result	3.22
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	30
Celerion Study Number	AA99128-05
Date of Collection	2014-MAY-04
Timepoint-minutes	
Urine Start Day	30

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

Form: Biomarker-Urine (HEMA) (1)

Data signed: (hfarmer1) 30 Mar 2015 13:35:19

Generated On: 20 Jul 2016 22:28:45

Urine End Day

31

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)

Data signed: (hfarmer1) 30 Mar 2015 13:35:19

Generated On: 20 Jul 2016 22:28:45

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(1)**

Data signed: (hfarmer1) 30 Mar 2015 13:35:19

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112480000779
Analyte	COT
Sample type	URINE
Result	1040
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	30
Celerion Study Number	AA99128-06
Date of Collection	2014-MAY-04
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(1)**

Data signed: (hfarmer1) 30 Mar 2015 13:35:19

Generated On: 20 Jul 2016 22:28:45

Urine Start Day	30
<hr/>	
Urine End Day	31
<hr/>	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(2)**

Data signed: (hfarmer1) 30 Mar 2015 13:35:19

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112480000779
Analyte	COT-GLUC
Sample type	URINE
Result	4640
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	30
Celerion Study Number	AA99128-06
Date of Collection	2014-MAY-04
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(2)**

Data signed: (hfarmer1) 30 Mar 2015 13:35:19

Generated On: 20 Jul 2016 22:28:45

Urine Start Day	30
<hr/>	
Urine End Day	31
<hr/>	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(3)**

Data signed: (hfarmer1) 30 Mar 2015 13:35:19

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112480000779
Analyte	NIC
Sample type	URINE
Result	284
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	30
Celerion Study Number	AA99128-06
Date of Collection	2014-MAY-04
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(3)**

Data signed: (hfarmer1) 30 Mar 2015 13:35:19

Generated On: 20 Jul 2016 22:28:45

Urine Start Day	30
<hr/>	
Urine End Day	31
<hr/>	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(4)**

Data signed: (hfarmer1) 30 Mar 2015 13:35:19

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112480000779
Analyte	NIC-GLUC
Sample type	URINE
Result	478
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	30
Celerion Study Number	AA99128-06
Date of Collection	2014-MAY-04
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(4)**

Data signed: (hfarmer1) 30 Mar 2015 13:35:19

Generated On: 20 Jul 2016 22:28:45

Urine Start Day	30
<hr/>	
Urine End Day	31
<hr/>	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(5)**

Data signed: (hfarmer1) 30 Mar 2015 13:35:19

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112480000779
Analyte	THCOT
Sample type	URINE
Result	9340
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	30
Celerion Study Number	AA99128-06
Date of Collection	2014-MAY-04
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(5)**

Data signed: (hfarmer1) 30 Mar 2015 13:35:19

Generated On: 20 Jul 2016 22:28:45

Urine Start Day	30
<hr/>	
Urine End Day	31
<hr/>	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(6)**

Data signed: (hfarmer1) 30 Mar 2015 13:35:19

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112480000779
Analyte	THCOT-GLUC
Sample type	URINE
Result	6910
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	30
Celerion Study Number	AA99128-06
Date of Collection	2014-MAY-04
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(6)**

Data signed: (hfarmer1) 30 Mar 2015 13:35:19

Generated On: 20 Jul 2016 22:28:45

Urine Start Day	30
<hr/>	
Urine End Day	31
<hr/>	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

Form: Biomarker-Urine (3-OH BaP)

Data signed: (hfarmer1) 30 Mar 2015 13:35:20

Generated On: 20 Jul 2016 22:28:45

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

Form: Biomarker-Urine (3-OH BaP) (1)

Data signed: (hfarmer1) 30 Mar 2015 13:35:20

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112490001714
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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	OK
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Sample comment	ANALYSIS NOT PERFORMED IN ERROR
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Detection method	LC-MS/MS
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Planned time point (Hour)	0
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Day of Visit	30
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Celerion Study Number	AA99128-07
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Date of Collection	2014-MAY-04
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Timepoint-minutes	
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

Form: Biomarker-Urine (3-OH BaP) (1)

Data signed: (hfarmer1) 30 Mar 2015 13:35:20

Generated On: 20 Jul 2016 22:28:45

Urine Start Day	30
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Urine End Day	31
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP)

Data signed: (hfarmer1) 30 Mar 2015 13:35:20

Generated On: 20 Jul 2016 22:28:45

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (1)

Data signed: (hfarmer1) 30 Mar 2015 13:35:20

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112510001736
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Analyte	1-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	OK
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Sample comment	ANALYSIS NOT PERFORMED IN ERROR
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Detection method	LC-MS/MS
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Planned time point (Hour)	0
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Day of Visit	30
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Celerion Study Number	AA99128-09
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Date of Collection	2014-MAY-04
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Timepoint-minutes	
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (1)

Data signed: (hfarmer1) 30 Mar 2015 13:35:20

Generated On: 20 Jul 2016 22:28:45

Urine Start Day	30
<hr/>	
Urine End Day	31
<hr/>	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (2)

Data signed: (hfarmer1) 30 Mar 2015 13:35:20

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112510001736
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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	OK
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Sample comment	ANALYSIS NOT PERFORMED IN ERROR
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Detection method	LC-MS/MS
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Planned time point (Hour)	0
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Day of Visit	30
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Celerion Study Number	AA99128-09
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Date of Collection	2014-MAY-04
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Timepoint-minutes	
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (2)

Data signed: (hfarmer1) 30 Mar 2015 13:35:20

Generated On: 20 Jul 2016 22:28:45

Urine Start Day	30
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Urine End Day	31
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (3)

Data signed: (hfarmer1) 30 Mar 2015 13:35:20

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112510001736
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Analyte	4-ABP
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Sample type	URINE
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Result	.
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Result Unit	PG/ML
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Lab Status	OK
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Sample comment	ANALYSIS NOT PERFORMED IN ERROR
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Detection method	LC-MS/MS
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Planned time point (Hour)	0
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Day of Visit	30
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Celerion Study Number	AA99128-09
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Date of Collection	2014-MAY-04
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Timepoint-minutes	
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (3)

Data signed: (hfarmer1) 30 Mar 2015 13:35:20

Generated On: 20 Jul 2016 22:28:45

Urine Start Day	30
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Urine End Day	31
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (4)

Data signed: (hfarmer1) 30 Mar 2015 13:35:20

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112510001736
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Analyte	O-TOL
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Sample type	URINE
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Result	.
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Result Unit	PG/ML
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Lab Status	OK
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Sample comment	ANALYSIS NOT PERFORMED IN ERROR
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Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
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Day of Visit	30
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Celerion Study Number	AA99128-09
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Date of Collection	2014-MAY-04
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Timepoint-minutes	
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (4)

Data signed: (hfarmer1) 30 Mar 2015 13:35:20

Generated On: 20 Jul 2016 22:28:45

Urine Start Day	30
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Urine End Day	31
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

Form: Biomarker-Urine (11-dTXb2)

Data signed: (hfarmer1) 30 Mar 2015 13:35:19

Generated On: 20 Jul 2016 22:28:45

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

Form: Biomarker-Urine (11-dTXb2) (1)

Data signed: (hfarmer1) 30 Mar 2015 13:35:19

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112530000544
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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	OK
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Sample comment	ANALYSIS NOT PERFORMED IN ERROR
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Detection method	LC-MS/MS
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Planned time point (Hour)	0
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Day of Visit	30
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Celerion Study Number	AA99128-11
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Date of Collection	2014-MAY-04
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Timepoint-minutes	
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

Form: Biomarker-Urine (11-dTXb2) (1)

Data signed: (hfarmer1) 30 Mar 2015 13:35:19

Generated On: 20 Jul 2016 22:28:45

Urine Start Day	30
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Urine End Day	31
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

Form: Biomarker-Urine (iPF2a-III)

Data signed: (hfarmer1) 30 Mar 2015 13:35:19

Generated On: 20 Jul 2016 22:28:45

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

Form: Biomarker-Urine (iPF2a-III) (1)

Data signed: (hfarmer1) 30 Mar 2015 13:35:19

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112540000537
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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	OK
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Sample comment	ANALYSIS NOT PERFORMED IN ERROR
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Detection method	LC-MS/MS
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Planned time point (Hour)	0
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Day of Visit	30
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Celerion Study Number	AA99128-12
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Date of Collection	2014-MAY-04
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Timepoint-minutes	
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

Form: Biomarker-Urine (iPF2a-III) (1)

Data signed: (hfarmer1) 30 Mar 2015 13:35:19

Generated On: 20 Jul 2016 22:28:45

Urine Start Day	30
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Urine End Day	31
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

Form: Biomarker-Urine (1-OHP)

Data signed: (hfarmer1) 30 Mar 2015 13:35:21

Generated On: 20 Jul 2016 22:28:45

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

Form: Biomarker-Urine (1-OHP) (1)

Data signed: (hfarmer1) 30 Mar 2015 13:35:21

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05115190003738
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Analyte	1-OHP
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Sample type	URINE
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Result	.
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Result Unit	PG/ML
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Lab Status	OK
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Sample comment	NOT ANALYZED IN ERROR
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Detection method	LC-MS/MS
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Planned time point (Hour)	0
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Day of Visit	30
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Celerion Study Number	AA99598-03
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Date of Collection	2014-MAY-04
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Timepoint-minutes	
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Urine Start Day	30
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

Form: Biomarker-Urine (1-OHP) (1)

Data signed: (hfarmer1) 30 Mar 2015 13:35:21

Generated On: 20 Jul 2016 22:28:45

Urine End Day

31

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

Form: Biomarker-Urine (SPMA, SBMA)

Data signed: (hfarmer1) 30 Mar 2015 13:35:19

Generated On: 20 Jul 2016 22:28:45

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

Form: Biomarker-Urine (SPMA, SBMA) (1)

Data signed: (hfarmer1) 30 Mar 2015 13:35:19

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05115170003729
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Analyte	SPMA
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Sample type	URINE
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Result	.
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Result Unit	NG/ML
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Lab Status	OK
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Sample comment	NOT ANALYZED IN ERROR
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Detection method	LC-MS/MS
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Planned time point (Hour)	0
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Day of Visit	30
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Celerion Study Number	AA99598-01
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Date of Collection	2014-MAY-04
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Timepoint-minutes	
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Urine Start Day	30
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

Form: Biomarker-Urine (SPMA, SBMA) (1)

Data signed: (hfarmer1) 30 Mar 2015 13:35:19

Generated On: 20 Jul 2016 22:28:45

Urine End Day

31

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

Form: Biomarker-Urine (SPMA, SBMA) (2)

Data signed: (hfarmer1) 30 Mar 2015 13:35:19

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05115170003738
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Analyte	SBMA
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Sample type	URINE
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Result	.
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Result Unit	NG/ML
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Lab Status	OK
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Sample comment	NOT ANALYZED IN ERROR
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Detection method	LC-MS/MS
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Planned time point (Hour)	0
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Day of Visit	30
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Celerion Study Number	AA99598-01
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Date of Collection	2014-MAY-04
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Timepoint-minutes	
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Urine Start Day	30
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

Form: Biomarker-Urine (SPMA, SBMA) (2)

Data signed: (hfarmer1) 30 Mar 2015 13:35:19

Generated On: 20 Jul 2016 22:28:45

Urine End Day

31

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

Form: Biomarker-Urine (MHBMA)

Data signed: (hfarmer1) 30 Mar 2015 13:35:19

Generated On: 20 Jul 2016 22:28:45

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

Form: Biomarker-Urine (MHBMA) (1)

Data signed: (hfarmer1) 30 Mar 2015 13:35:19

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05115180003738
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Analyte	MHBMA
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Sample type	URINE
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Result	.
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Result Unit	NG/ML
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Lab Status	OK
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Sample comment	NOT ANALYZED IN ERROR
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Detection method	LC-MS/MS
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Planned time point (Hour)	0
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Day of Visit	30
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Celerion Study Number	AA99598-02
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Date of Collection	2014-MAY-04
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Timepoint-minutes	
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Urine Start Day	30
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

Form: Biomarker-Urine (MHBMA) (1)

Data signed: (hfarmer1) 30 Mar 2015 13:35:19

Generated On: 20 Jul 2016 22:28:45

Urine End Day

31

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

Form: Biomarker-Urine (Creatinine)

Data signed: (hfarmer1) 30 Mar 2015 13:35:20

Generated On: 20 Jul 2016 22:28:45

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

Form: Biomarker-Urine (Creatinine) (1)

Data signed: (hfarmer1) 30 Mar 2015 13:35:20

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05115160001714
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Analyte	CREATININE
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Sample type	URINE
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Result	.
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Result Unit	MG/DL
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Lab Status	OK
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Sample comment	ANALYSIS NOT PERFORMED IN ERROR
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Detection method	SPECTROPHOTOMETRIC
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Planned time point (Hour)	0
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Day of Visit	30
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Celerion Study Number	AA99128-14
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Date of Collection	2014-MAY-04
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Timepoint-minutes	
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

Form: Biomarker-Urine (Creatinine) (1)

Data signed: (hfarmer1) 30 Mar 2015 13:35:20

Generated On: 20 Jul 2016 22:28:45

Urine Start Day	30
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Urine End Day	31
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

Form: Biomarker-Plasma (Nic, Cot, tHCot)

Data signed: (hfarmer1) 30 Mar 2015 13:35:19

Generated On: 20 Jul 2016 22:28:45

Sample type

PLASMA

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

Form: Biomarker-Plasma (Nic, Cot, tHCot) (1)

Data signed: (hfarmer1) 30 Mar 2015 13:35:19

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112430001822
Analyte	COT
Sample type	PLASMA
Result	207
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	30
Celerion Study Number	AA99128-01
Date of Collection	2014-MAY-04
Timepoint-minutes	0
Urine Start Day	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

Form: Biomarker-Plasma (Nic, Cot, tHCot) (1)

Data signed: (hfarmer1) 30 Mar 2015 13:35:19

Generated On: 20 Jul 2016 22:28:45

Urine End Day

30

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

Form: Biomarker-Plasma (Nic, Cot, tHCot) (2)

Data signed: (hfarmer1) 30 Mar 2015 13:35:19

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112430001822
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Analyte	NIC
---------	-----

Sample type	PLASMA
-------------	--------

Result	5.72
--------	------

Result Unit	NG/ML
-------------	-------

Lab Status	OK
------------	----

Sample comment	ANALYZED IN ERROR
----------------	-------------------

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	30
--------------	----

Celerion Study Number	AA99128-01
-----------------------	------------

Date of Collection	2014-MAY-04
--------------------	-------------

Timepoint-minutes	0
-------------------	---

Urine Start Day	
-----------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 30

Form: Biomarker-Plasma (Nic, Cot, tHCot) (2)

Data signed: (hfarmer1) 30 Mar 2015 13:35:19

Generated On: 20 Jul 2016 22:28:45

Urine End Day

30

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

Form: Date of Visit

Data signed: (hfarmer1) 30 Mar 2015 13:35:23

Generated On: 20 Jul 2016 22:28:45

Visit Not Done	False
----------------	-------

If Not Done, Specify Reason	<hr/>
-----------------------------	-------

Date of Visit	03 JUN 2014 DD/MMM/YYYY
---------------	----------------------------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

Form: Vital Signs

Data signed: (hfarmer1) 30 Mar 2015 13:35:23

Generated On: 20 Jul 2016 22:28:45

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

03 JUN 2014
DD/MMM/YYYY

Time of assessment

14:55
hour:min 24-hour clock

Pulse rate

63
beats per minute

Respiratory rate

20
breaths per minute

Blood Pressure (systolic)

128
mmHg

Blood Pressure (diastolic)

81
mmHg

Vital Signs Position of Subject

Supine ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

Form: Advice on the risk of smoking and debriefing

Data signed: (hfarmer1) 30 Mar 2015 13:35:23

Generated On: 20 Jul 2016 22:28:45

Date	04 JUN 2014 DD/MMM/YYYY
------	----------------------------

Has the subject received advices on the risks of smoking?	Yes <input type="radio"/>
---	---------------------------

Has a debriefing been performed about THS 2.2?	Yes <input type="radio"/>
--	---------------------------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

Form: Physical Examination

Data signed: (hfarmer1) 30 Mar 2015 13:35:21

Generated On: 20 Jul 2016 22:28:45

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of Assessment

03 JUN 2014
DD/MMM/YYYY

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

Form: Physical Examination (1)

Data signed: (hfarmer1) 30 Mar 2015 13:35:21

Generated On: 20 Jul 2016 22:28:45

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of Assessment 03 JUN 2014
DD/MMM/YYYY

System General Appearance ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

Form: Physical Examination (2)

Data signed: (hfarmer1) 30 Mar 2015 13:35:21

Generated On: 20 Jul 2016 22:28:45

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of Assessment

03 JUN 2014
DD/MMM/YYYY

System

HEENT ☒
(head, eyes, ears, nose,
throat)

Outcome

Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done

False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

Form: Physical Examination (3)

Data signed: (hfarmer1) 30 Mar 2015 13:35:21

Generated On: 20 Jul 2016 22:28:45

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of Assessment 03 JUN 2014
DD/MMM/YYYY

System Thyroid Gland ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

Form: Physical Examination (4)

Data signed: (hfarmer1) 30 Mar 2015 13:35:21

Generated On: 20 Jul 2016 22:28:45

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of Assessment 03 JUN 2014
DD/MMM/YYYY

System Heart ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

Form: Physical Examination (5)

Data signed: (hfarmer1) 30 Mar 2015 13:35:21

Generated On: 20 Jul 2016 22:28:45

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of Assessment 03 JUN 2014
DD/MMM/YYYY

System Chest ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

Form: Physical Examination (6)

Data signed: (hfarmer1) 30 Mar 2015 13:35:21

Generated On: 20 Jul 2016 22:28:45

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of Assessment 03 JUN 2014
DD/MMM/YYYY

System Lungs ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

Form: Physical Examination (7)

Data signed: (hfarmer1) 30 Mar 2015 13:35:21

Generated On: 20 Jul 2016 22:28:45

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of Assessment 03 JUN 2014
DD/MMM/YYYY

System Gastrointestinal ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

Form: Physical Examination (8)

Data signed: (hfarmer1) 30 Mar 2015 13:35:21

Generated On: 20 Jul 2016 22:28:45

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of Assessment 03 JUN 2014
DD/MMM/YYYY

System Cardiovascular System ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

Form: Physical Examination (9)

Data signed: (hfarmer1) 30 Mar 2015 13:35:21

Generated On: 20 Jul 2016 22:28:45

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of Assessment 03 JUN 2014
DD/MMM/YYYY

System Neurologic ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

Form: Physical Examination (10)

Data signed: (hfarmer1) 30 Mar 2015 13:35:21

Generated On: 20 Jul 2016 22:28:45

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of Assessment 03 JUN 2014
DD/MMM/YYYY

System Skin ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

Form: Physical Examination (11)

Data signed: (hfarmer1) 30 Mar 2015 13:35:21

Generated On: 20 Jul 2016 22:28:45

Was the physical examination performed? Yes ☐

If No, please specify the reason: _____

Date of Assessment 03 JUN 2014
DD/MMM/YYYY

System Back ☐

Outcome Normal ☐

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

Form: Physical Examination (12)

Data signed: (hfarmer1) 30 Mar 2015 13:35:21

Generated On: 20 Jul 2016 22:28:45

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of Assessment 03 JUN 2014
DD/MMM/YYYY

System Musculoskeletal ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

Form: Physical Examination (13)

Data signed: (hfarmer1) 30 Mar 2015 13:35:21

Generated On: 20 Jul 2016 22:28:45

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of Assessment 03 JUN 2014
DD/MMM/YYYY

System Abdomen ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

Form: Physical Examination (14)

Data signed: (hfarmer1) 30 Mar 2015 13:35:21

Generated On: 20 Jul 2016 22:28:45

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of Assessment 03 JUN 2014
DD/MMM/YYYY

System Dentition ☒

Outcome Abnormal ☒

Abnormal, please specify MISSING AND DECAYED
TEETH

Clinically significant No ☒

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

Form: Physical Examination (15)

Data signed: (hfarmer1) 30 Mar 2015 13:35:21

Generated On: 20 Jul 2016 22:28:45

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of Assessment

03 JUN 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: 1252**

Folder: Day 60

Form: Physical Examination (16)

Data signed: (hfarmer1) 30 Mar 2015 13:35:21

Generated On: 20 Jul 2016 22:28:45

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of Assessment

03 JUN 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: 1252**

Folder: Day 60

Form: Physical Examination (17)

Data signed: (hfarmer1) 30 Mar 2015 13:35:21

Generated On: 20 Jul 2016 22:28:45

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of Assessment

03 JUN 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: 1252**

Folder: Day 60

Form: Physical Examination (18)

Data signed: (hfarmer1) 30 Mar 2015 13:35:21

Generated On: 20 Jul 2016 22:28:45

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of Assessment

03 JUN 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: 1252**

Folder: Day 60

Form: Physical Examination (19)

Data signed: (hfarmer1) 30 Mar 2015 13:35:21

Generated On: 20 Jul 2016 22:28:45

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of Assessment

03 JUN 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: 1252**

Folder: Day 60

Form: Weight

Data signed: (hfarmer1) 30 Mar 2015 13:35:23

Generated On: 20 Jul 2016 22:28:45

Measurement(s) assessed?

Yes ☒

If No, please specify the reason: _____

Date of Assessment

03 JUN 2014
DD/MMM/YYYY

Time of assessment

15:51
hour:min 24-hour clock

Weight

83.4
kg

BMI

26.8

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

Form: ECG (12-Lead Standard)

Data signed: (hfarmer1) 30 Mar 2015 13:35:21

Generated On: 20 Jul 2016 22:28:45

Was the ECG performed?

Yes ☒

If No, please specify the reason: _____

Date of Assessment

03 JUN 2014
DD/MMM/YYYY

Position

Supine ☒

Heart Rate

66
beats per minute

QRS Interval

90
msec

QT Interval

436
msec

QTcB Interval

459
msec

PR Interval

142
msec

QTcF Interval

451
msec

Interpretation

Normal ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

Form: ECG (12-Lead Standard)

Data signed: (hfarmer1) 30 Mar 2015 13:35:21

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Day 60

Form: Haematology

Data signed: (hfarmer1) 30 Mar 2015 13:35:21

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Day 60

Form: Clinical Chemistry

Data signed: (hfarmer1) 30 Mar 2015 13:35:21

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Day 60

Form: Urine analysis

Data signed: (hfarmer1) 30 Mar 2015 13:35:21

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Day 60

Form: Plasma Nicotine Sample

Data signed: (hfarmer1) 30 Mar 2015 13:35:21

Generated On: 20 Jul 2016 22:28:45

Not Done	False
----------	-------

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	03 JUN 2014
---------------------	-------------

Time hour:min 24-hour clock	10:18
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

Form: Plasma Cotinine Sample

Data signed: (hfarmer1) 30 Mar 2015 13:35:21

Generated On: 20 Jul 2016 22:28:45

Not Done	False
----------	-------

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	03 JUN 2014
---------------------	-------------

Time hour:min 24-hour clock	10:18
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

Form: CoHb Blood Sample <D30_D60>

Data signed: (hfarmer1) 30 Mar 2015 13:35:21

Generated On: 20 Jul 2016 22:28:45

Not Done	False
----------	-------

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	03 JUN 2014
---------------------	-------------

Timepoint	10:00 - 11:30 <input checked="" type="radio"/>
-----------	--

Time hour:min 24-hour clock	10:18
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

Form: CO Breath Test

Data signed: (hfarmer1) 30 Mar 2015 13:35:21

Generated On: 20 Jul 2016 22:28:45

Assessment not done	False
---------------------	-------

If Not Done, please specify the reason: _____

Actual Date of Assessment	03 JUN 2014 DD/MMM/YYYY
---------------------------	----------------------------

Actual Time of Assessment	10:21 hour:min 24-hour clock
---------------------------	---------------------------------

Result	21 ppm
--------	-----------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

Form: Risk markers: hs-CRP, fibrinogen, homocysteine, LDL, HDL, sICAM-1

Data signed: (hfarmer1) 30 Mar 2015 13:35:21

Generated On: 20 Jul 2016 22:28:45

Not Done	False
----------	-------

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	04 JUN 2014
---------------------	-------------

Time hour:min 24-hour clock	06:30
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

Form: 24 hour urine collections

Data signed: (hfarmer1) 30 Mar 2015 13:35:23

Generated On: 20 Jul 2016 22:28:45

Start Date	03 JUN 2014 DD/MMM/YYYY
------------	----------------------------

Start Time	09:14 hour:min 24-hour clock
------------	---------------------------------

End Date	04 JUN 2014 DD/MMM/YYYY
----------	----------------------------

End Time	09:03 hour:min 24-hour clock
----------	---------------------------------

Volume	1304 mL
--------	------------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

Form: Sample Urine Collection

Data signed: (hfarmer1) 30 Mar 2015 13:35:23

Generated On: 20 Jul 2016 22:28:45

Were samples for 24h collected?

Yes ☒

If No, please specify the reason: _____

How many primary tubes were collected?

13

How many back up tubes were collected?

13

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

Form: Lab_BU_CCLS (1)

Data signed: (hfarmer1) 30 Mar 2015 13:35:26

Generated On: 20 Jul 2016 22:28:45

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6) ☒

Visit Name _____

Visit Type Scheduled ☒

Accession ID X312798

Actual Collection Date 2014 06 04

Actual Collection Time 06:30

Specimen Condition _____

Battery ID RC1029

Battery Name TRIGLYCERIDES

Lab Test ID RCT19

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

Form: Lab_BU_CCLS (1)

Data signed: (hfarmer1) 30 Mar 2015 13:35:26

Generated On: 20 Jul 2016 22:28:45

Lab Test Name	TRIGLYCERIDES (GPO)
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	85
Reported Numeric Result	85
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: 1252**

Folder: Day 60

Form: Lab_BU_CCLS (1)

Data signed: (hfarmer1) 30 Mar 2015 13:35:26

Generated On: 20 Jul 2016 22:28:45

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

Form: Lab_BU_CCLS (2)

Data signed: (hfarmer1) 30 Mar 2015 13:35:26

Generated On: 20 Jul 2016 22:28:45

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6) ☒

Visit Name _____

Visit Type Scheduled ☒

Accession ID X312798

Actual Collection Date 2014 06 04

Actual Collection Time 06:30

Specimen Condition _____

Battery ID RC1092

Battery Name FASTING GLUCOSE

Lab Test ID RCT142

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

Form: Lab_BU_CCLS (2)

Data signed: (hfarmer1) 30 Mar 2015 13:35:26

Generated On: 20 Jul 2016 22:28:45

Lab Test Name	FASTING GLUCOSE
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	91
Reported Numeric Result	91
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: 1252**

Folder: Day 60

Form: Lab_BU_CCLS (2)

Data signed: (hfarmer1) 30 Mar 2015 13:35:26

Generated On: 20 Jul 2016 22:28:45

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

Form: Lab_BU_CCLS (3)

Data signed: (hfarmer1) 30 Mar 2015 13:35:26

Generated On: 20 Jul 2016 22:28:45

Transmission Type Cumulative ☐

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6)

Visit Name _____

Visit Type Scheduled ☐

Accession ID X312798

Actual Collection Date 2014 06 04

Actual Collection Time 06:30

Specimen Condition _____

Battery ID RC272

Battery Name TOTAL CHOLESTEROL

Lab Test ID RCT20

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

Form: Lab_BU_CCLS (3)

Data signed: (hfarmer1) 30 Mar 2015 13:35:26

Generated On: 20 Jul 2016 22:28:45

Lab Test Name	CHOLESTEROL (HIGH PERFORMANCE)
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	193
Reported Numeric Result	193
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: 1252**

Folder: Day 60

Form: Lab_BU_CCLS (3)

Data signed: (hfarmer1) 30 Mar 2015 13:35:26

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Day 60

Form: Lab_BU_CCLS (4)

Data signed: (hfarmer1) 30 Mar 2015 13:35:26

Generated On: 20 Jul 2016 22:28:45

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	X312798
--------------	---------

Actual Collection Date	2014 06 04
------------------------	------------

Actual Collection Time	06:30
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	RC9255
------------	--------

Battery Name	CHEMISTRY PANEL
--------------	-----------------

Lab Test ID	RCT1
-------------	------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

Form: Lab_BU_CCLS (4)

Data signed: (hfarmer1) 30 Mar 2015 13:35:26

Generated On: 20 Jul 2016 22:28:45

Lab Test Name	TOTAL BILIRUBIN
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	0.9
Reported Numeric Result	0.9
Reference Range low	0.2
Reference Range high	1.2
Range Units	MG/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

Form: Lab_BU_CCLS (4)

Data signed: (hfarmer1) 30 Mar 2015 13:35:26

Generated On: 20 Jul 2016 22:28:45

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

Form: Lab_BU_CCLS (5)

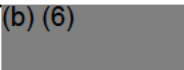
Data signed: (hfarmer1) 30 Mar 2015 13:35:26

Generated On: 20 Jul 2016 22:28:45

Transmission Type Cumulative ☒

Subject ID or Number

Subject Sex M

Subject Date of Birth (b) (6) 

Visit Name

Visit Type Scheduled ☒

Accession ID X312798

Actual Collection Date 2014 06 04

Actual Collection Time 06:30

Specimen Condition

Battery ID RC9255

Battery Name CHEMISTRY PANEL

Lab Test ID RCT12

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

Form: Lab_BU_CCLS (5)

Data signed: (hfarmer1) 30 Mar 2015 13:35:26

Generated On: 20 Jul 2016 22:28:45

Lab Test Name	TOTAL PROTEIN
Test ID	
Test Status	Done <input type="checkbox"/>
Reported Text Result	7.0
Reported Numeric Result	7.0
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: 1252**

Folder: Day 60

Form: Lab_BU_CCLS (5)

Data signed: (hfarmer1) 30 Mar 2015 13:35:26

Generated On: 20 Jul 2016 22:28:45

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

Form: Lab_BU_CCLS (6)

Data signed: (hfarmer1) 30 Mar 2015 13:35:26

Generated On: 20 Jul 2016 22:28:45

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6) 

Visit Name _____

Visit Type Scheduled ☒

Accession ID X312798

Actual Collection Date 2014 06 04

Actual Collection Time 06:30

Specimen Condition _____

Battery ID RC9255

Battery Name CHEMISTRY PANEL

Lab Test ID RCT13

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

Form: Lab_BU_CCLS (6)

Data signed: (hfarmer1) 30 Mar 2015 13:35:26

Generated On: 20 Jul 2016 22:28:45

Lab Test Name	ALBUMIN
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	4.3
Reported Numeric Result	4.3
Reference Range low	3.3
Reference Range high	4.9
Range Units	G/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

Form: Lab_BU_CCLS (6)

Data signed: (hfarmer1) 30 Mar 2015 13:35:26

Generated On: 20 Jul 2016 22:28:45

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

Form: Lab_BU_CCLS (7)

Data signed: (hfarmer1) 30 Mar 2015 13:35:26

Generated On: 20 Jul 2016 22:28:45

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6)

Visit Name _____

Visit Type Scheduled ☒

Accession ID X312798

Actual Collection Date 2014 06 04

Actual Collection Time 06:30

Specimen Condition _____

Battery ID RC9255

Battery Name CHEMISTRY PANEL

Lab Test ID RCT1407

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

Form: Lab_BU_CCLS (7)

Data signed: (hfarmer1) 30 Mar 2015 13:35:26

Generated On: 20 Jul 2016 22:28:45

Lab Test Name	ALKALINE PHOSPHATASE
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	58
Reported Numeric Result	58
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: 1252**

Folder: Day 60

Form: Lab_BU_CCLS (7)

Data signed: (hfarmer1) 30 Mar 2015 13:35:26

Generated On: 20 Jul 2016 22:28:45

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

Form: Lab_BU_CCLS (8)

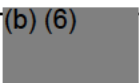
Data signed: (hfarmer1) 30 Mar 2015 13:35:26

Generated On: 20 Jul 2016 22:28:45

Transmission Type Cumulative ☒

Subject ID or Number

Subject Sex M

Subject Date of Birth (b) (6) 

Visit Name

Visit Type Scheduled ☒

Accession ID X312798

Actual Collection Date 2014 06 04

Actual Collection Time 06:30

Specimen Condition

Battery ID RC9255

Battery Name CHEMISTRY PANEL

Lab Test ID RCT1408

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

Form: Lab_BU_CCLS (8)

Data signed: (hfarmer1) 30 Mar 2015 13:35:26

Generated On: 20 Jul 2016 22:28:45

Lab Test Name	LDH
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	253
Reported Numeric Result	253
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: 1252**

Folder: Day 60

Form: Lab_BU_CCLS (8)

Data signed: (hfarmer1) 30 Mar 2015 13:35:26

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Day 60

Form: Lab_BU_CCLS (9)

Data signed: (hfarmer1) 30 Mar 2015 13:35:26

Generated On: 20 Jul 2016 22:28:45

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	X312798
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Actual Collection Date	2014 06 04
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Actual Collection Time	06:30
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Specimen Condition	<hr/>
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Battery ID	RC9255
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Battery Name	CHEMISTRY PANEL
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Lab Test ID	RCT15
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

Form: Lab_BU_CCLS (9)

Data signed: (hfarmer1) 30 Mar 2015 13:35:26

Generated On: 20 Jul 2016 22:28:45

Lab Test Name	SERUM SODIUM
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	139
Reported Numeric Result	139
Reference Range low	132
Reference Range high	147
Range Units	MEQ/L
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

Form: Lab_BU_CCLS (9)

Data signed: (hfarmer1) 30 Mar 2015 13:35:26

Generated On: 20 Jul 2016 22:28:45

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

Form: Lab_BU_CCLS (10)

Data signed: (hfarmer1) 30 Mar 2015 13:35:26

Generated On: 20 Jul 2016 22:28:45

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6) 

Visit Name _____

Visit Type Scheduled ☒

Accession ID X312798

Actual Collection Date 2014 06 04

Actual Collection Time 06:30

Specimen Condition _____

Battery ID RC9255

Battery Name CHEMISTRY PANEL

Lab Test ID RCT16

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Day 60

Form: Lab_BU_CCLS (10)

Data signed: (hfarmer1) 30 Mar 2015 13:35:26

Generated On: 20 Jul 2016 22:28:45

Lab Test Name	SERUM POTASSIUM
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	4.2
Reported Numeric Result	4.2
Reference Range low	3.4
Reference Range high	5.4
Range Units	MEQ/L
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

Form: Lab_BU_CCLS (10)

Data signed: (hfarmer1) 30 Mar 2015 13:35:26

Generated On: 20 Jul 2016 22:28:45

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

Form: Lab_BU_CCLS (11)


Data signed: (hfarmer1) 30 Mar 2015 13:35:26

Generated On: 20 Jul 2016 22:28:45

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6) 

Visit Name _____

Visit Type Scheduled ☒

Accession ID X312798

Actual Collection Date 2014 06 04

Actual Collection Time 06:30

Specimen Condition _____

Battery ID RC9255

Battery Name CHEMISTRY PANEL

Lab Test ID RCT29

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

Form: Lab_BU_CCLS (11)

Data signed: (hfarmer1) 30 Mar 2015 13:35:26

Generated On: 20 Jul 2016 22:28:45

Lab Test Name	DIRECT BILIRUBIN
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	0.2
Reported Numeric Result	0.2
Reference Range low	0.0
Reference Range high	0.4
Range Units	MG/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

Form: Lab_BU_CCLS (11)

Data signed: (hfarmer1) 30 Mar 2015 13:35:26

Generated On: 20 Jul 2016 22:28:45

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

Form: Lab_BU_CCLS (12)

Data signed: (hfarmer1) 30 Mar 2015 13:35:26

Generated On: 20 Jul 2016 22:28:45

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6) 

Visit Name _____

Visit Type Scheduled ☒

Accession ID X312798

Actual Collection Date 2014 06 04

Actual Collection Time 06:30

Specimen Condition _____

Battery ID RC9255

Battery Name CHEMISTRY PANEL

Lab Test ID RCT3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

Form: Lab_BU_CCLS (12)

Data signed: (hfarmer1) 30 Mar 2015 13:35:26

Generated On: 20 Jul 2016 22:28:45

Lab Test Name	GGT
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	50
Reported Numeric Result	50
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: 1252**

Folder: Day 60

Form: Lab_BU_CCLS (12)

Data signed: (hfarmer1) 30 Mar 2015 13:35:26

Generated On: 20 Jul 2016 22:28:45

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

Form: Lab_BU_CCLS (13)

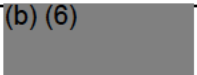
Data signed: (hfarmer1) 30 Mar 2015 13:35:26

Generated On: 20 Jul 2016 22:28:45

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6) 

Visit Name _____

Visit Type Scheduled ☒

Accession ID X312798

Actual Collection Date 2014 06 04

Actual Collection Time 06:30

Specimen Condition _____

Battery ID RC9255

Battery Name CHEMISTRY PANEL

Lab Test ID RCT392

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

Form: Lab_BU_CCLS (13)

Data signed: (hfarmer1) 30 Mar 2015 13:35:26

Generated On: 20 Jul 2016 22:28:45

Lab Test Name	CREATININE (RATE BLANKED)
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Test ID	<hr/>
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Test Status	Done <input checked="" type="radio"/>
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Reported Text Result	0.9
----------------------	-----

Reported Numeric Result	0.9
-------------------------	-----

Reference Range low	0.5
---------------------	-----

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: 1252**

Folder: Day 60

Form: Lab_BU_CCLS (13)

Data signed: (hfarmer1) 30 Mar 2015 13:35:26

Generated On: 20 Jul 2016 22:28:45

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

Form: Lab_BU_CCLS (14)

Data signed: (hfarmer1) 30 Mar 2015 13:35:26

Generated On: 20 Jul 2016 22:28:45

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6) ☒

Visit Name _____

Visit Type Scheduled ☒

Accession ID X312798

Actual Collection Date 2014 06 04

Actual Collection Time 06:30

Specimen Condition _____

Battery ID RC9255

Battery Name CHEMISTRY PANEL

Lab Test ID RCT4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

Form: Lab_BU_CCLS (14)

Data signed: (hfarmer1) 30 Mar 2015 13:35:26

Generated On: 20 Jul 2016 22:28:45

Lab Test Name	ALT (SGPT)
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	97
Reported Numeric Result	97
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: 1252**

Folder: Day 60

Form: Lab_BU_CCLS (14)

Data signed: (hfarmer1) 30 Mar 2015 13:35:26

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Day 60

Form: Lab_BU_CCLS (15)

Data signed: (hfarmer1) 30 Mar 2015 13:35:26

Generated On: 20 Jul 2016 22:28:45

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6) 

Visit Name _____

Visit Type Scheduled ☒

Accession ID X312798

Actual Collection Date 2014 06 04

Actual Collection Time 06:30

Specimen Condition _____

Battery ID RC9255

Battery Name CHEMISTRY PANEL

Lab Test ID RCT5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

Form: Lab_BU_CCLS (15)

Data signed: (hfarmer1) 30 Mar 2015 13:35:26

Generated On: 20 Jul 2016 22:28:45

Lab Test Name	AST (SGOT)
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	97
Reported Numeric Result	97
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: 1252**

Folder: Day 60

Form: Lab_BU_CCLS (15)

Data signed: (hfarmer1) 30 Mar 2015 13:35:26

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Day 60

Form: Lab_BU_CCLS (16)

Data signed: (hfarmer1) 30 Mar 2015 13:35:26

Generated On: 20 Jul 2016 22:28:45

Transmission Type Cumulative ☐

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6) 

Visit Name _____

Visit Type Scheduled ☐

Accession ID X312798

Actual Collection Date 2014 06 04

Actual Collection Time 06:30

Specimen Condition _____

Battery ID RC9255

Battery Name CHEMISTRY PANEL

Lab Test ID RCT6

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

Form: Lab_BU_CCLS (16)

Data signed: (hfarmer1) 30 Mar 2015 13:35:26

Generated On: 20 Jul 2016 22:28:45

Lab Test Name	UREA NITROGEN
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	12
Reported Numeric Result	12
Reference Range low	4
Reference Range high	24
Range Units	MG/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

Form: Lab_BU_CCLS (16)

Data signed: (hfarmer1) 30 Mar 2015 13:35:26

Generated On: 20 Jul 2016 22:28:45

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

Form: Lab_BU_CCLS (17)

Data signed: (hfarmer1) 30 Mar 2015 13:35:26

Generated On: 20 Jul 2016 22:28:45

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6) 

Visit Name _____

Visit Type Scheduled ☒

Accession ID X312798

Actual Collection Date 2014 06 04

Actual Collection Time 06:30

Specimen Condition _____

Battery ID HM1604

Battery Name HEMATOLOGY
&DIFFERENTIAL PANEL

Lab Test ID HMT10

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

Form: Lab_BU_CCLS (17)

Data signed: (hfarmer1) 30 Mar 2015 13:35:26

Generated On: 20 Jul 2016 22:28:45

Lab Test Name	MONOCYTES
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	0.25
Reported Numeric Result	0.25
Reference Range low	0.12
Reference Range high	0.92
Range Units	X10^3/UL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

Form: Lab_BU_CCLS (17)

Data signed: (hfarmer1) 30 Mar 2015 13:35:26

Generated On: 20 Jul 2016 22:28:45

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

Form: Lab_BU_CCLS (18)

Data signed: (hfarmer1) 30 Mar 2015 13:35:26

Generated On: 20 Jul 2016 22:28:45

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	X312798
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Actual Collection Date	2014 06 04
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Actual Collection Time	06:30
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Specimen Condition	<hr/>
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Battery ID	HM1604
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Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
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Lab Test ID	HMT100
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

Form: Lab_BU_CCLS (18)

Data signed: (hfarmer1) 30 Mar 2015 13:35:26

Generated On: 20 Jul 2016 22:28:45

Lab Test Name	MCH
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	34
Reported Numeric Result	34
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: 1252**

Folder: Day 60

Form: Lab_BU_CCLS (18)

Data signed: (hfarmer1) 30 Mar 2015 13:35:26

Generated On: 20 Jul 2016 22:28:45

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

Form: Lab_BU_CCLS (19)

Data signed: (hfarmer1) 30 Mar 2015 13:35:26

Generated On: 20 Jul 2016 22:28:45

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	X312798
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Actual Collection Date	2014 06 04
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Actual Collection Time	06:30
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Specimen Condition	<hr/>
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Battery ID	HM1604
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Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
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Lab Test ID	HMT102
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

Form: Lab_BU_CCLS (19)

Data signed: (hfarmer1) 30 Mar 2015 13:35:26

Generated On: 20 Jul 2016 22:28:45

Lab Test Name	MCHC
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	33
Reported Numeric Result	33
Reference Range low	31
Reference Range high	38
Range Units	G/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

Form: Lab_BU_CCLS (19)

Data signed: (hfarmer1) 30 Mar 2015 13:35:26

Generated On: 20 Jul 2016 22:28:45

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

Form: Lab_BU_CCLS (20)

Data signed: (hfarmer1) 30 Mar 2015 13:35:26

Generated On: 20 Jul 2016 22:28:45

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	X312798
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Actual Collection Date	2014 06 04
------------------------	------------

Actual Collection Time	06:30
------------------------	-------

Specimen Condition	<hr/>
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Battery ID	HM1604
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Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
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Lab Test ID	HMT11
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

Form: Lab_BU_CCLS (20)

Data signed: (hfarmer1) 30 Mar 2015 13:35:26

Generated On: 20 Jul 2016 22:28:45

Lab Test Name	EOSINOPHILS
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	0.10
Reported Numeric Result	0.10
Reference Range low	0.00
Reference Range high	0.57
Range Units	X10^3/UL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

Form: Lab_BU_CCLS (20)

Data signed: (hfarmer1) 30 Mar 2015 13:35:26

Generated On: 20 Jul 2016 22:28:45

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

Form: Lab_BU_CCLS (21)

Data signed: (hfarmer1) 30 Mar 2015 13:35:26

Generated On: 20 Jul 2016 22:28:45

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	X312798
--------------	---------

Actual Collection Date	2014 06 04
------------------------	------------

Actual Collection Time	06:30
------------------------	-------

Specimen Condition	<hr/>
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Battery ID	HM1604
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Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
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Lab Test ID	HMT12
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

Form: Lab_BU_CCLS (21)

Data signed: (hfarmer1) 30 Mar 2015 13:35:26

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Day 60

Form: Lab_BU_CCLS (21)

Data signed: (hfarmer1) 30 Mar 2015 13:35:26

Generated On: 20 Jul 2016 22:28:45

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

Form: Lab_BU_CCLS (22)

Data signed: (hfarmer1) 30 Mar 2015 13:35:26

Generated On: 20 Jul 2016 22:28:45

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	X312798
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Actual Collection Date	2014 06 04
------------------------	------------

Actual Collection Time	06:30
------------------------	-------

Specimen Condition	<hr/>
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Battery ID	HM1604
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Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
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Lab Test ID	HMT13
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

Form: Lab_BU_CCLS (22)

Data signed: (hfarmer1) 30 Mar 2015 13:35:26

Generated On: 20 Jul 2016 22:28:45

Lab Test Name	PLATELETS
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	237
Reported Numeric Result	237
Reference Range low	140
Reference Range high	400
Range Units	X10^3/UL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

Form: Lab_BU_CCLS (22)

Data signed: (hfarmer1) 30 Mar 2015 13:35:26

Generated On: 20 Jul 2016 22:28:45

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

Form: Lab_BU_CCLS (23)

Data signed: (hfarmer1) 30 Mar 2015 13:35:26

Generated On: 20 Jul 2016 22:28:45

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	X312798
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Actual Collection Date	2014 06 04
------------------------	------------

Actual Collection Time	06:30
------------------------	-------

Specimen Condition	<hr/>
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Battery ID	HM1604
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Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
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Lab Test ID	HMT15
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Day 60

Form: Lab_BU_CCLS (23)

Data signed: (hfarmer1) 30 Mar 2015 13:35:26

Generated On: 20 Jul 2016 22:28:45

Lab Test Name	NEUTROPHILS (%)
Test ID	
Test Status	Done <input checked="" type="checkbox"/>
Reported Text Result	68.0
Reported Numeric Result	68.0
Reference Range low	40.5
Reference Range high	75.0
Range Units	%
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

Form: Lab_BU_CCLS (23)

Data signed: (hfarmer1) 30 Mar 2015 13:35:26

Generated On: 20 Jul 2016 22:28:45

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

Form: Lab_BU_CCLS (24)

Data signed: (hfarmer1) 30 Mar 2015 13:35:26

Generated On: 20 Jul 2016 22:28:45

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	X312798
--------------	---------

Actual Collection Date	2014 06 04
------------------------	------------

Actual Collection Time	06:30
------------------------	-------

Specimen Condition	<hr/>
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Battery ID	HM1604
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Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
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Lab Test ID	HMT16
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

Form: Lab_BU_CCLS (24)

Data signed: (hfarmer1) 30 Mar 2015 13:35:26

Generated On: 20 Jul 2016 22:28:45

Lab Test Name	LYMPHOCYTES (%)
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	22.4
Reported Numeric Result	22.4
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: 1252**

Folder: Day 60

Form: Lab_BU_CCLS (24)

Data signed: (hfarmer1) 30 Mar 2015 13:35:26

Generated On: 20 Jul 2016 22:28:45

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

Form: Lab_BU_CCLS (25)

Data signed: (hfarmer1) 30 Mar 2015 13:35:26

Generated On: 20 Jul 2016 22:28:45

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	X312798
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Actual Collection Date	2014 06 04
------------------------	------------

Actual Collection Time	06:30
------------------------	-------

Specimen Condition	<hr/>
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Battery ID	HM1604
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Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
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Lab Test ID	HMT17
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

Form: Lab_BU_CCLS (25)

Data signed: (hfarmer1) 30 Mar 2015 13:35:26

Generated On: 20 Jul 2016 22:28:45

Lab Test Name	MONOCYTES (%)
Test ID	
Test Status	Done <input checked="" type="checkbox"/>
Reported Text Result	6.1
Reported Numeric Result	6.1
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: 1252**

Folder: Day 60

Form: Lab_BU_CCLS (25)

Data signed: (hfarmer1) 30 Mar 2015 13:35:26

Generated On: 20 Jul 2016 22:28:45

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

Form: Lab_BU_CCLS (26)

Data signed: (hfarmer1) 30 Mar 2015 13:35:26

Generated On: 20 Jul 2016 22:28:45

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	X312798
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Actual Collection Date	2014 06 04
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Actual Collection Time	06:30
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Specimen Condition	<hr/>
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Battery ID	HM1604
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Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
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Lab Test ID	HMT18
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

Form: Lab_BU_CCLS (26)

Data signed: (hfarmer1) 30 Mar 2015 13:35:26

Generated On: 20 Jul 2016 22:28:45

Lab Test Name	EOSINOPHILS (%)
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	2.5
Reported Numeric Result	2.5
Reference Range low	0.0
Reference Range high	6.8
Range Units	%
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

Form: Lab_BU_CCLS (26)

Data signed: (hfarmer1) 30 Mar 2015 13:35:26

Generated On: 20 Jul 2016 22:28:45

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

Form: Lab_BU_CCLS (27)

Data signed: (hfarmer1) 30 Mar 2015 13:35:26

Generated On: 20 Jul 2016 22:28:45

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	X312798
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Actual Collection Date	2014 06 04
------------------------	------------

Actual Collection Time	06:30
------------------------	-------

Specimen Condition	<hr/>
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Battery ID	HM1604
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Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
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Lab Test ID	HMT19
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

Form: Lab_BU_CCLS (27)

Data signed: (hfarmer1) 30 Mar 2015 13:35:26

Generated On: 20 Jul 2016 22:28:45

Lab Test Name	BASOPHILS (%)
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	1.0
Reported Numeric Result	1.0
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: 1252**

Folder: Day 60

Form: Lab_BU_CCLS (27)

Data signed: (hfarmer1) 30 Mar 2015 13:35:26

Generated On: 20 Jul 2016 22:28:45

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

Form: Lab_BU_CCLS (28)

Data signed: (hfarmer1) 30 Mar 2015 13:35:26

Generated On: 20 Jul 2016 22:28:45

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	X312798
--------------	---------

Actual Collection Date	2014 06 04
------------------------	------------

Actual Collection Time	06:30
------------------------	-------

Specimen Condition	<hr/>
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Battery ID	HM1604
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Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
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Lab Test ID	HMT2
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

Form: Lab_BU_CCLS (28)

Data signed: (hfarmer1) 30 Mar 2015 13:35:26

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Day 60

Form: Lab_BU_CCLS (28)

Data signed: (hfarmer1) 30 Mar 2015 13:35:26

Generated On: 20 Jul 2016 22:28:45

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

Form: Lab_BU_CCLS (29)

Data signed: (hfarmer1) 30 Mar 2015 13:35:26

Generated On: 20 Jul 2016 22:28:45

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	X312798
--------------	---------

Actual Collection Date	2014 06 04
------------------------	------------

Actual Collection Time	06:30
------------------------	-------

Specimen Condition	<hr/>
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Battery ID	HM1604
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Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
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Lab Test ID	HMT3
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

Form: Lab_BU_CCLS (29)

Data signed: (hfarmer1) 30 Mar 2015 13:35:26

Generated On: 20 Jul 2016 22:28:45

Lab Test Name	RBC
Test ID	
Test Status	Done <input checked="" type="checkbox"/>
Reported Text Result	4.6
Reported Numeric Result	4.6
Reference Range low	4.5
Reference Range high	6.4
Range Units	X10^6/UL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

Form: Lab_BU_CCLS (29)

Data signed: (hfarmer1) 30 Mar 2015 13:35:26

Generated On: 20 Jul 2016 22:28:45

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

Form: Lab_BU_CCLS (30)

Data signed: (hfarmer1) 30 Mar 2015 13:35:26

Generated On: 20 Jul 2016 22:28:45

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	X312798
--------------	---------

Actual Collection Date	2014 06 04
------------------------	------------

Actual Collection Time	06:30
------------------------	-------

Specimen Condition	<hr/>
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Battery ID	HM1604
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Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
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Lab Test ID	HMT4
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

Form: Lab_BU_CCLS (30)

Data signed: (hfarmer1) 30 Mar 2015 13:35:26

Generated On: 20 Jul 2016 22:28:45

Lab Test Name	MCV
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	103
Reported Numeric Result	103
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: 1252**

Folder: Day 60

Form: Lab_BU_CCLS (30)

Data signed: (hfarmer1) 30 Mar 2015 13:35:26

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Day 60

Form: Lab_BU_CCLS (31)

Data signed: (hfarmer1) 30 Mar 2015 13:35:26

Generated On: 20 Jul 2016 22:28:45

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	X312798
--------------	---------

Actual Collection Date	2014 06 04
------------------------	------------

Actual Collection Time	06:30
------------------------	-------

Specimen Condition	<hr/>
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Battery ID	HM1604
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Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
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Lab Test ID	HMT40
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

Form: Lab_BU_CCLS (31)

Data signed: (hfarmer1) 30 Mar 2015 13:35:26

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Day 60

Form: Lab_BU_CCLS (31)

Data signed: (hfarmer1) 30 Mar 2015 13:35:26

Generated On: 20 Jul 2016 22:28:45

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

Form: Lab_BU_CCLS (32)

Data signed: (hfarmer1) 30 Mar 2015 13:35:26

Generated On: 20 Jul 2016 22:28:45

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	X312798
--------------	---------

Actual Collection Date	2014 06 04
------------------------	------------

Actual Collection Time	06:30
------------------------	-------

Specimen Condition	<hr/>
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Battery ID	HM1604
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Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
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Lab Test ID	HMT7
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

Form: Lab_BU_CCLS (32)

Data signed: (hfarmer1) 30 Mar 2015 13:35:26

Generated On: 20 Jul 2016 22:28:45

Lab Test Name	WBC
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	4.11
Reported Numeric Result	4.11
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: 1252**

Folder: Day 60

Form: Lab_BU_CCLS (32)

Data signed: (hfarmer1) 30 Mar 2015 13:35:26

Generated On: 20 Jul 2016 22:28:45

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

Form: Lab_BU_CCLS (33)

Data signed: (hfarmer1) 30 Mar 2015 13:35:26

Generated On: 20 Jul 2016 22:28:45

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	X312798
--------------	---------

Actual Collection Date	2014 06 04
------------------------	------------

Actual Collection Time	06:30
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	HM1604
------------	--------

Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
--------------	-----------------------------------

Lab Test ID	HMT71
-------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

Form: Lab_BU_CCLS (33)

Data signed: (hfarmer1) 30 Mar 2015 13:35:26


Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Day 60

Form: Lab_BU_CCLS (33)

Data signed: (hfarmer1) 30 Mar 2015 13:35:26

Generated On: 20 Jul 2016 22:28:45

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

Form: Lab_BU_CCLS (34)

Data signed: (hfarmer1) 30 Mar 2015 13:35:26

Generated On: 20 Jul 2016 22:28:45

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	X312798
--------------	---------

Actual Collection Date	2014 06 04
------------------------	------------

Actual Collection Time	06:30
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	HM1604
------------	--------

Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
--------------	-----------------------------------

Lab Test ID	HMT8
-------------	------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

Form: Lab_BU_CCLS (34)

Data signed: (hfarmer1) 30 Mar 2015 13:35:26

Generated On: 20 Jul 2016 22:28:45

Lab Test Name	NEUTROPHILS
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	2.79
Reported Numeric Result	2.79
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: 1252**

Folder: Day 60

Form: Lab_BU_CCLS (34)

Data signed: (hfarmer1) 30 Mar 2015 13:35:26

Generated On: 20 Jul 2016 22:28:45

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

Form: Lab_BU_CCLS (35)

Data signed: (hfarmer1) 30 Mar 2015 13:35:26

Generated On: 20 Jul 2016 22:28:45

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	X312798
--------------	---------

Actual Collection Date	2014 06 04
------------------------	------------

Actual Collection Time	06:30
------------------------	-------

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: 1252**

Folder: Day 60

Form: Lab_BU_CCLS (35)

Data signed: (hfarmer1) 30 Mar 2015 13:35:26

Generated On: 20 Jul 2016 22:28:45

Lab Test Name	LYMPHOCYTES
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	0.92
Reported Numeric Result	0.92
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: 1252**

Folder: Day 60

Form: Lab_BU_CCLS (35)

Data signed: (hfarmer1) 30 Mar 2015 13:35:26

Generated On: 20 Jul 2016 22:28:45

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

Form: Lab_BU_CCLS (36)

Data signed: (hfarmer1) 30 Mar 2015 13:35:26

Generated On: 20 Jul 2016 22:28:45

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	X312798
--------------	---------

Actual Collection Date	2014 06 04
------------------------	------------

Actual Collection Time	06:30
------------------------	-------

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: 1252**

Folder: Day 60

Form: Lab_BU_CCLS (36)

Data signed: (hfarmer1) 30 Mar 2015 13:35:26


Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Day 60

Form: Lab_BU_CCLS (36)

Data signed: (hfarmer1) 30 Mar 2015 13:35:26

Generated On: 20 Jul 2016 22:28:45

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

Form: Lab_BU_CCLS (37)

Data signed: (hfarmer1) 30 Mar 2015 13:35:26

Generated On: 20 Jul 2016 22:28:45

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	X312798
--------------	---------

Actual Collection Date	2014 06 04
------------------------	------------

Actual Collection Time	06:30
------------------------	-------

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: 1252**

Folder: Day 60

Form: Lab_BU_CCLS (37)

Data signed: (hfarmer1) 30 Mar 2015 13:35:26

Generated On: 20 Jul 2016 22:28:45

Lab Test Name	UR SPECIFIC GRAVITY
Test ID	
Test Status	Done <input type="checkbox"/>
Reported Text Result	1.023
Reported Numeric Result	1.023
Reference Range low	1.003
Reference Range high	1.035
Range Units	
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

Form: Lab_BU_CCLS (37)

Data signed: (hfarmer1) 30 Mar 2015 13:35:26

Generated On: 20 Jul 2016 22:28:45

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

Form: Lab_BU_CCLS (38)

Data signed: (hfarmer1) 30 Mar 2015 13:35:26

Generated On: 20 Jul 2016 22:28:45

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	X312798
--------------	---------

Actual Collection Date	2014 06 04
------------------------	------------

Actual Collection Time	06:30
------------------------	-------

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: 1252**

Folder: Day 60

Form: Lab_BU_CCLS (38)

Data signed: (hfarmer1) 30 Mar 2015 13:35:26

Generated On: 20 Jul 2016 22:28:45

Lab Test Name	UR PH
Test ID	
Test Status	Done <input type="checkbox"/>
Reported Text Result	6.0
Reported Numeric Result	6.0
Reference Range low	5.0
Reference Range high	8.0
Range Units	
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

Form: Lab_BU_CCLS (38)

Data signed: (hfarmer1) 30 Mar 2015 13:35:26

Generated On: 20 Jul 2016 22:28:45

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

Form: Lab_BU_CCLS (39)

Data signed: (hfarmer1) 30 Mar 2015 13:35:26

Generated On: 20 Jul 2016 22:28:45

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	X312798
--------------	---------

Actual Collection Date	2014 06 04
------------------------	------------

Actual Collection Time	06:30
------------------------	-------

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: 1252**

Folder: Day 60

Form: Lab_BU_CCLS (39)

Data signed: (hfarmer1) 30 Mar 2015 13:35:26


Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Day 60

Form: Lab_BU_CCLS (39)

Data signed: (hfarmer1) 30 Mar 2015 13:35:26

Generated On: 20 Jul 2016 22:28:45

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

Form: Lab_BU_CCLS (40)

Data signed: (hfarmer1) 30 Mar 2015 13:35:26

Generated On: 20 Jul 2016 22:28:45

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	X312798
--------------	---------

Actual Collection Date	2014 06 04
------------------------	------------

Actual Collection Time	06:30
------------------------	-------

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: 1252**

Folder: Day 60

Form: Lab_BU_CCLS (40)

Data signed: (hfarmer1) 30 Mar 2015 13:35:26


Generated On: 20 Jul 2016 22:28:45

Lab Test Name

UR PROTEIN

Test ID

Test Status

Done 

Reported Text Result

TRACE

Reported Numeric Result

Reference Range low

Reference Range high

Range Units

Conventional Text Result

Conventional Numeric Result

Conventional Reference Range Low

Conventional Reference Range High

Conventional Units

SI Text Result

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

Form: Lab_BU_CCLS (40)

Data signed: (hfarmer1) 30 Mar 2015 13:35:26

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Day 60

Form: Lab_BU_CCLS (41)

Data signed: (hfarmer1) 30 Mar 2015 13:35:26

Generated On: 20 Jul 2016 22:28:45

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	X312798
--------------	---------

Actual Collection Date	2014 06 04
------------------------	------------

Actual Collection Time	06:30
------------------------	-------

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: 1252**

Folder: Day 60

Form: Lab_BU_CCLS (41)

Data signed: (hfarmer1) 30 Mar 2015 13:35:26


Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Day 60

Form: Lab_BU_CCLS (41)

Data signed: (hfarmer1) 30 Mar 2015 13:35:26

Generated On: 20 Jul 2016 22:28:45

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

Form: Lab_BU_CCLS (42)

Data signed: (hfarmer1) 30 Mar 2015 13:35:26

Generated On: 20 Jul 2016 22:28:45

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	X312798
--------------	---------

Actual Collection Date	2014 06 04
------------------------	------------

Actual Collection Time	06:30
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	UA1538
------------	--------

Battery Name	URINE MACRO PANEL
--------------	-------------------

Lab Test ID	UAT7
-------------	------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

Form: Lab_BU_CCLS (42)

Data signed: (hfarmer1) 30 Mar 2015 13:35:26


Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Day 60

Form: Lab_BU_CCLS (42)

Data signed: (hfarmer1) 30 Mar 2015 13:35:26

Generated On: 20 Jul 2016 22:28:45

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

Form: Lab_BU_COHB (1)

Data signed: (hfarmer1) 30 Mar 2015 13:35:42

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05115150004510
Analyte	CARBOXYHEMOGLOBIN
Sample type	BLOOD
Result	5.80
Result Unit	%
Lab Status	OK
Sample comment	.
Detection method	SPECTROPHOTOMETRIC
Lower limit of quantification	0.500
Planned time point (Hour)	10
Day of Visit	60
Celerion Study Number	AA99128-16
Date of Collection	2014-JUN-03
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

Form: Lab_BU_COHB (1)

Data signed: (hfarmer1) 30 Mar 2015 13:35:42

Generated On: 20 Jul 2016 22:28:45

Start Day (24 hour urine only) _____

End Day (24 hour Urine Only) _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

Form: Cough Assessment (Paper)

Data signed: (hfarmer1) 30 Mar 2015 13:35:22

Generated On: 20 Jul 2016 22:28:45

Was paper questionnaire used? Yes ☐

Reason not done _____

Date of assessment 04 JUN 2014
DD/MMM/YYYY DD/MMM/YYYY

Time of assessment 06:18
hour:min 24-hour clock

Have you experienced a regular need to cough e.g.
coughing several times in the last 24 hrs? No ☐

If YES, please answer the following questions:

First Question: Cough Impact Scale
How much is your cough bothering you? _____

Second Question: Cough Intensity Scale:
How intense is your cough? _____

Third Question: Cough Frequency Scale:
How frequently do you normally have to cough each
day? _____

Fourth Question: Sputum Production
To what extent do you produce sputum when coughing? _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

Form: Cough Assessment (Paper)

Data signed: (hfarmer1) 30 Mar 2015 13:35:22

Generated On: 20 Jul 2016 22:28:45

Are there any other important observations that you
would like to share with us about you coughing? (open
question)

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Day 60

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS) (Paper)

Data signed: (hfarmer1) 30 Mar 2015 13:35:23

Generated On: 20 Jul 2016 22:28:45

Was paper questionnaire used?

Yes ☒

Reason not done

Date of assessment
DD/MMM/YYYY

04 JUN 2014
DD/MMM/YYYY

Time of assessment

06:15
hour:min 24-hour clock

Please indicate for each of the items below, how you have been feeling over the past 24 hours

Result

1. Angry, irritable, frustrated

None

2. Anxious, tense

None

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Day 60

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS) (Paper) (3)

Data signed: (hfarmer1) 30 Mar 2015 13:35:23

Generated On: 20 Jul 2016 22:28:45

	Result
3. Depressed Mood, sad	None
4. Desire or craving to smoke	Moderate
5. Difficulty concentrating	None
6. Increased appetite, hungry, weight gain	None
7. Insomnia, sleep problems, awakening at night	None
8. Restless	None
9. Impatient	None

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Day 60

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS) (Paper) (10)

Data signed: (hfarmer1) 30 Mar 2015 13:35:23

Generated On: 20 Jul 2016 22:28:45

	Result
10. Constipation	None
11. Dizziness	None
12. Coughing	None
13. Dreaming or nightmares	None
14. Nausea	None
15. Sore throat	None

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

**Form: Prochaska "Stage of Change" Questionnaire: Intention to Quit
Smoking**

Data signed: (hfarmer1) 30 Mar 2015 13:35:23

Generated On: 20 Jul 2016 22:28:45

Was paper questionnaire used? Yes ☒

Reason not done _____

Type PROCHASKA STAGE OF
CHANGE QUESTIONNAIRE:
INTENTION TO QUIT
SMOKING

Date of assessment 03 JUN 2014
DD/MMM/YYYY

Time of assessment 20:32
hour:min 24-hour clock

1. Are you currently a smoker? Yes, I currently smoke ☒

2. In the last year, how many times have you quit
smoking for at least 24 hours? 0

3. Are you seriously thinking of quitting smoking? No, not thinking of quitting ☒

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Day 60

Form: Human Smoking Topography Questionnaire

Data signed: (hfarmer1) 30 Mar 2015 13:35:24

Generated On: 20 Jul 2016 22:28:45

Type	HUMAN SMOKING TOPOGRAPHY QUESTIONNAIRE
------	--

Was paper questionnaire used?	Yes <input type="radio"/>
-------------------------------	---------------------------

Reason not done	<hr/>
-----------------	-------

Date of assessment	03 JUN 2014 DD/MMM/YYYY
--------------------	----------------------------

Time of assessment	20:29 hour:min 24-hour clock
--------------------	---------------------------------

How do you agree with the following sentences/affirmations :

1. The smoking of the conventional cigarettes/products is different with the device.	Strongly disagree <input type="radio"/>
--	---

If you agree or strongly agree, please describe :	<hr/>
---	-------

2. You enjoy smoking with the device as much as without it.	Strongly agree <input type="radio"/>
---	--------------------------------------

If you disagree or strongly disagree, please describe :	<hr/>
---	-------

3. The taste of the conventional cigarettes/products is different with the device.	Strongly disagree <input type="radio"/>
--	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

Form: Human Smoking Topography Questionnaire

Data signed: (hfarmer1) 30 Mar 2015 13:35:24

Generated On: 20 Jul 2016 22:28:45

If you agree or strongly agree, please describe : _____

4. The device is easy to use.

Strongly agree ☒

If you disagree or strongly disagree, please describe : _____

5. Your smoking is disturbed by the device.

Strongly disagree ☒

If you agree or strongly agree, please describe : _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

Form: Questionnaire on smoking urges (QSU) (Paper)

Data signed: (hfarmer1) 30 Mar 2015 13:35:23

Generated On: 20 Jul 2016 22:28:45

Type	QUESTIONNAIRE ON SMOKING URGES
------	-----------------------------------

Was paper questionnaire used?	Yes <input type="radio"/>
-------------------------------	---------------------------

Reason not done	<hr/>
-----------------	-------

Date of assessment	03 JUN 2014
--------------------	-------------

DD/MMM/YYYY

Time of assessment	20:29
--------------------	-------

hour:min 24-hour clock

1. I have a desire for a cigarette right now	Strongly agree <input type="radio"/>
--	--------------------------------------

2. Nothing would be better than smoking a cigarette right now	Strongly disagree <input type="radio"/>
--	---

3. If it were possible I would probably smoke now	Strongly agree <input type="radio"/>
---	--------------------------------------

4. I could control things better right now if I could smoke	Strongly disagree <input type="radio"/>
---	---

5. All I want right now is a cigarette	Strongly disagree <input type="radio"/>
--	---

6. I have an urge for a cigarette	Strongly agree <input type="radio"/>
-----------------------------------	--------------------------------------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

Form: Questionnaire on smoking urges (QSU) (Paper)

Data signed: (hfarmer1) 30 Mar 2015 13:35:23

Generated On: 20 Jul 2016 22:28:45

7. A cigarette would taste good now Strongly agree ☐

8. I would do almost anything for a cigarette now Strongly disagree ☐

9. Smoking would make me less depressed Strongly disagree ☐

10. I am going to smoke as soon as possible Strongly agree ☐

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper)

Data signed: (hfarmer1) 30 Mar 2015 13:35:22

Generated On: 20 Jul 2016 22:28:45

Was paper questionnaire used?

Yes ☒

Reason not done

Date of assessment

03 JUN 2014
DD/MMM/YYYY

DD/MMM/YYYY

Time of assessment

20:26
hour:min 24-hour clock

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper) (1)

Data signed: (hfarmer1) 30 Mar 2015 13:35:22

Generated On: 20 Jul 2016 22:28:45

Was paper questionnaire used? Yes ☒

Reason not done _____

Date of assessment 03 JUN 2014
DD/MMM/YYYY

Time of assessment 20:26
hour:min 24-hour clock

If you have smoked since you last completed this questionnaire,
please mark what best represents how smoking made you feel

Was smoking satisfying? ☒

Response Extremely ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper) (2)

Data signed: (hfarmer1) 30 Mar 2015 13:35:22

Generated On: 20 Jul 2016 22:28:45

Was paper questionnaire used? Yes ☒

Reason not done _____

Date of assessment 03 JUN 2014
DD/MMM/YYYY

Time of assessment 20:26
hour:min 24-hour clock

If you have smoked since you last completed this questionnaire,
please mark what best represents how smoking made you feel

Did cigarettes taste good? ☒

Response Moderately ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper) (3)

Data signed: (hfarmer1) 30 Mar 2015 13:35:22

Generated On: 20 Jul 2016 22:28:45

Was paper questionnaire used? Yes ☒

Reason not done _____

Date of assessment 03 JUN 2014
DD/MMM/YYYY

Time of assessment 20:26
hour:min 24-hour clock

If you have smoked since you last completed this questionnaire,
please mark what best represents how smoking made you feel

Did you enjoy the sensation in your throat and chest? ☒

Response Moderately ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper) (4)

Data signed: (hfarmer1) 30 Mar 2015 13:35:22

Generated On: 20 Jul 2016 22:28:45

Was paper questionnaire used? Yes ☒

Reason not done _____

Date of assessment 03 JUN 2014
DD/MMM/YYYY

Time of assessment 20:26
hour:min 24-hour clock

If you have smoked since you last completed this questionnaire,
please mark what best represents how smoking made you feel

Did smoking calm you down? ☒

Response Moderately ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper) (5)

Data signed: (hfarmer1) 30 Mar 2015 13:35:22

Generated On: 20 Jul 2016 22:28:45

Was paper questionnaire used? Yes ☒

Reason not done _____

Date of assessment 03 JUN 2014
DD/MMM/YYYY

Time of assessment 20:26
hour:min 24-hour clock

If you have smoked since you last completed this questionnaire,
please mark what best represents how smoking made you feel

Did smoking make you feel more awake? ☒

Response Moderately ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper) (6)

Data signed: (hfarmer1) 30 Mar 2015 13:35:22

Generated On: 20 Jul 2016 22:28:45

Was paper questionnaire used? Yes ☒

Reason not done _____

Date of assessment 03 JUN 2014
DD/MMM/YYYY

Time of assessment 20:26
hour:min 24-hour clock

If you have smoked since you last completed this questionnaire,
please mark what best represents how smoking made you feel

Did smoking make you feel less irritable? ☒

Response Moderately ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper) (7)

Data signed: (hfarmer1) 30 Mar 2015 13:35:22

Generated On: 20 Jul 2016 22:28:45

Was paper questionnaire used? Yes ☒

Reason not done _____

Date of assessment 03 JUN 2014
DD/MMM/YYYY

Time of assessment 20:26
hour:min 24-hour clock

If you have smoked since you last completed this questionnaire,
please mark what best represents how smoking made you feel Did smoking help you
concentrate? ☒

Response Not at all ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper) (8)

Data signed: (hfarmer1) 30 Mar 2015 13:35:22

Generated On: 20 Jul 2016 22:28:45

Was paper questionnaire used? Yes ☒

Reason not done _____

Date of assessment 03 JUN 2014
DD/MMM/YYYY

Time of assessment 20:26
hour:min 24-hour clock

If you have smoked since you last completed this questionnaire,
please mark what best represents how smoking made you feel

Did smoking reduce your hunger for food? ☒

Response Moderately ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper) (9)

Data signed: (hfarmer1) 30 Mar 2015 13:35:22

Generated On: 20 Jul 2016 22:28:45

Was paper questionnaire used? Yes ☒

Reason not done _____

Date of assessment 03 JUN 2014
DD/MMM/YYYY

Time of assessment 20:26
hour:min 24-hour clock

If you have smoked since you last completed this questionnaire,
please mark what best represents how smoking made you feel Did smoking make you dizzy? ☒

Response Not at all ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper) (10)

Data signed: (hfarmer1) 30 Mar 2015 13:35:22

Generated On: 20 Jul 2016 22:28:45

Was paper questionnaire used? Yes ☒

Reason not done _____

Date of assessment 03 JUN 2014
DD/MMM/YYYY

Time of assessment 20:26
hour:min 24-hour clock

If you have smoked since you last completed this questionnaire,
please mark what best represents how smoking made you feel Did smoking make you
nauseous? ☒

Response Not at all ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper) (11)

Data signed: (hfarmer1) 30 Mar 2015 13:35:22

Generated On: 20 Jul 2016 22:28:45

Was paper questionnaire used? Yes ☒

Reason not done _____

Date of assessment 03 JUN 2014
DD/MMM/YYYY

Time of assessment 20:26
hour:min 24-hour clock

If you have smoked since you last completed this questionnaire,
please mark what best represents how smoking made you feel

Did smoking immediately relieve your craving for a cigarette? ☒

Response Extremely ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper) (12)

Data signed: (hfarmer1) 30 Mar 2015 13:35:22

Generated On: 20 Jul 2016 22:28:45

Was paper questionnaire used? Yes ☒

Reason not done _____

Date of assessment 03 JUN 2014
DD/MMM/YYYY

Time of assessment 20:26
hour:min 24-hour clock

If you have smoked since you last completed this questionnaire,
please mark what best represents how smoking made you feel

Did you enjoy smoking? ☒

Response Extremely ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

Form: Risk Markers(CCLS) (1)

Data signed: (hfarmer1) 30 Mar 2015 13:35:24

Generated On: 20 Jul 2016 22:28:45

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	1252
----------------------	------

Subject Sex	M
-------------	---

Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	DAY60
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	X312798
--------------	---------

Actual Collection Date	2014 06 04
------------------------	------------

Actual Collection Time	06:30
------------------------	-------

Specimen Condition	
--------------------	--

Battery ID	RC6871
------------	--------

Battery Name	HDL
--------------	-----

Lab Test ID	RCT1684
-------------	---------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

Form: Risk Markers(CCLS) (1)

Data signed: (hfarmer1) 30 Mar 2015 13:35:24


Generated On: 20 Jul 2016 22:28:45

Lab Test Name

DIRECT HDL-C 3RD
GENERATION

Test ID

Test Status

Done 

Reported Text Result

86

Reported Numeric Result

86

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: 1252**

Folder: Day 60

Form: Risk Markers(CCLS) (1)

Data signed: (hfarmer1) 30 Mar 2015 13:35:24

Generated On: 20 Jul 2016 22:28:45

SI Text Result

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

High ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

Form: Risk Markers(CCLS) (2)

Data signed: (hfarmer1) 30 Mar 2015 13:35:24

Generated On: 20 Jul 2016 22:28:45

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	1252
----------------------	------

Subject Sex	M
-------------	---

Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	DAY60
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	X312798
--------------	---------

Actual Collection Date	2014 06 04
------------------------	------------

Actual Collection Time	06:30
------------------------	-------

Specimen Condition	
--------------------	--

Battery ID	SC3249
------------	--------

Battery Name	HS-CRP
--------------	--------

Lab Test ID	SCT1528
-------------	---------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

Form: Risk Markers(CCLS) (2)

Data signed: (hfarmer1) 30 Mar 2015 13:35:24


Generated On: 20 Jul 2016 22:28:45

Lab Test Name

C-REACTIVE PROTEIN (N
HS)-QT

Test ID

Test Status

Done 

Reported Text Result

0.305

Reported Numeric Result

0.305

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: 1252**

Folder: Day 60

Form: Risk Markers(CCLS) (2)

Data signed: (hfarmer1) 30 Mar 2015 13:35:24

Generated On: 20 Jul 2016 22:28:45

SI Text Result

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

High ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

Form: Risk Markers(CCLS) (3)

Data signed: (hfarmer1) 30 Mar 2015 13:35:24

Generated On: 20 Jul 2016 22:28:45

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	1252
----------------------	------

Subject Sex	M
-------------	---

Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	DAY60
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	X312798
--------------	---------

Actual Collection Date	2014 06 04
------------------------	------------

Actual Collection Time	06:30
------------------------	-------

Specimen Condition	
--------------------	--

Battery ID	CG267
------------	-------

Battery Name	FIBRINOGEN
--------------	------------

Lab Test ID	CGT285
-------------	--------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

Form: Risk Markers(CCLS) (3)

Data signed: (hfarmer1) 30 Mar 2015 13:35:24

Generated On: 20 Jul 2016 22:28:45

Lab Test Name	FIBRINOGEN
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	340
Reported Numeric Result	340
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: 1252**

Folder: Day 60

Form: Risk Markers(CCLS) (3)

Data signed: (hfarmer1) 30 Mar 2015 13:35:24

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Day 60

Form: Risk Markers(CCLS) (4)

Data signed: (hfarmer1) 30 Mar 2015 13:35:24

Generated On: 20 Jul 2016 22:28:45

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	1252
----------------------	------

Subject Sex	M
-------------	---

Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	DAY60
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	X312798
--------------	---------

Actual Collection Date	2014 06 04
------------------------	------------

Actual Collection Time	06:30
------------------------	-------

Specimen Condition	
--------------------	--

Battery ID	CN236
------------	-------

Battery Name	HOMOCYSTEINE
--------------	--------------

Lab Test ID	CNT145
-------------	--------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

Form: Risk Markers(CCLS) (4)

Data signed: (hfarmer1) 30 Mar 2015 13:35:24

Generated On: 20 Jul 2016 22:28:45

Lab Test Name	HOMOCYSTEINE, EDTAPL
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	13.01
Reported Numeric Result	13.01
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: 1252**

Folder: Day 60

Form: Risk Markers(CCLS) (4)

Data signed: (hfarmer1) 30 Mar 2015 13:35:24

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Day 60

Form: Risk Markers(CCLS) (5)

Data signed: (hfarmer1) 30 Mar 2015 13:35:24

Generated On: 20 Jul 2016 22:28:45

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	1252
----------------------	------

Subject Sex	M
-------------	---

Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	DAY60
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	X312798
--------------	---------

Actual Collection Date	2014 06 04
------------------------	------------

Actual Collection Time	06:30
------------------------	-------

Specimen Condition	
--------------------	--

Battery ID	IM2293
------------	--------

Battery Name	SICAM-1
--------------	---------

Lab Test ID	IMT1768
-------------	---------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

Form: Risk Markers(CCLS) (5)

Data signed: (hfarmer1) 30 Mar 2015 13:35:24

Generated On: 20 Jul 2016 22:28:45

Lab Test Name	SICAM-1-RUO
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	235.0
Reported Numeric Result	235.0
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: 1252**

Folder: Day 60

Form: Risk Markers(CCLS) (5)

Data signed: (hfarmer1) 30 Mar 2015 13:35:24

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Day 60

Form: Risk Markers(CCLS) (6)

Data signed: (hfarmer1) 30 Mar 2015 13:35:24

Generated On: 20 Jul 2016 22:28:45

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	1252
----------------------	------

Subject Sex	M
-------------	---

Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	DAY60
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	X312798
--------------	---------

Actual Collection Date	2014 06 04
------------------------	------------

Actual Collection Time	06:30
------------------------	-------

Specimen Condition	
--------------------	--

Battery ID	RC9267
------------	--------

Battery Name	LDL
--------------	-----

Lab Test ID	RCT2394
-------------	---------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

Form: Risk Markers(CCLS) (6)

Data signed: (hfarmer1) 30 Mar 2015 13:35:24

Generated On: 20 Jul 2016 22:28:45

Lab Test Name	DIRECT LDL-C 2ND GEN (-70)
---------------	----------------------------

Test ID	<hr/>
---------	-------

Test Status	Done 
-------------	--

Reported Text Result	90
----------------------	----

Reported Numeric Result	90
-------------------------	----

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: 1252**

Folder: Day 60

Form: Risk Markers(CCLS) (6)

Data signed: (hfarmer1) 30 Mar 2015 13:35:24

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Day 60

Form: Biomarker-Urine (CEMA, HPMA, HBMA)

Data signed: (hfarmer1) 30 Mar 2015 13:35:43

Generated On: 20 Jul 2016 22:28:45

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

Form: Biomarker-Urine (CEMA, HPMa, HBMA) (1)

Data signed: (hfarmer1) 30 Mar 2015 13:35:43

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112450002860
----------------	----------------

Analyte	HPMA
---------	------

Sample type	URINE
-------------	-------

Result	.
--------	---

Result Unit	NG/ML
-------------	-------

Lab Status	OK
------------	----

Sample comment	ANALYSIS NOT PERFORMED IN ERROR
----------------	------------------------------------

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	60
--------------	----

Celerion Study Number	AA99128-03
-----------------------	------------

Date of Collection	2014-JUN-03
--------------------	-------------

Timepoint-minutes	
-------------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

Form: Biomarker-Urine (CEMA, HPMa, HBMA) (1)

Data signed: (hfarmer1) 30 Mar 2015 13:35:43

Generated On: 20 Jul 2016 22:28:45

Urine Start Day	60
<hr/>	
Urine End Day	61
<hr/>	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

Form: Biomarker-Urine (CEMA, HPMa, HBMA) (2)

Data signed: (hfarmer1) 30 Mar 2015 13:35:43

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112450002860
----------------	----------------

Analyte	CEMA
---------	------

Sample type	URINE
-------------	-------

Result	.
--------	---

Result Unit	NG/ML
-------------	-------

Lab Status	OK
------------	----

Sample comment	ANALYSIS NOT PERFORMED IN ERROR
----------------	------------------------------------

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	60
--------------	----

Celerion Study Number	AA99128-03
-----------------------	------------

Date of Collection	2014-JUN-03
--------------------	-------------

Timepoint-minutes	
-------------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

Form: Biomarker-Urine (CEMA, HPMa, HBMA) (2)

Data signed: (hfarmer1) 30 Mar 2015 13:35:43

Generated On: 20 Jul 2016 22:28:45

Urine Start Day	60
<hr/>	
Urine End Day	61
<hr/>	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

Form: Biomarker-Urine (CEMA, HPMa, HBMA) (3)

Data signed: (hfarmer1) 30 Mar 2015 13:35:43

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112450002860
----------------	----------------

Analyte	HBMA
---------	------

Sample type	URINE
-------------	-------

Result	.
--------	---

Result Unit	NG/ML
-------------	-------

Lab Status	OK
------------	----

Sample comment	ANALYSIS NOT PERFORMED IN ERROR
----------------	------------------------------------

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	60
--------------	----

Celerion Study Number	AA99128-03
-----------------------	------------

Date of Collection	2014-JUN-03
--------------------	-------------

Timepoint-minutes	
-------------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

Form: Biomarker-Urine (CEMA, HPMa, HBMA) (3)

Data signed: (hfarmer1) 30 Mar 2015 13:35:43

Generated On: 20 Jul 2016 22:28:45

Urine Start Day	60
-----------------	----

Urine End Day	61
---------------	----

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

Form: Biomarker-Urine (NNN, NNAL)

Data signed: (hfarmer1) 30 Mar 2015 13:35:43

Generated On: 20 Jul 2016 22:28:45

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

Form: Biomarker-Urine (NNN, NNAL) (1)

Data signed: (hfarmer1) 30 Mar 2015 13:35:43

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112460003431
----------------	----------------

Analyte	NNAL
---------	------

Sample type	URINE
-------------	-------

Result	.
--------	---

Result Unit	PG/ML
-------------	-------

Lab Status	OK
------------	----

Sample comment	ANALYSIS NOT PERFORMED IN ERROR
----------------	------------------------------------

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	60
--------------	----

Celerion Study Number	AA99128-04
-----------------------	------------

Date of Collection	2014-JUN-03
--------------------	-------------

Timepoint-minutes	
-------------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

Form: Biomarker-Urine (NNN, NNAL) (1)

Data signed: (hfarmer1) 30 Mar 2015 13:35:43

Generated On: 20 Jul 2016 22:28:45

Urine Start Day	60
-----------------	----

Urine End Day	61
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

Form: Biomarker-Urine (NNN, NNAL) (2)

Data signed: (hfarmer1) 30 Mar 2015 13:35:43

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112460003431
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Analyte	NNN
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Sample type	URINE
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Result	.
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Result Unit	PG/ML
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Lab Status	OK
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Sample comment	ANALYSIS NOT PERFORMED IN ERROR
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Detection method	LC-MS/MS
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Planned time point (Hour)	0
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Day of Visit	60
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Celerion Study Number	AA99128-04
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Date of Collection	2014-JUN-03
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Timepoint-minutes	
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

Form: Biomarker-Urine (NNN, NNAL) (2)

Data signed: (hfarmer1) 30 Mar 2015 13:35:43

Generated On: 20 Jul 2016 22:28:45

Urine Start Day	60
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Urine End Day	61
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

Form: Biomarker-Urine (HEMA)

Data signed: (hfarmer1) 30 Mar 2015 13:35:43

Generated On: 20 Jul 2016 22:28:45

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

Form: Biomarker-Urine (HEMA) (1)

Data signed: (hfarmer1) 30 Mar 2015 13:35:43

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112470001715
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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	OK
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Sample comment	ANALYSIS NOT PERFORMED IN ERROR
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Detection method	LC-MS/MS
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Planned time point (Hour)	0
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Day of Visit	60
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Celerion Study Number	AA99128-05
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Date of Collection	2014-JUN-03
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Timepoint-minutes	
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

Form: Biomarker-Urine (HEMA) (1)

Data signed: (hfarmer1) 30 Mar 2015 13:35:43

Generated On: 20 Jul 2016 22:28:45

Urine Start Day	60
<hr/>	
Urine End Day	61
<hr/>	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)

Data signed: (hfarmer1) 30 Mar 2015 13:35:44

Generated On: 20 Jul 2016 22:28:45

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(1)**

Data signed: (hfarmer1) 30 Mar 2015 13:35:44

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112480000780
Analyte	COT
Sample type	URINE
Result	.
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYSIS NOT PERFORMED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	60
Celerion Study Number	AA99128-06
Date of Collection	2014-JUN-03
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(1)**

Data signed: (hfarmer1) 30 Mar 2015 13:35:44

Generated On: 20 Jul 2016 22:28:45

Urine Start Day	60
<hr/>	
Urine End Day	61
<hr/>	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(2)**

Data signed: (hfarmer1) 30 Mar 2015 13:35:44

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112480000780
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Analyte	COT-GLUC
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Sample type	URINE
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Result	.
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Result Unit	NG/ML
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Lab Status	OK
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Sample comment	ANALYSIS NOT PERFORMED IN ERROR
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Detection method	LC-MS/MS
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Planned time point (Hour)	0
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Day of Visit	60
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Celerion Study Number	AA99128-06
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Date of Collection	2014-JUN-03
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Timepoint-minutes	
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(2)**

Data signed: (hfarmer1) 30 Mar 2015 13:35:44

Generated On: 20 Jul 2016 22:28:45

Urine Start Day	60
<hr/>	
Urine End Day	61
<hr/>	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(3)**

Data signed: (hfarmer1) 30 Mar 2015 13:35:44

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112480000780
Analyte	NIC
Sample type	URINE
Result	.
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYSIS NOT PERFORMED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	60
Celerion Study Number	AA99128-06
Date of Collection	2014-JUN-03
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(3)**

Data signed: (hfarmer1) 30 Mar 2015 13:35:44

Generated On: 20 Jul 2016 22:28:45

Urine Start Day	60
<hr/>	
Urine End Day	61
<hr/>	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(4)**

Data signed: (hfarmer1) 30 Mar 2015 13:35:44

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112480000780
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Analyte	NIC-GLUC
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Sample type	URINE
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Result	.
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Result Unit	NG/ML
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Lab Status	OK
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Sample comment	ANALYSIS NOT PERFORMED IN ERROR
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Detection method	LC-MS/MS
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Planned time point (Hour)	0
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Day of Visit	60
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Celerion Study Number	AA99128-06
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Date of Collection	2014-JUN-03
--------------------	-------------

Timepoint-minutes	
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(4)**

Data signed: (hfarmer1) 30 Mar 2015 13:35:44

Generated On: 20 Jul 2016 22:28:45

Urine Start Day	60
<hr/>	
Urine End Day	61
<hr/>	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(5)**

Data signed: (hfarmer1) 30 Mar 2015 13:35:44

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112480000780
Analyte	THCOT
Sample type	URINE
Result	.
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYSIS NOT PERFORMED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	60
Celerion Study Number	AA99128-06
Date of Collection	2014-JUN-03
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(5)**

Data signed: (hfarmer1) 30 Mar 2015 13:35:44

Generated On: 20 Jul 2016 22:28:45

Urine Start Day	60
<hr/>	
Urine End Day	61
<hr/>	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(6)**

Data signed: (hfarmer1) 30 Mar 2015 13:35:44

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112480000780
Analyte	THCOT-GLUC
Sample type	URINE
Result	.
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYSIS NOT PERFORMED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	60
Celerion Study Number	AA99128-06
Date of Collection	2014-JUN-03
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(6)**

Data signed: (hfarmer1) 30 Mar 2015 13:35:44

Generated On: 20 Jul 2016 22:28:45

Urine Start Day	60
<hr/>	
Urine End Day	61
<hr/>	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

Form: Biomarker-Urine (3-OH BaP)

Data signed: (hfarmer1) 30 Mar 2015 13:35:44

Generated On: 20 Jul 2016 22:28:45

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

Form: Biomarker-Urine (3-OH BaP) (1)

Data signed: (hfarmer1) 30 Mar 2015 13:35:44

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112490001715
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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	OK
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Sample comment	ANALYSIS NOT PERFORMED IN ERROR
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Detection method	LC-MS/MS
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Planned time point (Hour)	0
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Day of Visit	60
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Celerion Study Number	AA99128-07
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Date of Collection	2014-JUN-03
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Timepoint-minutes	
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

Form: Biomarker-Urine (3-OH BaP) (1)

Data signed: (hfarmer1) 30 Mar 2015 13:35:44

Generated On: 20 Jul 2016 22:28:45

Urine Start Day	60
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Urine End Day	61
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP)

Data signed: (hfarmer1) 30 Mar 2015 13:35:44

Generated On: 20 Jul 2016 22:28:45

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (1)

Data signed: (hfarmer1) 30 Mar 2015 13:35:44

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112510001737
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Analyte	1-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	OK
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Sample comment	ANALYSIS NOT PERFORMED IN ERROR
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Detection method	LC-MS/MS
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Planned time point (Hour)	0
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Day of Visit	60
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Celerion Study Number	AA99128-09
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Date of Collection	2014-JUN-03
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Timepoint-minutes	
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (1)

Data signed: (hfarmer1) 30 Mar 2015 13:35:44

Generated On: 20 Jul 2016 22:28:45

Urine Start Day	60
<hr/>	
Urine End Day	61
<hr/>	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (2)

Data signed: (hfarmer1) 30 Mar 2015 13:35:44

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112510001737
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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	OK
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Sample comment	ANALYSIS NOT PERFORMED IN ERROR
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Detection method	LC-MS/MS
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Planned time point (Hour)	0
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Day of Visit	60
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Celerion Study Number	AA99128-09
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Date of Collection	2014-JUN-03
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Timepoint-minutes	
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (2)

Data signed: (hfarmer1) 30 Mar 2015 13:35:44

Generated On: 20 Jul 2016 22:28:45

Urine Start Day	60
<hr/>	
Urine End Day	61
<hr/>	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (3)

Data signed: (hfarmer1) 30 Mar 2015 13:35:44

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112510001737
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Analyte	4-ABP
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Sample type	URINE
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Result	.
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Result Unit	PG/ML
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Lab Status	OK
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Sample comment	ANALYSIS NOT PERFORMED IN ERROR
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Detection method	LC-MS/MS
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Planned time point (Hour)	0
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Day of Visit	60
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Celerion Study Number	AA99128-09
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Date of Collection	2014-JUN-03
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Timepoint-minutes	
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (3)

Data signed: (hfarmer1) 30 Mar 2015 13:35:44

Generated On: 20 Jul 2016 22:28:45

Urine Start Day	60
<hr/>	
Urine End Day	61
<hr/>	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (4)

Data signed: (hfarmer1) 30 Mar 2015 13:35:44

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112510001737
Analyte	O-TOL
Sample type	URINE
Result	.
Result Unit	PG/ML
Lab Status	OK
Sample comment	ANALYSIS NOT PERFORMED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	60
Celerion Study Number	AA99128-09
Date of Collection	2014-JUN-03
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (4)

Data signed: (hfarmer1) 30 Mar 2015 13:35:44

Generated On: 20 Jul 2016 22:28:45

Urine Start Day	60
<hr/>	
Urine End Day	61
<hr/>	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

Form: Biomarker-Urine (11-dTXb2)

Data signed: (hfarmer1) 30 Mar 2015 13:35:43

Generated On: 20 Jul 2016 22:28:45

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

Form: Biomarker-Urine (11-dTXb2) (1)

Data signed: (hfarmer1) 30 Mar 2015 13:35:43

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112530000545
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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	OK
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Sample comment	ANALYSIS NOT PERFORMED IN ERROR
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Detection method	LC-MS/MS
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Planned time point (Hour)	0
---------------------------	---

Day of Visit	60
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Celerion Study Number	AA99128-11
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Date of Collection	2014-JUN-03
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Timepoint-minutes	
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

Form: Biomarker-Urine (11-dTXb2) (1)

Data signed: (hfarmer1) 30 Mar 2015 13:35:43

Generated On: 20 Jul 2016 22:28:45

Urine Start Day	60
<hr/>	
Urine End Day	61
<hr/>	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

Form: Biomarker-Urine (iPF2a-III)

Data signed: (hfarmer1) 30 Mar 2015 13:35:43

Generated On: 20 Jul 2016 22:28:45

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

Form: Biomarker-Urine (iPF2a-III) (1)

Data signed: (hfarmer1) 30 Mar 2015 13:35:43

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112540000538
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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	OK
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Sample comment	ANALYSIS NOT PERFORMED IN ERROR
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Detection method	LC-MS/MS
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Planned time point (Hour)	0
---------------------------	---

Day of Visit	60
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Celerion Study Number	AA99128-12
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Date of Collection	2014-JUN-03
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Timepoint-minutes	
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

Form: Biomarker-Urine (iPF2a-III) (1)

Data signed: (hfarmer1) 30 Mar 2015 13:35:43

Generated On: 20 Jul 2016 22:28:45

Urine Start Day	60
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Urine End Day	61
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

Form: Biomarker-Urine (1-OHP)

Data signed: (hfarmer1) 30 Mar 2015 13:35:45

Generated On: 20 Jul 2016 22:28:45

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

Form: Biomarker-Urine (1-OHP) (1)

Data signed: (hfarmer1) 30 Mar 2015 13:35:45

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05115190003739
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Analyte	1-OHP
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Sample type	URINE
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Result	.
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Result Unit	PG/ML
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Lab Status	OK
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Sample comment	NOT ANALYZED IN ERROR
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Detection method	LC-MS/MS
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Planned time point (Hour)	0
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Day of Visit	60
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Celerion Study Number	AA99598-03
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Date of Collection	2014-JUN-03
--------------------	-------------

Timepoint-minutes	
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Urine Start Day	60
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

Form: Biomarker-Urine (1-OHP) (1)

Data signed: (hfarmer1) 30 Mar 2015 13:35:45

Generated On: 20 Jul 2016 22:28:45

Urine End Day

61

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

Form: Biomarker-Urine (SPMA, SBMA)

Data signed: (hfarmer1) 30 Mar 2015 13:35:43

Generated On: 20 Jul 2016 22:28:45

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

Form: Biomarker-Urine (SPMA, SBMA) (1)

Data signed: (hfarmer1) 30 Mar 2015 13:35:43

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05115170003730
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Analyte	SPMA
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Sample type	URINE
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Result	.
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Result Unit	NG/ML
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Lab Status	OK
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Sample comment	NOT ANALYZED IN ERROR
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Detection method	LC-MS/MS
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Planned time point (Hour)	0
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Day of Visit	60
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Celerion Study Number	AA99598-01
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Date of Collection	2014-JUN-03
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Timepoint-minutes	
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Urine Start Day	60
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

Form: Biomarker-Urine (SPMA, SBMA) (1)

Data signed: (hfarmer1) 30 Mar 2015 13:35:43

Generated On: 20 Jul 2016 22:28:45

Urine End Day

61

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

Form: Biomarker-Urine (SPMA, SBMA) (2)

Data signed: (hfarmer1) 30 Mar 2015 13:35:43

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05115170003739
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Analyte	SBMA
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Sample type	URINE
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Result	.
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Result Unit	NG/ML
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Lab Status	OK
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Sample comment	NOT ANALYZED IN ERROR
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Detection method	LC-MS/MS
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Planned time point (Hour)	0
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Day of Visit	60
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Celerion Study Number	AA99598-01
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Date of Collection	2014-JUN-03
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Timepoint-minutes	
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Urine Start Day	60
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

Form: Biomarker-Urine (SPMA, SBMA) (2)

Data signed: (hfarmer1) 30 Mar 2015 13:35:43

Generated On: 20 Jul 2016 22:28:45

Urine End Day

61

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

Form: Biomarker-Urine (MHBMA)

Data signed: (hfarmer1) 30 Mar 2015 13:35:43

Generated On: 20 Jul 2016 22:28:45

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

Form: Biomarker-Urine (MHBMA) (1)

Data signed: (hfarmer1) 30 Mar 2015 13:35:43

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05115180003739
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Analyte	MHBMA
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Sample type	URINE
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Result	.
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Result Unit	NG/ML
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Lab Status	OK
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Sample comment	NOT ANALYZED IN ERROR
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Detection method	LC-MS/MS
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Planned time point (Hour)	0
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Day of Visit	60
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Celerion Study Number	AA99598-02
-----------------------	------------

Date of Collection	2014-JUN-03
--------------------	-------------

Timepoint-minutes	
-------------------	--

Urine Start Day	60
-----------------	----

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

Form: Biomarker-Urine (MHBMA) (1)

Data signed: (hfarmer1) 30 Mar 2015 13:35:43

Generated On: 20 Jul 2016 22:28:45

Urine End Day

61

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

Form: Biomarker-Urine (Creatinine)

Data signed: (hfarmer1) 30 Mar 2015 13:35:45

Generated On: 20 Jul 2016 22:28:45

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

Form: Biomarker-Urine (Creatinine) (1)

Data signed: (hfarmer1) 30 Mar 2015 13:35:45

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05115160001715
----------------	----------------

Analyte	CREATININE
---------	------------

Sample type	URINE
-------------	-------

Result	.
--------	---

Result Unit	MG/DL
-------------	-------

Lab Status	OK
------------	----

Sample comment	ANALYSIS NOT PERFORMED IN ERROR
----------------	------------------------------------

Detection method	SPECTROPHOTOMETRIC
------------------	--------------------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	60
--------------	----

Celerion Study Number	AA99128-14
-----------------------	------------

Date of Collection	2014-JUN-03
--------------------	-------------

Timepoint-minutes	
-------------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

Form: Biomarker-Urine (Creatinine) (1)

Data signed: (hfarmer1) 30 Mar 2015 13:35:45

Generated On: 20 Jul 2016 22:28:45

Urine Start Day	60
<hr/>	
Urine End Day	61
<hr/>	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

Form: Biomarker-Plasma (Nic, Cot, tHCot)

Data signed: (hfarmer1) 30 Mar 2015 13:35:43

Generated On: 20 Jul 2016 22:28:45

Sample type

PLASMA

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

Form: Biomarker-Plasma (Nic, Cot, tHCot) (1)

Data signed: (hfarmer1) 30 Mar 2015 13:35:43

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112430001823
Analyte	COT
Sample type	PLASMA
Result	174
Result Unit	NG/ML
Lab Status	OK
Sample comment	ANALYZED IN ERROR
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	60
Celerion Study Number	AA99128-01
Date of Collection	2014-MAY-12
Timepoint-minutes	0
Urine Start Day	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

Form: Biomarker-Plasma (Nic, Cot, tHCot) (1)

Data signed: (hfarmer1) 30 Mar 2015 13:35:43

Generated On: 20 Jul 2016 22:28:45

Urine End Day

60

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

Form: Biomarker-Plasma (Nic, Cot, tHCot) (2)

Data signed: (hfarmer1) 30 Mar 2015 13:35:43

Generated On: 20 Jul 2016 22:28:45

Sample Barcode	05112430001823
----------------	----------------

Analyte	NIC
---------	-----

Sample type	PLASMA
-------------	--------

Result	14.4
--------	------

Result Unit	NG/ML
-------------	-------

Lab Status	OK
------------	----

Sample comment	ANALYZED IN ERROR
----------------	-------------------

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	60
--------------	----

Celerion Study Number	AA99128-01
-----------------------	------------

Date of Collection	2014-MAY-12
--------------------	-------------

Timepoint-minutes	0
-------------------	---

Urine Start Day	
-----------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Day 60

Form: Biomarker-Plasma (Nic, Cot, tHCot) (2)

Data signed: (hfarmer1) 30 Mar 2015 13:35:43

Generated On: 20 Jul 2016 22:28:45

Urine End Day

60

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Product administration-mCC

Data signed: (hfarmer1) 30 Mar 2015 13:35:45

Generated On: 20 Jul 2016 22:28:45

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Product administration-mCC (1)

Data signed: (hfarmer1) 30 Mar 2015 13:35:45

Generated On: 20 Jul 2016 22:28:45

Date of product use DD/MMM/YYYY	03 APR 2014
------------------------------------	-------------

Visit	Day -1 <input checked="" type="radio"/>
-------	---

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	06:35
----------------------	-------

Time of butt return	06:43
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Product Use

Form: Product administration-mCC (1)

Data signed: (hfarmer1) 30 Mar 2015 13:35:45

Generated On: 20 Jul 2016 22:28:45

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Product Use

Form: Product administration-mCC (2)

Data signed: (hfarmer1) 30 Mar 2015 13:35:45

Generated On: 20 Jul 2016 22:28:45

Date of product use DD/MMM/YYYY	03 APR 2014
------------------------------------	-------------

Visit	Day -1 <input checked="" type="radio"/>
-------	---

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	07:22
----------------------	-------

Time of butt return	07:28
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Product Use

Form: Product administration-mCC (2)

Data signed: (hfarmer1) 30 Mar 2015 13:35:45

Generated On: 20 Jul 2016 22:28:45

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Product administration-mCC (3)

Data signed: (hfarmer1) 30 Mar 2015 13:35:45

Generated On: 20 Jul 2016 22:28:45

Date of product use DD/MMM/YYYY	03 APR 2014
------------------------------------	-------------

Visit	Day -1 <input checked="" type="radio"/>
-------	---

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	09:00
----------------------	-------

Time of butt return	09:07
---------------------	-------

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: 1252

Folder: Product Use

Form: Product administration-mCC (3)

Data signed: (hfarmer1) 30 Mar 2015 13:35:45

Generated On: 20 Jul 2016 22:28:45

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Product administration-mCC (4)

Data signed: (hfarmer1) 30 Mar 2015 13:35:45

Generated On: 20 Jul 2016 22:28:45

Date of product use DD/MMM/YYYY	03 APR 2014
------------------------------------	-------------

Visit	Day -1 <input checked="" type="radio"/>
-------	---

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	09:57
----------------------	-------

Time of butt return	10:12
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Product Use

Form: Product administration-mCC (4)

Data signed: (hfarmer1) 30 Mar 2015 13:35:45

Generated On: 20 Jul 2016 22:28:45

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Product administration-mCC (5)

Data signed: (hfarmer1) 30 Mar 2015 13:35:45

Generated On: 20 Jul 2016 22:28:45

Date of product use DD/MMM/YYYY	03 APR 2014
------------------------------------	-------------

Visit	Day -1 <input checked="" type="radio"/>
-------	---

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	10:51
----------------------	-------

Time of butt return	10:56
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Product Use

Form: Product administration-mCC (5)

Data signed: (hfarmer1) 30 Mar 2015 13:35:45

Generated On: 20 Jul 2016 22:28:45

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Product administration-mCC (6)

Data signed: (hfarmer1) 30 Mar 2015 13:35:45

Generated On: 20 Jul 2016 22:28:45

Date of product use DD/MMM/YYYY	03 APR 2014
------------------------------------	-------------

Visit	Day -1 <input checked="" type="radio"/>
-------	---

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	11:29
----------------------	-------

Time of butt return	11:35
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Product Use

Form: Product administration-mCC (6)

Data signed: (hfarmer1) 30 Mar 2015 13:35:45

Generated On: 20 Jul 2016 22:28:45

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Product Use

Form: Product administration-mCC (7)

Data signed: (hfarmer1) 30 Mar 2015 13:35:45

Generated On: 20 Jul 2016 22:28:45

Date of product use DD/MMM/YYYY	03 APR 2014
------------------------------------	-------------

Visit	Day -1 <input checked="" type="radio"/>
-------	---

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	12:19
----------------------	-------

Time of butt return	12:26
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Product Use

Form: Product administration-mCC (7)

Data signed: (hfarmer1) 30 Mar 2015 13:35:45

Generated On: 20 Jul 2016 22:28:45

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Product administration-mCC (8)

Data signed: (hfarmer1) 30 Mar 2015 13:35:45

Generated On: 20 Jul 2016 22:28:45

Date of product use DD/MMM/YYYY	03 APR 2014
------------------------------------	-------------

Visit	Day -1 <input checked="" type="radio"/>
-------	---

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	13:23
----------------------	-------

Time of butt return	13:31
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Product Use

Form: Product administration-mCC (8)

Data signed: (hfarmer1) 30 Mar 2015 13:35:45

Generated On: 20 Jul 2016 22:28:45

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Product administration-mCC (9)

Data signed: (hfarmer1) 30 Mar 2015 13:35:45

Generated On: 20 Jul 2016 22:28:45

Date of product use DD/MMM/YYYY	03 APR 2014
------------------------------------	-------------

Visit	Day -1 <input checked="" type="radio"/>
-------	---

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	14:28
----------------------	-------

Time of butt return	_____
---------------------	-------

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: 1252

Folder: Product Use

Form: Product administration-mCC (9)

Data signed: (hfarmer1) 30 Mar 2015 13:35:45

Generated On: 20 Jul 2016 22:28:45

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Product administration-mCC (10)

Data signed: (hfarmer1) 30 Mar 2015 13:35:45

Generated On: 20 Jul 2016 22:28:45

Date of product use DD/MMM/YYYY	03 APR 2014
------------------------------------	-------------

Visit	Day -1 <input checked="" type="radio"/>
-------	---

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	14:52
----------------------	-------

Time of butt return	14:59
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Product Use

Form: Product administration-mCC (10)

Data signed: (hfarmer1) 30 Mar 2015 13:35:45

Generated On: 20 Jul 2016 22:28:45

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Product administration-mCC (11)

Data signed: (hfarmer1) 30 Mar 2015 13:35:45

Generated On: 20 Jul 2016 22:28:45

Date of product use DD/MMM/YYYY	03 APR 2014
------------------------------------	-------------

Visit	Day -1 <input checked="" type="radio"/>
-------	---

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	15:42
----------------------	-------

Time of butt return	15:48
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Product Use

Form: Product administration-mCC (11)

Data signed: (hfarmer1) 30 Mar 2015 13:35:45

Generated On: 20 Jul 2016 22:28:45

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Product administration-mCC (12)

Data signed: (hfarmer1) 30 Mar 2015 13:35:45

Generated On: 20 Jul 2016 22:28:45

Date of product use DD/MMM/YYYY	03 APR 2014
------------------------------------	-------------

Visit	Day -1 <input checked="" type="radio"/>
-------	---

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	16:57
----------------------	-------

Time of butt return	17:02
---------------------	-------

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: 1252

Folder: Product Use

Form: Product administration-mCC (12)

Data signed: (hfarmer1) 30 Mar 2015 13:35:45

Generated On: 20 Jul 2016 22:28:45

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Product administration-mCC (13)

Data signed: (hfarmer1) 30 Mar 2015 13:35:45

Generated On: 20 Jul 2016 22:28:45

Date of product use DD/MMM/YYYY	03 APR 2014
------------------------------------	-------------

Visit	Day -1 <input checked="" type="radio"/>
-------	---

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	18:00
----------------------	-------

Time of butt return	18:05
---------------------	-------

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: 1252

Folder: Product Use

Form: Product administration-mCC (13)

Data signed: (hfarmer1) 30 Mar 2015 13:35:45

Generated On: 20 Jul 2016 22:28:45

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Product administration-mCC (14)

Data signed: (hfarmer1) 30 Mar 2015 13:35:45

Generated On: 20 Jul 2016 22:28:45

Date of product use DD/MMM/YYYY	03 APR 2014
------------------------------------	-------------

Visit	Day -1 <input checked="" type="radio"/>
-------	---

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	18:43
----------------------	-------

Time of butt return	18:50
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Product Use

Form: Product administration-mCC (14)

Data signed: (hfarmer1) 30 Mar 2015 13:35:45

Generated On: 20 Jul 2016 22:28:45

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Product administration-mCC (15)

Data signed: (hfarmer1) 30 Mar 2015 13:35:45

Generated On: 20 Jul 2016 22:28:45

Date of product use DD/MMM/YYYY	03 APR 2014
------------------------------------	-------------

Visit	Day -1 <input checked="" type="radio"/>
-------	---

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	19:26
----------------------	-------

Time of butt return	19:34
---------------------	-------

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: 1252

Folder: Product Use

Form: Product administration-mCC (15)

Data signed: (hfarmer1) 30 Mar 2015 13:35:45

Generated On: 20 Jul 2016 22:28:45

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Product administration-mCC (16)

Data signed: (hfarmer1) 30 Mar 2015 13:35:45

Generated On: 20 Jul 2016 22:28:45

Date of product use DD/MMM/YYYY	03 APR 2014
------------------------------------	-------------

Visit	Day -1 <input checked="" type="radio"/>
-------	---

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	20:23
----------------------	-------

Time of butt return	20:30
---------------------	-------

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: 1252

Folder: Product Use

Form: Product administration-mCC (16)

Data signed: (hfarmer1) 30 Mar 2015 13:35:45

Generated On: 20 Jul 2016 22:28:45

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Product Use

Form: Product administration-mCC (17)

Data signed: (hfarmer1) 30 Mar 2015 13:35:45

Generated On: 20 Jul 2016 22:28:45

Date of product use DD/MMM/YYYY	03 APR 2014
------------------------------------	-------------

Visit	Day -1 <input checked="" type="radio"/>
-------	---

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	21:43
----------------------	-------

Time of butt return	21:50
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Product Use

Form: Product administration-mCC (17)

Data signed: (hfarmer1) 30 Mar 2015 13:35:45

Generated On: 20 Jul 2016 22:28:45

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Product administration-mCC (18)

Data signed: (hfarmer1) 30 Mar 2015 13:35:45

Generated On: 20 Jul 2016 22:28:45

Date of product use DD/MMM/YYYY	03 APR 2014
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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	22:30
----------------------	-------

Time of butt return	22:37
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Product Use

Form: Product administration-mCC (18)

Data signed: (hfarmer1) 30 Mar 2015 13:35:45

Generated On: 20 Jul 2016 22:28:45

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Product administration-mCC (19)

Data signed: (hfarmer1) 30 Mar 2015 13:35:45

Generated On: 20 Jul 2016 22:28:45

Date of product use DD/MMM/YYYY	04 APR 2014
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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	09:21
----------------------	-------

Time of butt return	09:28
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	157
---------------------	-----

SODIM sample holder number	0212
----------------------------	------

SODIM file number	08DY0157COHM10212001
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Product Use

Form: Product administration-mCC (19)

Data signed: (hfarmer1) 30 Mar 2015 13:35:45

Generated On: 20 Jul 2016 22:28:45

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Product administration-mCC (20)

Data signed: (hfarmer1) 30 Mar 2015 13:35:45

Generated On: 20 Jul 2016 22:28:45

Date of product use DD/MMM/YYYY	04 APR 2014
------------------------------------	-------------

Visit	Day 0 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	10:02
----------------------	-------

Time of butt return	10:08
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	157
---------------------	-----

SODIM sample holder number	0212
----------------------------	------

SODIM file number	08DY0157COHM10212002
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Product Use

Form: Product administration-mCC (20)

Data signed: (hfarmer1) 30 Mar 2015 13:35:45

Generated On: 20 Jul 2016 22:28:45

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Product administration-mCC (21)

Data signed: (hfarmer1) 30 Mar 2015 13:35:45

Generated On: 20 Jul 2016 22:28:45

Date of product use DD/MMM/YYYY	04 APR 2014
------------------------------------	-------------

Visit	Day 0 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	10:34
----------------------	-------

Time of butt return	10:41
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	157
---------------------	-----

SODIM sample holder number	0212
----------------------------	------

SODIM file number	08DY0157COHM10212003
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Product Use

Form: Product administration-mCC (21)

Data signed: (hfarmer1) 30 Mar 2015 13:35:45

Generated On: 20 Jul 2016 22:28:45

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Product administration-mCC (22)

Data signed: (hfarmer1) 30 Mar 2015 13:35:45

Generated On: 20 Jul 2016 22:28:45

Date of product use DD/MMM/YYYY	04 APR 2014
------------------------------------	-------------

Visit	Day 0 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	11:15
----------------------	-------

Time of butt return	11:22
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	157
---------------------	-----

SODIM sample holder number	0212
----------------------------	------

SODIM file number	08DY0157COHM10212004
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Product Use

Form: Product administration-mCC (22)

Data signed: (hfarmer1) 30 Mar 2015 13:35:45

Generated On: 20 Jul 2016 22:28:45

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Product administration-mCC (23)

Data signed: (hfarmer1) 30 Mar 2015 13:35:45

Generated On: 20 Jul 2016 22:28:45

Date of product use DD/MMM/YYYY	04 APR 2014
------------------------------------	-------------

Visit	Day 0 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	12:04
----------------------	-------

Time of butt return	12:10
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	157
---------------------	-----

SODIM sample holder number	0212
----------------------------	------

SODIM file number	08DY0157COHM10212005
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Product Use

Form: Product administration-mCC (23)

Data signed: (hfarmer1) 30 Mar 2015 13:35:45

Generated On: 20 Jul 2016 22:28:45

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Product administration-mCC (24)

Data signed: (hfarmer1) 30 Mar 2015 13:35:45

Generated On: 20 Jul 2016 22:28:45

Date of product use DD/MMM/YYYY	04 APR 2014
------------------------------------	-------------

Visit	Day 0 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	12:44
----------------------	-------

Time of butt return	12:50
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	157
---------------------	-----

SODIM sample holder number	0212
----------------------------	------

SODIM file number	08DY0157COHM10212006
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Product Use

Form: Product administration-mCC (24)

Data signed: (hfarmer1) 30 Mar 2015 13:35:45

Generated On: 20 Jul 2016 22:28:45

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Product administration-mCC (25)

Data signed: (hfarmer1) 30 Mar 2015 13:35:45

Generated On: 20 Jul 2016 22:28:45

Date of product use DD/MMM/YYYY	04 APR 2014
------------------------------------	-------------

Visit	Day 0 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	13:26
----------------------	-------

Time of butt return	13:32
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	157
---------------------	-----

SODIM sample holder number	0212
----------------------------	------

SODIM file number	08DY0157COHM10212007
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Product Use

Form: Product administration-mCC (25)

Data signed: (hfarmer1) 30 Mar 2015 13:35:45

Generated On: 20 Jul 2016 22:28:45

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Product administration-mCC (26)

Data signed: (hfarmer1) 30 Mar 2015 13:35:45

Generated On: 20 Jul 2016 22:28:45

Date of product use DD/MMM/YYYY	04 APR 2014
------------------------------------	-------------

Visit	Day 0 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	14:24
----------------------	-------

Time of butt return	14:29
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	157
---------------------	-----

SODIM sample holder number	0212
----------------------------	------

SODIM file number	08DY0157COHM10212008
-------------------	----------------------

Comment	_____
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Product Use

Form: Product administration-mCC (26)

Data signed: (hfarmer1) 30 Mar 2015 13:35:45

Generated On: 20 Jul 2016 22:28:45

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Product administration-mCC (27)

Data signed: (hfarmer1) 30 Mar 2015 13:35:45

Generated On: 20 Jul 2016 22:28:45

Date of product use DD/MMM/YYYY	04 APR 2014
------------------------------------	-------------

Visit	Day 0 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	15:15
----------------------	-------

Time of butt return	15:22
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	157
---------------------	-----

SODIM sample holder number	0212
----------------------------	------

SODIM file number	08DY0157COHM10212009
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Product Use

Form: Product administration-mCC (27)

Data signed: (hfarmer1) 30 Mar 2015 13:35:45

Generated On: 20 Jul 2016 22:28:45

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Product administration-mCC (28)

Data signed: (hfarmer1) 30 Mar 2015 13:35:45

Generated On: 20 Jul 2016 22:28:45

Date of product use DD/MMM/YYYY	04 APR 2014
------------------------------------	-------------

Visit	Day 0 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	15:55
----------------------	-------

Time of butt return	16:01
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	157
---------------------	-----

SODIM sample holder number	0212
----------------------------	------

SODIM file number	08DY0157COHM10212010
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Product Use

Form: Product administration-mCC (28)

Data signed: (hfarmer1) 30 Mar 2015 13:35:45

Generated On: 20 Jul 2016 22:28:45

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Product administration-mCC (29)

Data signed: (hfarmer1) 30 Mar 2015 13:35:45

Generated On: 20 Jul 2016 22:28:45

Date of product use DD/MMM/YYYY	04 APR 2014
------------------------------------	-------------

Visit	Day 0 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	17:05
----------------------	-------

Time of butt return	17:11
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	157
---------------------	-----

SODIM sample holder number	0212
----------------------------	------

SODIM file number	08DY0157COHM10212011
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Product Use

Form: Product administration-mCC (29)

Data signed: (hfarmer1) 30 Mar 2015 13:35:45

Generated On: 20 Jul 2016 22:28:45

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Product administration-mCC (30)

Data signed: (hfarmer1) 30 Mar 2015 13:35:45

Generated On: 20 Jul 2016 22:28:45

Date of product use DD/MMM/YYYY	04 APR 2014
------------------------------------	-------------

Visit	Day 0 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	18:21
----------------------	-------

Time of butt return	18:31
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	157
---------------------	-----

SODIM sample holder number	0212
----------------------------	------

SODIM file number	08DY0157COHM10212012
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Product Use

Form: Product administration-mCC (30)

Data signed: (hfarmer1) 30 Mar 2015 13:35:45

Generated On: 20 Jul 2016 22:28:45

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Product administration-mCC (31)

Data signed: (hfarmer1) 30 Mar 2015 13:35:45

Generated On: 20 Jul 2016 22:28:45

Date of product use DD/MMM/YYYY	04 APR 2014
------------------------------------	-------------

Visit	Day 0 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	19:06
----------------------	-------

Time of butt return	19:13
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	157
---------------------	-----

SODIM sample holder number	0212
----------------------------	------

SODIM file number	08DY0157COHM10212013
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Product Use

Form: Product administration-mCC (31)

Data signed: (hfarmer1) 30 Mar 2015 13:35:45

Generated On: 20 Jul 2016 22:28:45

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Product administration-mCC (32)

Data signed: (hfarmer1) 30 Mar 2015 13:35:45

Generated On: 20 Jul 2016 22:28:45

Date of product use DD/MMM/YYYY	04 APR 2014
------------------------------------	-------------

Visit	Day 0 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	19:52
----------------------	-------

Time of butt return	19:58
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	157
---------------------	-----

SODIM sample holder number	0212
----------------------------	------

SODIM file number	08DY0157COHM10212014
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Product Use

Form: Product administration-mCC (32)

Data signed: (hfarmer1) 30 Mar 2015 13:35:45

Generated On: 20 Jul 2016 22:28:45

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Product administration-mCC (33)

Data signed: (hfarmer1) 30 Mar 2015 13:35:45

Generated On: 20 Jul 2016 22:28:45

Date of product use DD/MMM/YYYY	04 APR 2014
------------------------------------	-------------

Visit	Day 0 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	20:49
----------------------	-------

Time of butt return	20:54
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	157
---------------------	-----

SODIM sample holder number	0212
----------------------------	------

SODIM file number	08DY0157COHM10212015
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Product Use

Form: Product administration-mCC (33)

Data signed: (hfarmer1) 30 Mar 2015 13:35:45

Generated On: 20 Jul 2016 22:28:45

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Product administration-mCC (34)

Data signed: (hfarmer1) 30 Mar 2015 13:35:45

Generated On: 20 Jul 2016 22:28:45

Date of product use DD/MMM/YYYY	04 APR 2014
------------------------------------	-------------

Visit	Day 0 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	21:25
----------------------	-------

Time of butt return	21:32
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	157
---------------------	-----

SODIM sample holder number	0212
----------------------------	------

SODIM file number	08DY0157COHM10212016
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Product Use

Form: Product administration-mCC (34)

Data signed: (hfarmer1) 30 Mar 2015 13:35:45

Generated On: 20 Jul 2016 22:28:45

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Product administration-mCC (35)

Data signed: (hfarmer1) 30 Mar 2015 13:35:45

Generated On: 20 Jul 2016 22:28:45

Date of product use DD/MMM/YYYY	04 APR 2014
------------------------------------	-------------

Visit	Day 0 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	22:16
----------------------	-------

Time of butt return	22:23
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	157
---------------------	-----

SODIM sample holder number	0212
----------------------------	------

SODIM file number	08DY0157COHM10212017
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Product Use

Form: Product administration-mCC (35)

Data signed: (hfarmer1) 30 Mar 2015 13:35:45

Generated On: 20 Jul 2016 22:28:45

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Product administration-THS menthol

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Product administration-THS menthol (1)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

Date of product use DD/MMM/YYYY	05 APR 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	07:28
----------------------	-------

Time of product return	07:34
------------------------	-------

SODIM device number	157
---------------------	-----

SODIM sample holder number	1010
----------------------------	------

Tobacco plug kit number	T1985
-------------------------	-------

Tobacco plug vial number	01
--------------------------	----

SODIM file number	08DY0157COHM11010001
-------------------	----------------------

Comment	_____
---------	-------

Batch Number	B08545
--------------	--------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Product Use

Form: Product administration-THS menthol (1)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Product administration-THS menthol (2)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

Date of product use DD/MMM/YYYY	05 APR 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	07:49
----------------------	-------

Time of product return	07:56
------------------------	-------

SODIM device number	157
---------------------	-----

SODIM sample holder number	1010
----------------------------	------

Tobacco plug kit number	T1985
-------------------------	-------

Tobacco plug vial number	02
--------------------------	----

SODIM file number	08DY0157COHM11010002
-------------------	----------------------

Comment	_____
---------	-------

Batch Number	B08545
--------------	--------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Product Use

Form: Product administration-THS menthol (2)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Product administration-THS menthol (3)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

Date of product use DD/MMM/YYYY	05 APR 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	08:32
----------------------	-------

Time of product return	08:39
------------------------	-------

SODIM device number	157
---------------------	-----

SODIM sample holder number	1010
----------------------------	------

Tobacco plug kit number	T1985
-------------------------	-------

Tobacco plug vial number	03
--------------------------	----

SODIM file number	08DY0157COHM11010003
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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: 1252

Folder: Product Use

Form: Product administration-THS menthol (3)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Product administration-THS menthol (4)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

Date of product use DD/MMM/YYYY	05 APR 2014
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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	09:07
----------------------	-------

Time of product return	09:13
------------------------	-------

SODIM device number	157
---------------------	-----

SODIM sample holder number	1010
----------------------------	------

Tobacco plug kit number	T1985
-------------------------	-------

Tobacco plug vial number	04
--------------------------	----

SODIM file number	08DY0157COHM11010004
-------------------	----------------------

Comment	_____
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Batch Number	B08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Product Use

Form: Product administration-THS menthol (4)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Product administration-THS menthol (5)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

Date of product use DD/MMM/YYYY	05 APR 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	10:34
----------------------	-------

Time of product return	10:39
------------------------	-------

SODIM device number	157
---------------------	-----

SODIM sample holder number	1010
----------------------------	------

Tobacco plug kit number	T1985
-------------------------	-------

Tobacco plug vial number	05
--------------------------	----

SODIM file number	08DY0157COHM11010005
-------------------	----------------------

Comment	_____
---------	-------

Batch Number	B08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Product Use

Form: Product administration-THS menthol (5)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Product administration-THS menthol (6)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

Date of product use DD/MMM/YYYY	05 APR 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	11:21
----------------------	-------

Time of product return	11:25
------------------------	-------

SODIM device number	157
---------------------	-----

SODIM sample holder number	1010
----------------------------	------

Tobacco plug kit number	T1985
-------------------------	-------

Tobacco plug vial number	06
--------------------------	----

SODIM file number	08DY0157COHM11010006
-------------------	----------------------

Comment	_____
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Batch Number	B08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Product Use

Form: Product administration-THS menthol (6)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Product administration-THS menthol (7)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

Date of product use DD/MMM/YYYY	05 APR 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	12:12
----------------------	-------

Time of product return	12:20
------------------------	-------

SODIM device number	157
---------------------	-----

SODIM sample holder number	1010
----------------------------	------

Tobacco plug kit number	T1985
-------------------------	-------

Tobacco plug vial number	07
--------------------------	----

SODIM file number	08DY0157COHM11010007
-------------------	----------------------

Comment	_____
---------	-------

Batch Number	B08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Product Use

Form: Product administration-THS menthol (7)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Product administration-THS menthol (8)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

Date of product use DD/MMM/YYYY	05 APR 2014
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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	12:53
----------------------	-------

Time of product return	12:59
------------------------	-------

SODIM device number	157
---------------------	-----

SODIM sample holder number	1010
----------------------------	------

Tobacco plug kit number	T1985
-------------------------	-------

Tobacco plug vial number	08
--------------------------	----

SODIM file number	08DY0157COHM11010008
-------------------	----------------------

Comment	_____
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Batch Number	B08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Product Use

Form: Product administration-THS menthol (8)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Product administration-THS menthol (9)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

Date of product use DD/MMM/YYYY	05 APR 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	13:39
----------------------	-------

Time of product return	13:45
------------------------	-------

SODIM device number	157
---------------------	-----

SODIM sample holder number	1010
----------------------------	------

Tobacco plug kit number	T1985
-------------------------	-------

Tobacco plug vial number	09
--------------------------	----

SODIM file number	08DY0157COHM11010008
-------------------	----------------------

Comment	_____
---------	-------

Batch Number	B08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Product Use

Form: Product administration-THS menthol (9)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Product administration-THS menthol (10)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

Date of product use DD/MMM/YYYY	05 APR 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	14:59
----------------------	-------

Time of product return	15:06
------------------------	-------

SODIM device number	157
---------------------	-----

SODIM sample holder number	1010
----------------------------	------

Tobacco plug kit number	T1985
-------------------------	-------

Tobacco plug vial number	10
--------------------------	----

SODIM file number	08DY0157COHM11010009
-------------------	----------------------

Comment	_____
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Batch Number	B08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Product Use

Form: Product administration-THS menthol (10)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Product administration-THS menthol (11)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

Date of product use DD/MMM/YYYY	05 APR 2014
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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	16:06
----------------------	-------

Time of product return	16:13
------------------------	-------

SODIM device number	157
---------------------	-----

SODIM sample holder number	1010
----------------------------	------

Tobacco plug kit number	T1985
-------------------------	-------

Tobacco plug vial number	11
--------------------------	----

SODIM file number	08DY0157COHM11010010
-------------------	----------------------

Comment	_____
---------	-------

Batch Number	B08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Product Use

Form: Product administration-THS menthol (11)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Product administration-THS menthol (12)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

Date of product use DD/MMM/YYYY	05 APR 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	17:10
----------------------	-------

Time of product return	17:17
------------------------	-------

SODIM device number	157
---------------------	-----

SODIM sample holder number	1010
----------------------------	------

Tobacco plug kit number	T1985
-------------------------	-------

Tobacco plug vial number	12
--------------------------	----

SODIM file number	08DY0157COHM11010012
-------------------	----------------------

Comment	_____
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Batch Number	B08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Product Use

Form: Product administration-THS menthol (12)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Product administration-THS menthol (13)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

Date of product use DD/MMM/YYYY	05 APR 2014
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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	18:36
----------------------	-------

Time of product return	18:42
------------------------	-------

SODIM device number	157
---------------------	-----

SODIM sample holder number	1010
----------------------------	------

Tobacco plug kit number	T1985
-------------------------	-------

Tobacco plug vial number	13
--------------------------	----

SODIM file number	08DY0157COHM11010012
-------------------	----------------------

Comment	_____
---------	-------

Batch Number	B08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Product Use

Form: Product administration-THS menthol (13)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Product administration-THS menthol (14)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

Date of product use DD/MMM/YYYY	05 APR 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	19:22
----------------------	-------

Time of product return	19:29
------------------------	-------

SODIM device number	157
---------------------	-----

SODIM sample holder number	1010
----------------------------	------

Tobacco plug kit number	T1985
-------------------------	-------

Tobacco plug vial number	14
--------------------------	----

SODIM file number	08DY0157COHM11010013
-------------------	----------------------

Comment	_____
---------	-------

Batch Number	B08545
--------------	--------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Product Use

Form: Product administration-THS menthol (14)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Product administration-THS menthol (15)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

Date of product use DD/MMM/YYYY	05 APR 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	20:39
----------------------	-------

Time of product return	20:46
------------------------	-------

SODIM device number	157
---------------------	-----

SODIM sample holder number	1010
----------------------------	------

Tobacco plug kit number	T1985
-------------------------	-------

Tobacco plug vial number	15
--------------------------	----

SODIM file number	08DY0157COHM11010014
-------------------	----------------------

Comment	_____
---------	-------

Batch Number	B08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Product Use

Form: Product administration-THS menthol (15)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Product administration-THS menthol (16)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

Date of product use DD/MMM/YYYY	05 APR 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	20:47
----------------------	-------

Time of product return	20:53
------------------------	-------

SODIM device number	157
---------------------	-----

SODIM sample holder number	1010
----------------------------	------

Tobacco plug kit number	T1985
-------------------------	-------

Tobacco plug vial number	16
--------------------------	----

SODIM file number	08DY0157COHM11010015
-------------------	----------------------

Comment	_____
---------	-------

Batch Number	B08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Product Use

Form: Product administration-THS menthol (16)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Product administration-THS menthol (17)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

Date of product use DD/MMM/YYYY	05 APR 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	21:46
----------------------	-------

Time of product return	21:52
------------------------	-------

SODIM device number	157
---------------------	-----

SODIM sample holder number	1010
----------------------------	------

Tobacco plug kit number	T1985
-------------------------	-------

Tobacco plug vial number	17
--------------------------	----

SODIM file number	08DY0157COHM11010016
-------------------	----------------------

Comment	_____
---------	-------

Batch Number	B08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Product Use

Form: Product administration-THS menthol (17)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Product administration-THS menthol (18)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

Date of product use DD/MMM/YYYY	05 APR 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	22:27
------------------------	-------

SODIM device number	157
---------------------	-----

SODIM sample holder number	1010
----------------------------	------

Tobacco plug kit number	T1985
-------------------------	-------

Tobacco plug vial number	18
--------------------------	----

SODIM file number	08DY0157COHM11010017
-------------------	----------------------

Comment	_____
---------	-------

Batch Number	B08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Product Use

Form: Product administration-THS menthol (18)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Product administration-THS menthol (19)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

Date of product use DD/MMM/YYYY	06 APR 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	06:39
----------------------	-------

Time of product return	06:45
------------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

Tobacco plug kit number	T1993
-------------------------	-------

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: 1252

Folder: Product Use

Form: Product administration-THS menthol (19)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Product administration-THS menthol (20)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

Date of product use DD/MMM/YYYY	06 APR 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	06:49
----------------------	-------

Time of product return	06:57
------------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

Tobacco plug kit number	T1993
-------------------------	-------

Tobacco plug vial number	02
--------------------------	----

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: 1252

Folder: Product Use

Form: Product administration-THS menthol (20)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Product administration-THS menthol (21)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

Date of product use DD/MMM/YYYY	06 APR 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	07:33
----------------------	-------

Time of product return	07:39
------------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

Tobacco plug kit number	T1993
-------------------------	-------

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: 1252

Folder: Product Use

Form: Product administration-THS menthol (21)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Product administration-THS menthol (22)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

Date of product use DD/MMM/YYYY	06 APR 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	09:03
----------------------	-------

Time of product return	09:09
------------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

Tobacco plug kit number	T1993
-------------------------	-------

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: 1252

Folder: Product Use

Form: Product administration-THS menthol (22)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Product administration-THS menthol (23)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

Date of product use DD/MMM/YYYY	06 APR 2014
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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	09:18
----------------------	-------

Time of product return	09:24
------------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

Tobacco plug kit number	T1993
-------------------------	-------

Tobacco plug vial number	05
--------------------------	----

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: 1252

Folder: Product Use

Form: Product administration-THS menthol (23)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Product administration-THS menthol (24)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

Date of product use DD/MMM/YYYY	06 APR 2014
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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	10:13
----------------------	-------

Time of product return	10:19
------------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

Tobacco plug kit number	T1993
-------------------------	-------

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: 1252

Folder: Product Use

Form: Product administration-THS menthol (24)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Product administration-THS menthol (25)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

Date of product use DD/MMM/YYYY	06 APR 2014
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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	11:13
----------------------	-------

Time of product return	11:18
------------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

Tobacco plug kit number	T1993
-------------------------	-------

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: 1252

Folder: Product Use

Form: Product administration-THS menthol (25)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Product administration-THS menthol (26)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

Date of product use DD/MMM/YYYY	06 APR 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	12:15
----------------------	-------

Time of product return	12:20
------------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

Tobacco plug kit number	T1993
-------------------------	-------

Tobacco plug vial number	09
--------------------------	----

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

Batch Number	B08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Product Use

Form: Product administration-THS menthol (26)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Product administration-THS menthol (27)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

Date of product use DD/MMM/YYYY	06 APR 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	12:21
----------------------	-------

Time of product return	12:28
------------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

Tobacco plug kit number	T1993
-------------------------	-------

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: 1252

Folder: Product Use

Form: Product administration-THS menthol (27)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Product administration-THS menthol (28)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

Date of product use DD/MMM/YYYY	06 APR 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	13:19
----------------------	-------

Time of product return	13:27
------------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

Tobacco plug kit number	T1993
-------------------------	-------

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: 1252

Folder: Product Use

Form: Product administration-THS menthol (28)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Product administration-THS menthol (29)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

Date of product use DD/MMM/YYYY	06 APR 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	14:25
----------------------	-------

Time of product return	14:30
------------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

Tobacco plug kit number	T1993
-------------------------	-------

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: 1252

Folder: Product Use

Form: Product administration-THS menthol (29)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Product administration-THS menthol (30)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

Date of product use DD/MMM/YYYY	06 APR 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	15:01
----------------------	-------

Time of product return	15:06
------------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

Tobacco plug kit number	T1993
-------------------------	-------

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: 1252

Folder: Product Use

Form: Product administration-THS menthol (30)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Product administration-THS menthol (31)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

Date of product use DD/MMM/YYYY	06 APR 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	15:55
----------------------	-------

Time of product return	16:02
------------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

Tobacco plug kit number	T1993
-------------------------	-------

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: 1252

Folder: Product Use

Form: Product administration-THS menthol (31)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Product administration-THS menthol (32)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

Date of product use DD/MMM/YYYY	06 APR 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	17:14
----------------------	-------

Time of product return	17:20
------------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

Tobacco plug kit number	T1993
-------------------------	-------

Tobacco plug vial number	15
--------------------------	----

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

Batch Number	B08545
--------------	--------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Product Use

Form: Product administration-THS menthol (32)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Product administration-THS menthol (33)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

Date of product use DD/MMM/YYYY	06 APR 2014
------------------------------------	-------------

Visit	Day 2 <input type="radio"/>
-------	-----------------------------

Type of Product Use	THS 2.2 Menthol <input type="radio"/>
---------------------	---------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	18:35
----------------------	-------

Time of product return	18:42
------------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

Tobacco plug kit number	T1993
-------------------------	-------

Tobacco plug vial number	16
--------------------------	----

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

Batch Number	B08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Product Use

Form: Product administration-THS menthol (33)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Product administration-THS menthol (34)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

Date of product use DD/MMM/YYYY	06 APR 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	19:29
----------------------	-------

Time of product return	19:36
------------------------	-------

SODIM device number	
---------------------	--

SODIM sample holder number	
----------------------------	--

Tobacco plug kit number	T1993
-------------------------	-------

Tobacco plug vial number	17
--------------------------	----

SODIM file number	
-------------------	--

Comment	
---------	--

Batch Number	B08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Product Use

Form: Product administration-THS menthol (34)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Product administration-THS menthol (35)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

Date of product use DD/MMM/YYYY	06 APR 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	20:32
----------------------	-------

Time of product return	20:38
------------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

Tobacco plug kit number	T1993
-------------------------	-------

Tobacco plug vial number	18
--------------------------	----

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

Batch Number	B08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Product Use

Form: Product administration-THS menthol (35)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Product administration-THS menthol (36)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

Date of product use DD/MMM/YYYY	06 APR 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	21:10
----------------------	-------

Time of product return	21:16
------------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

Tobacco plug kit number	T1993
-------------------------	-------

Tobacco plug vial number	19
--------------------------	----

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

Batch Number	B08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Product Use

Form: Product administration-THS menthol (36)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Product administration-THS menthol (37)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

Date of product use DD/MMM/YYYY	06 APR 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	22:03
----------------------	-------

Time of product return	22:10
------------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

Tobacco plug kit number	T1993
-------------------------	-------

Tobacco plug vial number	20
--------------------------	----

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

Batch Number	B08545
--------------	--------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Product Use

Form: Product administration-THS menthol (37)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Product administration-THS menthol (38)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

Date of product use DD/MMM/YYYY	07 APR 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	06:35
----------------------	-------

Time of product return	06:46
------------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

Tobacco plug kit number	T2096
-------------------------	-------

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: 1252

Folder: Product Use

Form: Product administration-THS menthol (38)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Product administration-THS menthol (39)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

Date of product use DD/MMM/YYYY	07 APR 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	06:47
----------------------	-------

Time of product return	06:53
------------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

Tobacco plug kit number	T2096
-------------------------	-------

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: 1252

Folder: Product Use

Form: Product administration-THS menthol (39)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Product administration-THS menthol (40)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

Date of product use DD/MMM/YYYY	07 APR 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	07:30
----------------------	-------

Time of product return	07:37
------------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

Tobacco plug kit number	T2096
-------------------------	-------

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: 1252

Folder: Product Use

Form: Product administration-THS menthol (40)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Product administration-THS menthol (41)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

Date of product use DD/MMM/YYYY	07 APR 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	07:59
----------------------	-------

Time of product return	08:07
------------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

Tobacco plug kit number	T2096
-------------------------	-------

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: 1252

Folder: Product Use

Form: Product administration-THS menthol (41)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Product administration-THS menthol (42)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

Date of product use DD/MMM/YYYY	07 APR 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	09:23
----------------------	-------

Time of product return	09:30
------------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

Tobacco plug kit number	T2096
-------------------------	-------

Tobacco plug vial number	05
--------------------------	----

SODIM file number	_____
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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: 1252

Folder: Product Use

Form: Product administration-THS menthol (42)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Product administration-THS menthol (43)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

Date of product use DD/MMM/YYYY	07 APR 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	09:40
----------------------	-------

Time of product return	09:47
------------------------	-------

SODIM device number	
---------------------	--

SODIM sample holder number	
----------------------------	--

Tobacco plug kit number	T2096
-------------------------	-------

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: 1252

Folder: Product Use

Form: Product administration-THS menthol (43)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Product administration-THS menthol (44)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

Date of product use DD/MMM/YYYY	07 APR 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	10:42
----------------------	-------

Time of product return	10:49
------------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

Tobacco plug kit number	T2096
-------------------------	-------

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: 1252

Folder: Product Use

Form: Product administration-THS menthol (44)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Product administration-THS menthol (45)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

Date of product use DD/MMM/YYYY	07 APR 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	10:49
----------------------	-------

Time of product return	10:55
------------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

Tobacco plug kit number	T2096
-------------------------	-------

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: 1252

Folder: Product Use

Form: Product administration-THS menthol (45)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Product administration-THS menthol (46)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

Date of product use DD/MMM/YYYY	07 APR 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	11:54
----------------------	-------

Time of product return	12:00
------------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

Tobacco plug kit number	T2096
-------------------------	-------

Tobacco plug vial number	09
--------------------------	----

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

Batch Number	B08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Product Use

Form: Product administration-THS menthol (46)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Product administration-THS menthol (47)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

Date of product use DD/MMM/YYYY	07 APR 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	12:27
----------------------	-------

Time of product return	12:33
------------------------	-------

SODIM device number	<hr/>
---------------------	-------

SODIM sample holder number	<hr/>
----------------------------	-------

Tobacco plug kit number	T2096
-------------------------	-------

Tobacco plug vial number	10
--------------------------	----

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: 1252

Folder: Product Use

Form: Product administration-THS menthol (47)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Product administration-THS menthol (48)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

Date of product use DD/MMM/YYYY	07 APR 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	12:55
----------------------	-------

Time of product return	13:01
------------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

Tobacco plug kit number	T2096
-------------------------	-------

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: 1252

Folder: Product Use

Form: Product administration-THS menthol (48)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Product administration-THS menthol (49)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

Date of product use DD/MMM/YYYY	07 APR 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	13:02
----------------------	-------

Time of product return	13:08
------------------------	-------

SODIM device number	<hr/>
---------------------	-------

SODIM sample holder number	<hr/>
----------------------------	-------

Tobacco plug kit number	T2096
-------------------------	-------

Tobacco plug vial number	12
--------------------------	----

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: 1252

Folder: Product Use

Form: Product administration-THS menthol (49)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Product administration-THS menthol (50)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

Date of product use DD/MMM/YYYY	07 APR 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	14:08
----------------------	-------

Time of product return	14:13
------------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

Tobacco plug kit number	T2096
-------------------------	-------

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: 1252

Folder: Product Use

Form: Product administration-THS menthol (50)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Product administration-THS menthol (51)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

Date of product use DD/MMM/YYYY	07 APR 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	14:56
----------------------	-------

Time of product return	15:03
------------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

Tobacco plug kit number	T2096
-------------------------	-------

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: 1252

Folder: Product Use

Form: Product administration-THS menthol (51)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Product administration-THS menthol (52)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

Date of product use DD/MMM/YYYY	07 APR 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	15:57
----------------------	-------

Time of product return	16:05
------------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

Tobacco plug kit number	T2096
-------------------------	-------

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: 1252

Folder: Product Use

Form: Product administration-THS menthol (52)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Product administration-THS menthol (53)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

Date of product use DD/MMM/YYYY	07 APR 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	16:58
----------------------	-------

Time of product return	17:03
------------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

Tobacco plug kit number	T2096
-------------------------	-------

Tobacco plug vial number	16
--------------------------	----

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: 1252

Folder: Product Use

Form: Product administration-THS menthol (53)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Product administration-THS menthol (54)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

Date of product use DD/MMM/YYYY	07 APR 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	17:51
----------------------	-------

Time of product return	17:57
------------------------	-------

SODIM device number	<hr/>
---------------------	-------

SODIM sample holder number	<hr/>
----------------------------	-------

Tobacco plug kit number	T2096
-------------------------	-------

Tobacco plug vial number	17
--------------------------	----

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: 1252

Folder: Product Use

Form: Product administration-THS menthol (54)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Product administration-THS menthol (55)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

Date of product use DD/MMM/YYYY	07 APR 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	19:02
----------------------	-------

Time of product return	19:08
------------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

Tobacco plug kit number	T2096
-------------------------	-------

Tobacco plug vial number	18
--------------------------	----

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: 1252

Folder: Product Use

Form: Product administration-THS menthol (55)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Product administration-THS menthol (56)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

Date of product use DD/MMM/YYYY	07 APR 2014
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Visit	Day 3 <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	19:09
----------------------	-------

Time of product return	19:15
------------------------	-------

SODIM device number	<hr/>
---------------------	-------

SODIM sample holder number	<hr/>
----------------------------	-------

Tobacco plug kit number	T2096
-------------------------	-------

Tobacco plug vial number	19
--------------------------	----

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: 1252

Folder: Product Use

Form: Product administration-THS menthol (56)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Product administration-THS menthol (57)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

Date of product use DD/MMM/YYYY	07 APR 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	20:34
----------------------	-------

Time of product return	20:40
------------------------	-------

SODIM device number	<hr/>
---------------------	-------

SODIM sample holder number	<hr/>
----------------------------	-------

Tobacco plug kit number	T2096
-------------------------	-------

Tobacco plug vial number	20
--------------------------	----

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: 1252

Folder: Product Use

Form: Product administration-THS menthol (57)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Product administration-THS menthol (58)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

Date of product use DD/MMM/YYYY	07 APR 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	21:21
----------------------	-------

Time of product return	21:27
------------------------	-------

SODIM device number	<hr/>
---------------------	-------

SODIM sample holder number	<hr/>
----------------------------	-------

Tobacco plug kit number	T2096
-------------------------	-------

Tobacco plug vial number	21
--------------------------	----

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: 1252

Folder: Product Use

Form: Product administration-THS menthol (58)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Product administration-THS menthol (59)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

Date of product use DD/MMM/YYYY	07 APR 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	22:03
----------------------	-------

Time of product return	22:09
------------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

Tobacco plug kit number	T2096
-------------------------	-------

Tobacco plug vial number	22
--------------------------	----

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

Batch Number	B08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Product Use

Form: Product administration-THS menthol (59)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Product administration-THS menthol (60)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

Date of product use DD/MMM/YYYY	07 APR 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	22:20
----------------------	-------

Time of product return	22:25
------------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

Tobacco plug kit number	T2096
-------------------------	-------

Tobacco plug vial number	23
--------------------------	----

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

Batch Number	B08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Product Use

Form: Product administration-THS menthol (60)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Product administration-THS menthol (61)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

Date of product use DD/MMM/YYYY	08 APR 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	07:14
----------------------	-------

Time of product return	07:20
------------------------	-------

SODIM device number	157
---------------------	-----

SODIM sample holder number	1010
----------------------------	------

Tobacco plug kit number	T2100
-------------------------	-------

Tobacco plug vial number	01
--------------------------	----

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: 1252

Folder: Product Use

Form: Product administration-THS menthol (61)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Product administration-THS menthol (62)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

Date of product use DD/MMM/YYYY	08 APR 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	07:22
----------------------	-------

Time of product return	07:27
------------------------	-------

SODIM device number	157
---------------------	-----

SODIM sample holder number	1010
----------------------------	------

Tobacco plug kit number	T2100
-------------------------	-------

Tobacco plug vial number	02
--------------------------	----

SODIM file number	_____
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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: 1252

Folder: Product Use

Form: Product administration-THS menthol (62)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Product administration-THS menthol (63)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

Date of product use DD/MMM/YYYY	08 APR 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	08:03
----------------------	-------

Time of product return	08:10
------------------------	-------

SODIM device number	157
---------------------	-----

SODIM sample holder number	1010
----------------------------	------

Tobacco plug kit number	T2100
-------------------------	-------

Tobacco plug vial number	03
--------------------------	----

SODIM file number	08DY0157COHM11010001
-------------------	----------------------

Comment	_____
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Batch Number	B08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Product Use

Form: Product administration-THS menthol (63)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Product administration-THS menthol (64)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

Date of product use DD/MMM/YYYY	08 APR 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	08:12
----------------------	-------

Time of product return	08:18
------------------------	-------

SODIM device number	157
---------------------	-----

SODIM sample holder number	1010
----------------------------	------

Tobacco plug kit number	T2100
-------------------------	-------

Tobacco plug vial number	04
--------------------------	----

SODIM file number	08DY0157COHM11010002
-------------------	----------------------

Comment	_____
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Batch Number	B08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Product Use

Form: Product administration-THS menthol (64)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Product administration-THS menthol (65)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

Date of product use DD/MMM/YYYY	08 APR 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	09:13
----------------------	-------

Time of product return	09:19
------------------------	-------

SODIM device number	157
---------------------	-----

SODIM sample holder number	1010
----------------------------	------

Tobacco plug kit number	T2100
-------------------------	-------

Tobacco plug vial number	05
--------------------------	----

SODIM file number	08DY0157COHM11010003
-------------------	----------------------

Comment	_____
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Batch Number	B08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Product Use

Form: Product administration-THS menthol (65)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Product administration-THS menthol (66)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

Date of product use DD/MMM/YYYY	08 APR 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	09:21
----------------------	-------

Time of product return	09:28
------------------------	-------

SODIM device number	157
---------------------	-----

SODIM sample holder number	1010
----------------------------	------

Tobacco plug kit number	T2100
-------------------------	-------

Tobacco plug vial number	06
--------------------------	----

SODIM file number	08DY0157COHM11010004
-------------------	----------------------

Comment	_____
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Batch Number	B08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Product Use

Form: Product administration-THS menthol (66)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Product administration-THS menthol (67)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

Date of product use DD/MMM/YYYY	08 APR 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	10:37
----------------------	-------

Time of product return	10:44
------------------------	-------

SODIM device number	157
---------------------	-----

SODIM sample holder number	1010
----------------------------	------

Tobacco plug kit number	T2100
-------------------------	-------

Tobacco plug vial number	07
--------------------------	----

SODIM file number	08DY0157COHM11010005
-------------------	----------------------

Comment	_____
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Batch Number	B08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Product Use

Form: Product administration-THS menthol (67)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Product administration-THS menthol (68)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

Date of product use DD/MMM/YYYY	08 APR 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	10:45
----------------------	-------

Time of product return	10:51
------------------------	-------

SODIM device number	157
---------------------	-----

SODIM sample holder number	1010
----------------------------	------

Tobacco plug kit number	T2100
-------------------------	-------

Tobacco plug vial number	08
--------------------------	----

SODIM file number	08DY0157COHM11010006
-------------------	----------------------

Comment	_____
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Batch Number	B08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Product Use

Form: Product administration-THS menthol (68)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Product administration-THS menthol (69)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

Date of product use DD/MMM/YYYY	08 APR 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	11:53
----------------------	-------

Time of product return	11:58
------------------------	-------

SODIM device number	157
---------------------	-----

SODIM sample holder number	1010
----------------------------	------

Tobacco plug kit number	T2100
-------------------------	-------

Tobacco plug vial number	09
--------------------------	----

SODIM file number	08DY0157COHM11010007
-------------------	----------------------

Comment	_____
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Batch Number	B08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Product Use

Form: Product administration-THS menthol (69)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Product administration-THS menthol (70)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

Date of product use DD/MMM/YYYY	08 APR 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	12:13
----------------------	-------

Time of product return	12:21
------------------------	-------

SODIM device number	157
---------------------	-----

SODIM sample holder number	1010
----------------------------	------

Tobacco plug kit number	T2100
-------------------------	-------

Tobacco plug vial number	10
--------------------------	----

SODIM file number	08DY0157COHM11010008
-------------------	----------------------

Comment	_____
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Batch Number	B08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Product Use

Form: Product administration-THS menthol (70)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Product administration-THS menthol (71)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

Date of product use DD/MMM/YYYY	08 APR 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	13:06
----------------------	-------

Time of product return	13:13
------------------------	-------

SODIM device number	157
---------------------	-----

SODIM sample holder number	1010
----------------------------	------

Tobacco plug kit number	T2100
-------------------------	-------

Tobacco plug vial number	11
--------------------------	----

SODIM file number	08DY0157COHM11010009
-------------------	----------------------

Comment	_____
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Batch Number	B08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Product Use

Form: Product administration-THS menthol (71)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Product administration-THS menthol (72)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

Date of product use DD/MMM/YYYY	08 APR 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	13:14
----------------------	-------

Time of product return	13:20
------------------------	-------

SODIM device number	157
---------------------	-----

SODIM sample holder number	1010
----------------------------	------

Tobacco plug kit number	T2100
-------------------------	-------

Tobacco plug vial number	12
--------------------------	----

SODIM file number	08DY0157COHM11010010
-------------------	----------------------

Comment	_____
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Batch Number	B08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Product Use

Form: Product administration-THS menthol (72)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Product administration-THS menthol (73)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

Date of product use DD/MMM/YYYY	08 APR 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	14:28
----------------------	-------

Time of product return	14:34
------------------------	-------

SODIM device number	157
---------------------	-----

SODIM sample holder number	1010
----------------------------	------

Tobacco plug kit number	T2100
-------------------------	-------

Tobacco plug vial number	13
--------------------------	----

SODIM file number	08DY0157COHM11010011
-------------------	----------------------

Comment	_____
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Batch Number	B08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Product Use

Form: Product administration-THS menthol (73)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Product administration-THS menthol (74)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

Date of product use DD/MMM/YYYY	08 APR 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	15:43
----------------------	-------

Time of product return	15:50
------------------------	-------

SODIM device number	157
---------------------	-----

SODIM sample holder number	1010
----------------------------	------

Tobacco plug kit number	T2100
-------------------------	-------

Tobacco plug vial number	14
--------------------------	----

SODIM file number	08DY0157COHM11010012
-------------------	----------------------

Comment	_____
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Batch Number	B08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Product Use

Form: Product administration-THS menthol (74)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Product administration-THS menthol (75)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

Date of product use DD/MMM/YYYY	08 APR 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	17:23
----------------------	-------

Time of product return	17:28
------------------------	-------

SODIM device number	157
---------------------	-----

SODIM sample holder number	1010
----------------------------	------

Tobacco plug kit number	T2100
-------------------------	-------

Tobacco plug vial number	15
--------------------------	----

SODIM file number	08DY0157COHM11010012
-------------------	----------------------

Comment	_____
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Batch Number	B08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Product Use

Form: Product administration-THS menthol (75)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Product administration-THS menthol (76)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

Date of product use DD/MMM/YYYY	08 APR 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	18:02
----------------------	-------

Time of product return	18:08
------------------------	-------

SODIM device number	157
---------------------	-----

SODIM sample holder number	1010
----------------------------	------

Tobacco plug kit number	T2100
-------------------------	-------

Tobacco plug vial number	16
--------------------------	----

SODIM file number	08DY0157COHM11010013
-------------------	----------------------

Comment	_____
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Batch Number	B08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Product Use

Form: Product administration-THS menthol (76)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Product administration-THS menthol (77)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

Date of product use DD/MMM/YYYY	08 APR 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	19:21
----------------------	-------

Time of product return	19:28
------------------------	-------

SODIM device number	157
---------------------	-----

SODIM sample holder number	1010
----------------------------	------

Tobacco plug kit number	T2100
-------------------------	-------

Tobacco plug vial number	17
--------------------------	----

SODIM file number	08DY0157COHM11010014
-------------------	----------------------

Comment	_____
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Batch Number	B08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Product Use

Form: Product administration-THS menthol (77)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Product administration-THS menthol (78)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

Date of product use DD/MMM/YYYY	08 APR 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	20:35
----------------------	-------

Time of product return	20:41
------------------------	-------

SODIM device number	157
---------------------	-----

SODIM sample holder number	1010
----------------------------	------

Tobacco plug kit number	T2100
-------------------------	-------

Tobacco plug vial number	18
--------------------------	----

SODIM file number	08DY0157COHM11010015
-------------------	----------------------

Comment	_____
---------	-------

Batch Number	B08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Product Use

Form: Product administration-THS menthol (78)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Product administration-THS menthol (79)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

Date of product use DD/MMM/YYYY	08 APR 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	21:07
----------------------	-------

Time of product return	21:14
------------------------	-------

SODIM device number	157
---------------------	-----

SODIM sample holder number	1010
----------------------------	------

Tobacco plug kit number	T2100
-------------------------	-------

Tobacco plug vial number	19
--------------------------	----

SODIM file number	08DY0157COHM11010016
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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: 1252

Folder: Product Use

Form: Product administration-THS menthol (79)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Product administration-THS menthol (80)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

Date of product use DD/MMM/YYYY	08 APR 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	22:04
------------------------	-------

SODIM device number	157
---------------------	-----

SODIM sample holder number	1010
----------------------------	------

Tobacco plug kit number	T2100
-------------------------	-------

Tobacco plug vial number	20
--------------------------	----

SODIM file number	08DY0157COHM11010017
-------------------	----------------------

Comment	_____
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Batch Number	B08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Product Use

Form: Product administration-THS menthol (80)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Product administration-THS menthol (81)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

Date of product use DD/MMM/YYYY	08 APR 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	
----------------------	--

Time of product return	22:07
------------------------	-------

SODIM device number	157
---------------------	-----

SODIM sample holder number	1010
----------------------------	------

Tobacco plug kit number	T2100
-------------------------	-------

Tobacco plug vial number	21
--------------------------	----

SODIM file number	08DY0157COHM11010018
-------------------	----------------------

Comment	
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Batch Number	B08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Product Use

Form: Product administration-THS menthol (81)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Product administration-THS menthol (82)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

Date of product use DD/MMM/YYYY	09 APR 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	06:46
----------------------	-------

Time of product return	06:51
------------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

Tobacco plug kit number	T2104
-------------------------	-------

Tobacco plug vial number	01
--------------------------	----

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: 1252

Folder: Product Use

Form: Product administration-THS menthol (82)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Product administration-THS menthol (83)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

Date of product use DD/MMM/YYYY	09 APR 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	06:52
----------------------	-------

Time of product return	06:58
------------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

Tobacco plug kit number	T2104
-------------------------	-------

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: 1252

Folder: Product Use

Form: Product administration-THS menthol (83)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Product administration-THS menthol (84)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

Date of product use DD/MMM/YYYY	09 APR 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	07:42
----------------------	-------

Time of product return	07:47
------------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

Tobacco plug kit number	T2104
-------------------------	-------

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: 1252

Folder: Product Use

Form: Product administration-THS menthol (84)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Product administration-THS menthol (85)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

Date of product use DD/MMM/YYYY	09 APR 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	07:55
----------------------	-------

Time of product return	08:03
------------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

Tobacco plug kit number	T2104
-------------------------	-------

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: 1252

Folder: Product Use

Form: Product administration-THS menthol (85)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Product administration-THS menthol (86)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

Date of product use DD/MMM/YYYY	09 APR 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	08:52
----------------------	-------

Time of product return	08:58
------------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

Tobacco plug kit number	T2104
-------------------------	-------

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: 1252

Folder: Product Use

Form: Product administration-THS menthol (86)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Product administration-THS menthol (87)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

Date of product use DD/MMM/YYYY	09 APR 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	09:33
----------------------	-------

Time of product return	09:40
------------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

Tobacco plug kit number	T2104
-------------------------	-------

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: 1252

Folder: Product Use

Form: Product administration-THS menthol (87)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Product administration-THS menthol (88)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

Date of product use DD/MMM/YYYY	09 APR 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	10:49
----------------------	-------

Time of product return	10:55
------------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

Tobacco plug kit number	T2104
-------------------------	-------

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: 1252

Folder: Product Use

Form: Product administration-THS menthol (88)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Product administration-THS menthol (89)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

Date of product use DD/MMM/YYYY	09 APR 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	11:30
----------------------	-------

Time of product return	11:36
------------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

Tobacco plug kit number	T2104
-------------------------	-------

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: 1252

Folder: Product Use

Form: Product administration-THS menthol (89)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Product administration-THS menthol (90)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

Date of product use DD/MMM/YYYY	09 APR 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	12:15
----------------------	-------

Time of product return	12:21
------------------------	-------

SODIM device number	<hr/>
---------------------	-------

SODIM sample holder number	<hr/>
----------------------------	-------

Tobacco plug kit number	T2104
-------------------------	-------

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: 1252

Folder: Product Use

Form: Product administration-THS menthol (90)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Product administration-THS menthol (91)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

Date of product use DD/MMM/YYYY	09 APR 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	12:49
----------------------	-------

Time of product return	12:54
------------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

Tobacco plug kit number	T2104
-------------------------	-------

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: 1252

Folder: Product Use

Form: Product administration-THS menthol (91)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Product administration-THS menthol (92)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

Date of product use DD/MMM/YYYY	09 APR 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	12:55
----------------------	-------

Time of product return	13:03
------------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

Tobacco plug kit number	T2104
-------------------------	-------

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: 1252

Folder: Product Use

Form: Product administration-THS menthol (92)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Product administration-THS menthol (93)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

Date of product use DD/MMM/YYYY	09 APR 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	14:11
----------------------	-------

Time of product return	14:17
------------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

Tobacco plug kit number	T2104
-------------------------	-------

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: 1252

Folder: Product Use

Form: Product administration-THS menthol (93)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Product administration-THS menthol (94)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

Date of product use DD/MMM/YYYY	09 APR 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	14:50
----------------------	-------

Time of product return	14:57
------------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

Tobacco plug kit number	T2104
-------------------------	-------

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: 1252

Folder: Product Use

Form: Product administration-THS menthol (94)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Product administration-THS menthol (95)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

Date of product use DD/MMM/YYYY	09 APR 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	15:27
----------------------	-------

Time of product return	15:34
------------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

Tobacco plug kit number	T2104
-------------------------	-------

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: 1252

Folder: Product Use

Form: Product administration-THS menthol (95)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Product administration-THS menthol (96)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

Date of product use DD/MMM/YYYY	09 APR 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	16:50
----------------------	-------

Time of product return	16:56
------------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

Tobacco plug kit number	T2104
-------------------------	-------

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: 1252

Folder: Product Use

Form: Product administration-THS menthol (96)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Product administration-THS menthol (97)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

Date of product use DD/MMM/YYYY	09 APR 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	16:57
----------------------	-------

Time of product return	17:02
------------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

Tobacco plug kit number	T2104
-------------------------	-------

Tobacco plug vial number	16
--------------------------	----

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

Batch Number	B08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Product Use

Form: Product administration-THS menthol (97)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Product administration-THS menthol (98)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

Date of product use DD/MMM/YYYY	09 APR 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	17:24
----------------------	-------

Time of product return	17:30
------------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

Tobacco plug kit number	T2104
-------------------------	-------

Tobacco plug vial number	17
--------------------------	----

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

Batch Number	B08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Product Use

Form: Product administration-THS menthol (98)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Product administration-THS menthol (99)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

Date of product use DD/MMM/YYYY	09 APR 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	18:00
----------------------	-------

Time of product return	18:07
------------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

Tobacco plug kit number	T2104
-------------------------	-------

Tobacco plug vial number	18
--------------------------	----

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

Batch Number	B08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Product Use

Form: Product administration-THS menthol (99)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Product administration-THS menthol (100)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

Date of product use DD/MMM/YYYY	09 APR 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	18:48
----------------------	-------

Time of product return	18:52
------------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

Tobacco plug kit number	T2104
-------------------------	-------

Tobacco plug vial number	19
--------------------------	----

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

Batch Number	B08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Product Use

Form: Product administration-THS menthol (100)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Product administration-THS menthol (101)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

Date of product use DD/MMM/YYYY	09 APR 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	19:32
----------------------	-------

Time of product return	19:38
------------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

Tobacco plug kit number	T2104
-------------------------	-------

Tobacco plug vial number	20
--------------------------	----

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

Batch Number	B08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Product Use

Form: Product administration-THS menthol (101)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Product administration-THS menthol (102)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

Date of product use DD/MMM/YYYY	09 APR 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	19:39
----------------------	-------

Time of product return	19:44
------------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

Tobacco plug kit number	T2104
-------------------------	-------

Tobacco plug vial number	21
--------------------------	----

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: 1252

Folder: Product Use

Form: Product administration-THS menthol (102)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Product administration-THS menthol (103)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

Date of product use DD/MMM/YYYY	09 APR 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	21:19
----------------------	-------

Time of product return	21:26
------------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

Tobacco plug kit number	T2104
-------------------------	-------

Tobacco plug vial number	22
--------------------------	----

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

Batch Number	B08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Product Use

Form: Product administration-THS menthol (103)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Product administration-THS menthol (104)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

Date of product use DD/MMM/YYYY	09 APR 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	21:27
----------------------	-------

Time of product return	21:33
------------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

Tobacco plug kit number	T2104
-------------------------	-------

Tobacco plug vial number	23
--------------------------	----

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

Batch Number	B08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Product Use

Form: Product administration-THS menthol (104)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Product administration-THS menthol (105)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

Date of product use DD/MMM/YYYY	09 APR 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	22:00
----------------------	-------

Time of product return	22:06
------------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

Tobacco plug kit number	T2104
-------------------------	-------

Tobacco plug vial number	24
--------------------------	----

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: 1252

Folder: Product Use

Form: Product administration-THS menthol (105)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Product administration-THS menthol (106)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

Date of product use DD/MMM/YYYY	10 APR 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	08:53
----------------------	-------

Time of product return	09:00
------------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

Tobacco plug kit number	_____
-------------------------	-------

Tobacco plug vial number	_____
--------------------------	-------

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: 1252

Folder: Product Use

Form: Product administration-THS menthol (106)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Product administration-THS menthol (107)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

Date of product use DD/MMM/YYYY	10 APR 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	09:02
----------------------	-------

Time of product return	09:07
------------------------	-------

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: 1252

Folder: Product Use

Form: Product administration-THS menthol (107)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Product administration-THS menthol (108)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

Date of product use DD/MMM/YYYY	10 APR 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	09:22
----------------------	-------

Time of product return	09:29
------------------------	-------

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: 1252

Folder: Product Use

Form: Product administration-THS menthol (108)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Product administration-THS menthol (109)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

Date of product use DD/MMM/YYYY	10 APR 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	09:55
----------------------	-------

Time of product return	10:01
------------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

Tobacco plug kit number	_____
-------------------------	-------

Tobacco plug vial number	_____
--------------------------	-------

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: 1252

Folder: Product Use

Form: Product administration-THS menthol (109)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Product administration-THS menthol (110)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

Date of product use DD/MMM/YYYY	04 MAY 2014
------------------------------------	-------------

Visit	Day 30 <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	<hr/>
----------------------	-------

Time of product return	<hr/>
------------------------	-------

SODIM device number	101
---------------------	-----

SODIM sample holder number	1013
----------------------------	------

Tobacco plug kit number	T2014
-------------------------	-------

Tobacco plug vial number	01
--------------------------	----

SODIM file number	08DY0101COHM31013001
-------------------	----------------------

Comment	<hr/>
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Batch Number	B08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Product Use

Form: Product administration-THS menthol (110)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Product administration-THS menthol (111)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

Date of product use DD/MMM/YYYY	04 MAY 2014
------------------------------------	-------------

Visit	Day 30 <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	<hr/>
----------------------	-------

Time of product return	<hr/>
------------------------	-------

SODIM device number	101
---------------------	-----

SODIM sample holder number	1013
----------------------------	------

Tobacco plug kit number	T2014
-------------------------	-------

Tobacco plug vial number	02
--------------------------	----

SODIM file number	08DY0101COHM31013002
-------------------	----------------------

Comment	<hr/>
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Batch Number	B08545
--------------	--------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Product Use

Form: Product administration-THS menthol (111)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Product administration-THS menthol (112)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

Date of product use DD/MMM/YYYY	04 MAY 2014
------------------------------------	-------------

Visit	Day 30 <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	
----------------------	--

Time of product return	
------------------------	--

SODIM device number	101
---------------------	-----

SODIM sample holder number	1013
----------------------------	------

Tobacco plug kit number	T2014
-------------------------	-------

Tobacco plug vial number	03
--------------------------	----

SODIM file number	08DY0101COHM31013003
-------------------	----------------------

Comment	
---------	--

Batch Number	B08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Product Use

Form: Product administration-THS menthol (112)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Product administration-THS menthol (113)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

Date of product use DD/MMM/YYYY	04 MAY 2014
------------------------------------	-------------

Visit	Day 30 <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	<hr/>
----------------------	-------

Time of product return	<hr/>
------------------------	-------

SODIM device number	101
---------------------	-----

SODIM sample holder number	1013
----------------------------	------

Tobacco plug kit number	T2014
-------------------------	-------

Tobacco plug vial number	04
--------------------------	----

SODIM file number	08DY0101COHM31013004
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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: 1252

Folder: Product Use

Form: Product administration-THS menthol (113)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Product administration-THS menthol (114)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

Date of product use DD/MMM/YYYY	04 MAY 2014
------------------------------------	-------------

Visit	Day 30 <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	<hr/>
----------------------	-------

Time of product return	<hr/>
------------------------	-------

SODIM device number	101
---------------------	-----

SODIM sample holder number	1013
----------------------------	------

Tobacco plug kit number	T2014
-------------------------	-------

Tobacco plug vial number	05
--------------------------	----

SODIM file number	08DY0101COHM31013005
-------------------	----------------------

Comment	<hr/>
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Batch Number	B08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Product Use

Form: Product administration-THS menthol (114)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Product administration-THS menthol (115)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

Date of product use DD/MMM/YYYY	03 JUN 2014
------------------------------------	-------------

Visit	Day 60 <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	<hr/>
----------------------	-------

Time of product return	<hr/>
------------------------	-------

SODIM device number	165
---------------------	-----

SODIM sample holder number	0622
----------------------------	------

Tobacco plug kit number	T2040
-------------------------	-------

Tobacco plug vial number	01
--------------------------	----

SODIM file number	08DY0165COHM60622001
-------------------	----------------------

Comment	<hr/>
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Batch Number	B08545
--------------	--------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Product Use

Form: Product administration-THS menthol (115)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Product administration-THS menthol (116)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

Date of product use DD/MMM/YYYY	03 JUN 2014
------------------------------------	-------------

Visit	Day 60 <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	<hr/>
----------------------	-------

Time of product return	<hr/>
------------------------	-------

SODIM device number	165
---------------------	-----

SODIM sample holder number	0622
----------------------------	------

Tobacco plug kit number	T2040
-------------------------	-------

Tobacco plug vial number	02
--------------------------	----

SODIM file number	08DY0165COHM60622002
-------------------	----------------------

Comment	<hr/>
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Batch Number	B08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Product Use

Form: Product administration-THS menthol (116)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Product administration-THS menthol (117)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

Date of product use DD/MMM/YYYY	03 JUN 2014
------------------------------------	-------------

Visit	Day 60 <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	<hr/>
----------------------	-------

Time of product return	<hr/>
------------------------	-------

SODIM device number	165
---------------------	-----

SODIM sample holder number	0622
----------------------------	------

Tobacco plug kit number	T2040
-------------------------	-------

Tobacco plug vial number	03
--------------------------	----

SODIM file number	08DY0165COHM60622003
-------------------	----------------------

Comment	<hr/>
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Batch Number	B08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Product Use

Form: Product administration-THS menthol (117)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Product administration-THS menthol (118)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

Date of product use DD/MMM/YYYY	03 JUN 2014
------------------------------------	-------------

Visit	Day 60 <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	<hr/>
----------------------	-------

Time of product return	<hr/>
------------------------	-------

SODIM device number	165
---------------------	-----

SODIM sample holder number	0622
----------------------------	------

Tobacco plug kit number	T2040
-------------------------	-------

Tobacco plug vial number	04
--------------------------	----

SODIM file number	08DY0165COHM60622004
-------------------	----------------------

Comment	<hr/>
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Batch Number	B08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Product Use

Form: Product administration-THS menthol (118)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Product administration-THS menthol (119)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

Date of product use DD/MMM/YYYY	03 JUN 2014
------------------------------------	-------------

Visit	Day 60 <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	<hr/>
----------------------	-------

Time of product return	<hr/>
------------------------	-------

SODIM device number	165
---------------------	-----

SODIM sample holder number	0622
----------------------------	------

Tobacco plug kit number	T2040
-------------------------	-------

Tobacco plug vial number	05
--------------------------	----

SODIM file number	08DY0165COHM60622005
-------------------	----------------------

Comment	<hr/>
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Batch Number	B08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Product Use

Form: Product administration-THS menthol (119)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Product administration-THS menthol (120)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

Date of product use DD/MMM/YYYY	02 APR 2014
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Visit	Day -2 <input type="radio"/>
-------	------------------------------

Type of Product Use	THS 2.2 Menthol <input type="radio"/>
---------------------	---------------------------------------

If type of Product Use different from the randomization please explain PRODUCT TEST

Time of distribution	17:30
----------------------	-------

Time of product return	<hr/>
------------------------	-------

SODIM device number	<hr/>
---------------------	-------

SODIM sample holder number	<hr/>
----------------------------	-------

Tobacco plug kit number	<hr/>
-------------------------	-------

Tobacco plug vial number	<hr/>
--------------------------	-------

SODIM file number	<hr/>
-------------------	-------

Comment	<hr/>
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Batch Number	B08545
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Product Use

Form: Product administration-THS menthol (120)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Product administration-THS menthol (121)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

Date of product use DD/MMM/YYYY	06 APR 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	10:19
----------------------	-------

Time of product return	10:26
------------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

Tobacco plug kit number	T1993
-------------------------	-------

Tobacco plug vial number	07
--------------------------	----

SODIM file number	_____
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Comment	_____
---------	-------

Batch Number	B-08545
--------------	---------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Product Use

Form: Product administration-THS menthol (121)

Data signed: (hfarmer1) 30 Mar 2015 13:35:48

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: HST 4 hours (1)

Data signed: (hfarmer1) 30 Mar 2015 13:36:04

Generated On: 20 Jul 2016 22:28:45

Visit	Day 30 <input type="radio"/>
-------	------------------------------

Not Done	False
----------	-------

If Not Done, please specify _____

Date DD/MMM/YYYY	04 MAY 2014
---------------------	-------------

SODIM device distribution time hour:min 24-hour clock	09:37
--	-------

SODIM device collection time hour:min 24-hour clock	13:37
--	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: HST 4 hours (2)

Data signed: (hfarmer1) 30 Mar 2015 13:36:04

Generated On: 20 Jul 2016 22:28:45

Visit	Day 60 <input type="radio"/>
-------	------------------------------

Not Done	False
----------	-------

If Not Done, please specify _____

Date DD/MMM/YYYY	03 JUN 2014
---------------------	-------------

SODIM device distribution time hour:min 24-hour clock	08:42
--	-------

SODIM device collection time hour:min 24-hour clock	12:42
--	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: HST 4 hours (3)

Data signed: (hfarmer1) 30 Mar 2015 13:36:04

Generated On: 20 Jul 2016 22:28:45

Visit	Day 90 <input checked="" type="radio"/>
-------	---

Not Done	True
----------	------

If Not Done, please specify	SUBJECT LOST TO FOLLOW UP
-----------------------------	------------------------------

Date DD/MMM/YYYY	
---------------------	--

SODIM device distribution time hour:min 24-hour clock	
--	--

SODIM device collection time hour:min 24-hour clock	
--	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Topography files status for mCC (1)

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Topography files status for mCC (2)

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Topography files status for mCC (3)

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Topography files status for mCC (4)

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Topography files status for mCC (5)

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Topography files status for mCC (6)

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Topography files status for mCC (7)

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Topography files status for mCC (8)

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Topography files status for mCC (9)

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Topography files status for mCC (10)

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Topography files status for mCC (11)

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Topography files status for mCC (12)

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Topography files status for mCC (13)

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Topography files status for mCC (14)

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Topography files status for mCC (15)

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Topography files status for mCC (16)

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Topography files status for mCC (17)

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Topography files status for mCC (18)

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Topography files status for mCC (19)

Generated On: 20 Jul 2016 22:28:45

SODIM file number	08DY0157COHM10212001
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File Status	Accepted <input checked="" type="radio"/>
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Rejection / Error reason	
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Date of analysis DD/MMM/YYYY	05 SEP 2014
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Operator	Thierry Bachmann <input checked="" type="radio"/>
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Comment	
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Modified File Number	
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Topography files status for mCC (20)

Generated On: 20 Jul 2016 22:28:45

SODIM file number	08DY0157COHM10212002
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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	05 SEP 2014
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Operator	Thierry Bachmann <input checked="" type="radio"/>
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Comment	<hr/>
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Modified File Number	<hr/>
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Topography files status for mCC (21)

Generated On: 20 Jul 2016 22:28:45

SODIM file number	08DY0157COHM10212003
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File Status	Accepted 
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Rejection / Error reason	<hr/>
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Date of analysis DD/MMM/YYYY	05 SEP 2014
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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: 1252**

Folder: Product Use

Form: Topography files status for mCC (22)

Generated On: 20 Jul 2016 22:28:45

SODIM file number	08DY0157COHM10212004
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File Status	Accepted 
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Rejection / Error reason	<hr/>
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Date of analysis DD/MMM/YYYY	05 SEP 2014
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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: 1252**

Folder: Product Use

Form: Topography files status for mCC (23)

Generated On: 20 Jul 2016 22:28:45

SODIM file number	08DY0157COHM10212005
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File Status	Accepted <input checked="" type="radio"/>
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Rejection / Error reason	
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Date of analysis DD/MMM/YYYY	05 SEP 2014
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Operator	Thierry Bachmann <input checked="" type="radio"/>
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Comment	
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Modified File Number	
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Topography files status for mCC (24)

Generated On: 20 Jul 2016 22:28:45

SODIM file number	08DY0157COHM10212006
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File Status	Accepted 
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Rejection / Error reason	<hr/>
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Date of analysis DD/MMM/YYYY	05 SEP 2014
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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: 1252**

Folder: Product Use

Form: Topography files status for mCC (25)

Generated On: 20 Jul 2016 22:28:45

SODIM file number	08DY0157COHM10212007
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File Status	Accepted <input checked="" type="radio"/>
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Rejection / Error reason	
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Date of analysis DD/MMM/YYYY	05 SEP 2014
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Operator	Thierry Bachmann <input checked="" type="radio"/>
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Comment	
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Modified File Number	
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Topography files status for mCC (26)

Generated On: 20 Jul 2016 22:28:45

SODIM file number	08DY0157COHM10212008
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File Status	Accepted 
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Rejection / Error reason	<hr/>
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Date of analysis DD/MMM/YYYY	05 SEP 2014
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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: 1252**

Folder: Product Use

Form: Topography files status for mCC (27)

Generated On: 20 Jul 2016 22:28:45

SODIM file number	08DY0157COHM10212009
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File Status	Accepted 
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Rejection / Error reason	<hr/>
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Date of analysis DD/MMM/YYYY	05 SEP 2014
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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: 1252**

Folder: Product Use

Form: Topography files status for mCC (28)

Generated On: 20 Jul 2016 22:28:45

SODIM file number	08DY0157COHM10212010
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File Status	Accepted <input checked="" type="radio"/>
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Rejection / Error reason	
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Date of analysis DD/MMM/YYYY	05 SEP 2014
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Operator	Thierry Bachmann <input checked="" type="radio"/>
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Comment	
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Modified File Number	
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Topography files status for mCC (29)

Generated On: 20 Jul 2016 22:28:45

SODIM file number	08DY0157COHM10212011
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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	05 SEP 2014
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Operator	Thierry Bachmann <input checked="" type="radio"/>
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Comment	<hr/>
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Modified File Number	<hr/>
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Topography files status for mCC (30)

Generated On: 20 Jul 2016 22:28:45

SODIM file number	08DY0157COHM10212012
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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	05 SEP 2014
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Operator	Thierry Bachmann <input checked="" type="radio"/>
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Comment	<hr/>
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Modified File Number	<hr/>
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Topography files status for mCC (31)

Generated On: 20 Jul 2016 22:28:45

SODIM file number	08DY0157COHM10212013
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File Status	Accepted <input checked="" type="radio"/>
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Rejection / Error reason	
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Date of analysis DD/MMM/YYYY	05 SEP 2014
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Operator	Thierry Bachmann <input checked="" type="radio"/>
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Comment	
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Modified File Number	
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Topography files status for mCC (32)

Generated On: 20 Jul 2016 22:28:45

SODIM file number	08DY0157COHM10212014
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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	05 SEP 2014
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Operator	Thierry Bachmann <input checked="" type="radio"/>
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Comment	<hr/>
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Modified File Number	<hr/>
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Topography files status for mCC (33)

Generated On: 20 Jul 2016 22:28:45

SODIM file number	08DY0157COHM10212015
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File Status	Accepted 
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Rejection / Error reason	<hr/>
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Date of analysis DD/MMM/YYYY	05 SEP 2014
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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: 1252**

Folder: Product Use

Form: Topography files status for mCC (34)

Generated On: 20 Jul 2016 22:28:45

SODIM file number	08DY0157COHM10212016
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File Status	Accepted 
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Rejection / Error reason	<hr/>
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Date of analysis DD/MMM/YYYY	05 SEP 2014
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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: 1252**

Folder: Product Use

Form: Topography files status for mCC (35)

Generated On: 20 Jul 2016 22:28:45

SODIM file number	08DY0157COHM10212017
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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	05 SEP 2014
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Operator	Thierry Bachmann <input checked="" type="radio"/>
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Comment	<hr/>
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Modified File Number	<hr/>
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Topography files status for THS menthol (1)

Generated On: 20 Jul 2016 22:28:45

SODIM file number	08DY0157COHM11010001
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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	05 SEP 2014
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Operator	Thierry Bachmann <input checked="" type="radio"/>
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Comment	<hr/>
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Modified File Number	<hr/>
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Topography files status for THS menthol (2)

Generated On: 20 Jul 2016 22:28:45

SODIM file number	08DY0157COHM11010002
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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	05 SEP 2014
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Operator	Thierry Bachmann <input checked="" type="radio"/>
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Comment	<hr/>
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Modified File Number	<hr/>
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Topography files status for THS menthol (3)

Generated On: 20 Jul 2016 22:28:45

SODIM file number	08DY0157COHM11010003
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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	05 SEP 2014
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Operator	Thierry Bachmann <input checked="" type="radio"/>
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Comment	<hr/>
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Modified File Number	<hr/>
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Topography files status for THS menthol (4)

Generated On: 20 Jul 2016 22:28:45

SODIM file number	08DY0157COHM11010004
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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	05 SEP 2014
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Operator	Thierry Bachmann <input checked="" type="radio"/>
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Comment	<hr/>
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Modified File Number	<hr/>
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Topography files status for THS menthol (5)

Generated On: 20 Jul 2016 22:28:45

SODIM file number	08DY0157COHM11010005
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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	05 SEP 2014
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Operator	Thierry Bachmann <input checked="" type="radio"/>
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Comment	<hr/>
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Modified File Number	<hr/>
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Topography files status for THS menthol (6)

Generated On: 20 Jul 2016 22:28:45

SODIM file number	08DY0157COHM11010006
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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	05 SEP 2014
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Operator	Thierry Bachmann <input checked="" type="radio"/>
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Comment	<hr/>
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Modified File Number	<hr/>
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Topography files status for THS menthol (7)

Generated On: 20 Jul 2016 22:28:45

SODIM file number	08DY0157COHM11010007
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File Status	Accepted <input checked="" type="radio"/>
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Rejection / Error reason	<hr/>
--------------------------	-------

Date of analysis DD/MMM/YYYY	05 SEP 2014
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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: 1252**

Folder: Product Use

Form: Topography files status for THS menthol (8)

Generated On: 20 Jul 2016 22:28:45

SODIM file number	08DY0157COHM11010008
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File Status	Accepted <input checked="" type="radio"/>
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Rejection / Error reason	<hr/>
--------------------------	-------

Date of analysis DD/MMM/YYYY	05 SEP 2014
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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: 1252**

Folder: Product Use

Form: Topography files status for THS menthol (10)

Generated On: 20 Jul 2016 22:28:45

SODIM file number	08DY0157COHM11010009
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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	05 SEP 2014
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Operator	Thierry Bachmann <input checked="" type="radio"/>
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Comment	<hr/>
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Modified File Number	<hr/>
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Topography files status for THS menthol (11)

Generated On: 20 Jul 2016 22:28:45

SODIM file number	08DY0157COHM11010010
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File Status	Accepted <input checked="" type="radio"/>
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Rejection / Error reason	
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Date of analysis DD/MMM/YYYY	05 SEP 2014
---------------------------------	-------------

Operator	Thierry Bachmann <input checked="" type="radio"/>
----------	---

Comment	
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Modified File Number	
----------------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Topography files status for THS menthol (12)

Generated On: 20 Jul 2016 22:28:45

SODIM file number	08DY0157COHM11010012
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File Status	Accepted <input checked="" type="radio"/>
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Rejection / Error reason	
--------------------------	--

Date of analysis DD/MMM/YYYY	05 SEP 2014
---------------------------------	-------------

Operator	Thierry Bachmann <input checked="" type="radio"/>
----------	---

Comment	
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Modified File Number	08DY0157COHM11010011
----------------------	----------------------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Topography files status for THS menthol (13)

Generated On: 20 Jul 2016 22:28:45

SODIM file number	08DY0157COHM11010012
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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	05 SEP 2014
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Operator	Thierry Bachmann <input checked="" type="radio"/>
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Comment	<hr/>
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Modified File Number	<hr/>
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Topography files status for THS menthol (14)

Generated On: 20 Jul 2016 22:28:45

SODIM file number	08DY0157COHM11010013
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File Status	Accepted <input checked="" type="radio"/>
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Rejection / Error reason	
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Date of analysis DD/MMM/YYYY	05 SEP 2014
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Operator	Thierry Bachmann <input checked="" type="radio"/>
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Comment	
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Modified File Number	
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Topography files status for THS menthol (15)

Generated On: 20 Jul 2016 22:28:45

SODIM file number	08DY0157COHM11010014
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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	05 SEP 2014
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Operator	Thierry Bachmann <input checked="" type="radio"/>
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Comment	<hr/>
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Modified File Number	<hr/>
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Topography files status for THS menthol (16)

Generated On: 20 Jul 2016 22:28:45

SODIM file number	08DY0157COHM11010015
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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	05 SEP 2014
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Operator	Thierry Bachmann <input checked="" type="radio"/>
----------	---

Comment	<hr/>
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Modified File Number	<hr/>
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Topography files status for THS menthol (17)

Generated On: 20 Jul 2016 22:28:45

SODIM file number	08DY0157COHM11010016
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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	05 SEP 2014
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Operator	Thierry Bachmann <input checked="" type="radio"/>
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Comment	<hr/>
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Modified File Number	<hr/>
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Topography files status for THS menthol (18)

Generated On: 20 Jul 2016 22:28:45

SODIM file number	08DY0157COHM11010017
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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	05 SEP 2014
---------------------------------	-------------

Operator	Thierry Bachmann <input checked="" type="radio"/>
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Comment	<hr/>
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Modified File Number	<hr/>
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Topography files status for THS menthol (19)

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Topography files status for THS menthol (20)

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Topography files status for THS menthol (21)

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Topography files status for THS menthol (22)

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Topography files status for THS menthol (23)

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Topography files status for THS menthol (24)

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Topography files status for THS menthol (25)

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Topography files status for THS menthol (26)

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Topography files status for THS menthol (27)

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Topography files status for THS menthol (28)

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Topography files status for THS menthol (29)

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Topography files status for THS menthol (30)

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Topography files status for THS menthol (31)

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Topography files status for THS menthol (32)

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Topography files status for THS menthol (33)

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Topography files status for THS menthol (34)

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Topography files status for THS menthol (35)

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Topography files status for THS menthol (36)

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Topography files status for THS menthol (37)

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Topography files status for THS menthol (38)

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Topography files status for THS menthol (39)

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Topography files status for THS menthol (40)

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Topography files status for THS menthol (41)

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Topography files status for THS menthol (42)

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Topography files status for THS menthol (43)

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Topography files status for THS menthol (44)

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Topography files status for THS menthol (45)

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Topography files status for THS menthol (46)

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Topography files status for THS menthol (47)

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Topography files status for THS menthol (48)

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Topography files status for THS menthol (49)

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Topography files status for THS menthol (50)

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Topography files status for THS menthol (51)

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Topography files status for THS menthol (52)

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Topography files status for THS menthol (53)

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Topography files status for THS menthol (54)

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Topography files status for THS menthol (55)

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Topography files status for THS menthol (56)

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Topography files status for THS menthol (57)

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Topography files status for THS menthol (58)

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Topography files status for THS menthol (59)

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Topography files status for THS menthol (60)

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Topography files status for THS menthol (61)

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Topography files status for THS menthol (62)

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Topography files status for THS menthol (82)

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Topography files status for THS menthol (83)

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Topography files status for THS menthol (84)

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Topography files status for THS menthol (85)

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Topography files status for THS menthol (86)

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Topography files status for THS menthol (87)

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Topography files status for THS menthol (88)

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Topography files status for THS menthol (89)

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Topography files status for THS menthol (90)

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Topography files status for THS menthol (91)

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Topography files status for THS menthol (92)

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Topography files status for THS menthol (93)

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Topography files status for THS menthol (94)

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Topography files status for THS menthol (95)

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Topography files status for THS menthol (96)

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Topography files status for THS menthol (97)

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Topography files status for THS menthol (98)

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Topography files status for THS menthol (99)

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Topography files status for THS menthol (100)

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Topography files status for THS menthol (101)

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Topography files status for THS menthol (102)

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Topography files status for THS menthol (103)

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Topography files status for THS menthol (104)

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Topography files status for THS menthol (105)

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Topography files status for THS menthol (106)

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Topography files status for THS menthol (107)

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Topography files status for THS menthol (108)

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Topography files status for THS menthol (109)

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Topography files status for THS menthol (110)

Generated On: 20 Jul 2016 22:28:45

SODIM file number	08DY0101COHM31013001
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File Status	Accepted 
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Rejection / Error reason	<hr/>
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Date of analysis DD/MMM/YYYY	08 SEP 2014
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Operator	Thierry Bachmann 
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Comment	<hr/>
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Modified File Number	<hr/>
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Topography files status for THS menthol (111)

Generated On: 20 Jul 2016 22:28:45

SODIM file number	08DY0101COHM31013002
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File Status	Accepted <input checked="" type="radio"/>
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Rejection / Error reason	<hr/>
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Date of analysis DD/MMM/YYYY	08 SEP 2014
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Operator	Thierry Bachmann <input checked="" type="radio"/>
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Comment	<hr/>
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Modified File Number	<hr/>
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Topography files status for THS menthol (112)

Generated On: 20 Jul 2016 22:28:45

SODIM file number	08DY0101COHM31013003
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File Status	Accepted 
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Rejection / Error reason	<hr/>
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Date of analysis DD/MMM/YYYY	08 SEP 2014
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Operator	Thierry Bachmann 
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Comment	<hr/>
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Modified File Number	<hr/>
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Topography files status for THS menthol (113)

Generated On: 20 Jul 2016 22:28:45

SODIM file number	08DY0101COHM31013004
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File Status	Accepted 
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Rejection / Error reason	<hr/>
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Date of analysis DD/MMM/YYYY	08 SEP 2014
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Operator	Thierry Bachmann 
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Comment	<hr/>
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Modified File Number	<hr/>
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Topography files status for THS menthol (114)

Generated On: 20 Jul 2016 22:28:45

SODIM file number	08DY0101COHM31013005
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File Status	Rejected 
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Rejection / Error reason	BASELINE DEVIATION
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Date of analysis DD/MMM/YYYY	08 SEP 2014
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Operator	Thierry Bachmann 
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Comment	<hr/>
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Modified File Number	<hr/>
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Topography files status for THS menthol (115)

Generated On: 20 Jul 2016 22:28:45

SODIM file number	08DY0165COHM60622001
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File Status	Accepted 
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Rejection / Error reason	<hr/>
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Date of analysis DD/MMM/YYYY	08 SEP 2014
---------------------------------	-------------

Operator	Thierry Bachmann 
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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: 1252**

Folder: Product Use

Form: Topography files status for THS menthol (116)

Generated On: 20 Jul 2016 22:28:45

SODIM file number	08DY0165COHM60622002
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File Status	Accepted 
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Rejection / Error reason	<hr/>
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Date of analysis DD/MMM/YYYY	08 SEP 2014
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Operator	Thierry Bachmann 
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Comment	<hr/>
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Modified File Number	<hr/>
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Topography files status for THS menthol (117)

Generated On: 20 Jul 2016 22:28:45

SODIM file number	08DY0165COHM60622003
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File Status	Error 
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Rejection / Error reason	NB. PUFFS < 3
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Date of analysis DD/MMM/YYYY	08 SEP 2014
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Operator	Thierry Bachmann 
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Comment	<hr/>
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Modified File Number	<hr/>
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Topography files status for THS menthol (118)

Generated On: 20 Jul 2016 22:28:45

SODIM file number	08DY0165COHM60622004
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File Status	Accepted <input checked="" type="radio"/>
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Rejection / Error reason	<hr/>
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Date of analysis DD/MMM/YYYY	08 SEP 2014
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Operator	Thierry Bachmann <input checked="" type="radio"/>
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Comment	<hr/>
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Modified File Number	<hr/>
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Topography files status for THS menthol (119)

Generated On: 20 Jul 2016 22:28:45

SODIM file number	08DY0165COHM60622005
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File Status	Accepted <input checked="" type="radio"/>
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Rejection / Error reason	<hr/>
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Date of analysis DD/MMM/YYYY	08 SEP 2014
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Operator	Thierry Bachmann <input checked="" type="radio"/>
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Comment	<hr/>
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Modified File Number	<hr/>
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Topography files status for THS menthol (120)

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (1)

Generated On: 20 Jul 2016 22:28:45

Tobacco plug kit number	T1985
-------------------------	-------

Tobacco plug vial number	01
--------------------------	----

Level	0 <input checked="" type="radio"/>
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Observation	
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Picture File Name	T1985_01_8HXW.JPG
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Date of analysis DD/MMM/YYYY	18 JUL 2014
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (2)

Generated On: 20 Jul 2016 22:28:45

Tobacco plug kit number	T1985
-------------------------	-------

Tobacco plug vial number	02
--------------------------	----

Level	0 
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Observation	
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Picture File Name	T1985_02_TAZE.JPG
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Date of analysis DD/MMM/YYYY	18 JUL 2014
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (3)

Generated On: 20 Jul 2016 22:28:45

Tobacco plug kit number	T1985
-------------------------	-------

Tobacco plug vial number	03
--------------------------	----

Level	0 <input checked="" type="radio"/>
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Observation	
-------------	--

Picture File Name	T1985_03_8EUM.JPG
-------------------	-------------------

Date of analysis DD/MMM/YYYY	18 JUL 2014
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (4)

Generated On: 20 Jul 2016 22:28:45

Tobacco plug kit number	T1985
-------------------------	-------

Tobacco plug vial number	04
--------------------------	----

Level	0 
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Observation	
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Picture File Name	T1985_04_2VTS.JPG
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Date of analysis DD/MMM/YYYY	18 JUL 2014
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (5)

Generated On: 20 Jul 2016 22:28:45

Tobacco plug kit number	T1985
-------------------------	-------

Tobacco plug vial number	05
--------------------------	----

Level	0 
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Observation	<hr/>
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Picture File Name	T1985_05_RIWV.JPG
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Date of analysis DD/MMM/YYYY	18 JUL 2014
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (6)

Generated On: 20 Jul 2016 22:28:45

Tobacco plug kit number	T1985
-------------------------	-------

Tobacco plug vial number	06
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Level	0 <input checked="" type="radio"/>
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Observation	
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Picture File Name	T1985_06_P3AL.JPG
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Date of analysis DD/MMM/YYYY	18 JUL 2014
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (7)

Generated On: 20 Jul 2016 22:28:45

Tobacco plug kit number	T1985
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Tobacco plug vial number	07
--------------------------	----

Level	0 
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Observation	
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Picture File Name	T1985_07_YKI7.JPG
-------------------	-------------------

Date of analysis DD/MMM/YYYY	18 JUL 2014
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (8)

Generated On: 20 Jul 2016 22:28:45

Tobacco plug kit number	T1985
-------------------------	-------

Tobacco plug vial number	08
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Level	0 <input checked="" type="radio"/>
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Observation	
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Picture File Name	T1985_08_IN5S.JPG
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Date of analysis DD/MMM/YYYY	18 JUL 2014
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (9)

Generated On: 20 Jul 2016 22:28:45

Tobacco plug kit number	T1985
-------------------------	-------

Tobacco plug vial number	09
--------------------------	----

Level	0 
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Observation	
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Picture File Name	T1985_09_VRMC.JPG
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Date of analysis DD/MMM/YYYY	18 JUL 2014
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (10)

Generated On: 20 Jul 2016 22:28:45

Tobacco plug kit number	T1985
-------------------------	-------

Tobacco plug vial number	10
--------------------------	----

Level	0 
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Observation	
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Picture File Name	T1985_10_V0AA.JPG
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Date of analysis DD/MMM/YYYY	18 JUL 2014
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (11)

Generated On: 20 Jul 2016 22:28:45

Tobacco plug kit number	T1985
-------------------------	-------

Tobacco plug vial number	11
--------------------------	----

Level	0 <input checked="" type="radio"/>
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Observation	
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Picture File Name	T1985_11_PVYT.JPG
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Date of analysis DD/MMM/YYYY	18 JUL 2014
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (12)

Generated On: 20 Jul 2016 22:28:45

Tobacco plug kit number	T1985
-------------------------	-------

Tobacco plug vial number	12
--------------------------	----

Level	0 <input checked="" type="radio"/>
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Observation	
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Picture File Name	T1985_12_5HFT.JPG
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Date of analysis DD/MMM/YYYY	18 JUL 2014
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (13)

Generated On: 20 Jul 2016 22:28:45

Tobacco plug kit number	T1985
-------------------------	-------

Tobacco plug vial number	13
--------------------------	----

Level	0 <input checked="" type="radio"/>
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Observation	
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Picture File Name	T1985_13_8X8Z.JPG
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Date of analysis DD/MMM/YYYY	18 JUL 2014
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (14)

Generated On: 20 Jul 2016 22:28:45

Tobacco plug kit number	T1985
-------------------------	-------

Tobacco plug vial number	14
--------------------------	----

Level	0 <input type="radio"/>
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Observation	
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Picture File Name	T1985_14_WVU8.JPG
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Date of analysis DD/MMM/YYYY	18 JUL 2014
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (15)

Generated On: 20 Jul 2016 22:28:45

Tobacco plug kit number	T1985
-------------------------	-------

Tobacco plug vial number	15
--------------------------	----

Level	0 <input checked="" type="radio"/>
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Observation	
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Picture File Name	T1985_15_FTKL.JPG
-------------------	-------------------

Date of analysis DD/MMM/YYYY	18 JUL 2014
---------------------------------	-------------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (16)

Generated On: 20 Jul 2016 22:28:45

Tobacco plug kit number	T1985
-------------------------	-------

Tobacco plug vial number	16
--------------------------	----

Level	0 
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Observation	<hr/>
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Picture File Name	T1985_16_2N9B.JPG
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Date of analysis DD/MMM/YYYY	18 JUL 2014
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (17)

Generated On: 20 Jul 2016 22:28:45

Tobacco plug kit number	T1985
-------------------------	-------

Tobacco plug vial number	17
--------------------------	----

Level	0 <input checked="" type="radio"/>
-------	------------------------------------

Observation	
-------------	--

Picture File Name	T1985_17_FFBZ.JPG
-------------------	-------------------

Date of analysis DD/MMM/YYYY	18 JUL 2014
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (18)

Generated On: 20 Jul 2016 22:28:45

Tobacco plug kit number	T1985
-------------------------	-------

Tobacco plug vial number	18
--------------------------	----

Level	0 
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Observation	<hr/>
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Picture File Name	T1985_18_YIFW.JPG
-------------------	-------------------

Date of analysis DD/MMM/YYYY	18 JUL 2014
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (1)

Generated On: 20 Jul 2016 22:28:45

Tobacco plug kit number	T1993
-------------------------	-------

Tobacco plug vial number	01
--------------------------	----

Level	0 <input checked="" type="radio"/>
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Observation	
-------------	--

Picture File Name	T1993_01_H8CX.JPG
-------------------	-------------------

Date of analysis DD/MMM/YYYY	18 JUL 2014
---------------------------------	-------------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (2)

Generated On: 20 Jul 2016 22:28:45

Tobacco plug kit number	T1993
-------------------------	-------

Tobacco plug vial number	02
--------------------------	----

Level	0 
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Observation	
-------------	--

Picture File Name	T1993_02_Z6F9.JPG
-------------------	-------------------

Date of analysis DD/MMM/YYYY	18 JUL 2014
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (3)

Generated On: 20 Jul 2016 22:28:45

Tobacco plug kit number	T1993
-------------------------	-------

Tobacco plug vial number	03
--------------------------	----

Level	0 
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Observation	
-------------	--

Picture File Name	T1993_03_661Q.JPG
-------------------	-------------------

Date of analysis DD/MMM/YYYY	18 JUL 2014
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (4)

Generated On: 20 Jul 2016 22:28:45

Tobacco plug kit number	T1993
-------------------------	-------

Tobacco plug vial number	04
--------------------------	----

Level	0 
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Observation	
-------------	--

Picture File Name	T1993_04_KVPU.JPG
-------------------	-------------------

Date of analysis DD/MMM/YYYY	18 JUL 2014
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (5)

Generated On: 20 Jul 2016 22:28:45

Tobacco plug kit number	T1993
-------------------------	-------

Tobacco plug vial number	05
--------------------------	----

Level	0 <input checked="" type="radio"/>
-------	------------------------------------

Observation	
-------------	--

Picture File Name	T1993_05_K593.JPG
-------------------	-------------------

Date of analysis DD/MMM/YYYY	18 JUL 2014
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (6)

Generated On: 20 Jul 2016 22:28:45

Tobacco plug kit number	T1993
-------------------------	-------

Tobacco plug vial number	06
--------------------------	----

Level	0 
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Observation	<hr/>
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Picture File Name	T1993_06_2S66.JPG
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Date of analysis DD/MMM/YYYY	18 JUL 2014
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (7)

Generated On: 20 Jul 2016 22:28:45

Tobacco plug kit number	T1993
-------------------------	-------

Tobacco plug vial number	07
--------------------------	----

Level	0 
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Observation	
-------------	--

Picture File Name	T1993_07_ORW9.JPG
-------------------	-------------------

Date of analysis DD/MMM/YYYY	18 JUL 2014
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (8)

Generated On: 20 Jul 2016 22:28:45

Tobacco plug kit number	T1993
-------------------------	-------

Tobacco plug vial number	08
--------------------------	----

Level	0 
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Observation	
-------------	--

Picture File Name	T1993_08_RV02.JPG
-------------------	-------------------

Date of analysis DD/MMM/YYYY	18 JUL 2014
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (9)

Generated On: 20 Jul 2016 22:28:45

Tobacco plug kit number	T1993
-------------------------	-------

Tobacco plug vial number	09
--------------------------	----

Level	0 
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Observation	
-------------	--

Picture File Name	T1993_09_RTFB.JPG
-------------------	-------------------

Date of analysis DD/MMM/YYYY	18 JUL 2014
---------------------------------	-------------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (10)

Generated On: 20 Jul 2016 22:28:45

Tobacco plug kit number	T1993
-------------------------	-------

Tobacco plug vial number	10
--------------------------	----

Level	0 <input checked="" type="radio"/>
-------	------------------------------------

Observation	
-------------	--

Picture File Name	T1993_10_IVHJ.JPG
-------------------	-------------------

Date of analysis DD/MMM/YYYY	18 JUL 2014
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (11)

Generated On: 20 Jul 2016 22:28:45

Tobacco plug kit number	T1993
-------------------------	-------

Tobacco plug vial number	11
--------------------------	----

Level	0 
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Observation	
-------------	--

Picture File Name	T1993_11_LIAA.JPG
-------------------	-------------------

Date of analysis DD/MMM/YYYY	18 JUL 2014
---------------------------------	-------------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (12)

Generated On: 20 Jul 2016 22:28:45

Tobacco plug kit number	T1993
-------------------------	-------

Tobacco plug vial number	12
--------------------------	----

Level	0 
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Observation	
-------------	--

Picture File Name	T1993_12_IETC.JPG
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Date of analysis DD/MMM/YYYY	18 JUL 2014
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (13)

Generated On: 20 Jul 2016 22:28:45

Tobacco plug kit number	T1993
-------------------------	-------

Tobacco plug vial number	13
--------------------------	----

Level	0 
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Observation	
-------------	--

Picture File Name	T1993_13_3NKG.JPG
-------------------	-------------------

Date of analysis DD/MMM/YYYY	18 JUL 2014
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (14)

Generated On: 20 Jul 2016 22:28:45

Tobacco plug kit number	T1993
-------------------------	-------

Tobacco plug vial number	14
--------------------------	----

Level	0 
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Observation	
-------------	--

Picture File Name	T1993_14_IF2Z.JPG
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Date of analysis DD/MMM/YYYY	18 JUL 2014
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (15)

Generated On: 20 Jul 2016 22:28:45

Tobacco plug kit number	T1993
-------------------------	-------

Tobacco plug vial number	15
--------------------------	----

Level	0 
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Observation	<hr/>
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Picture File Name	T1993_15_6CTF.JPG
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Date of analysis DD/MMM/YYYY	18 JUL 2014
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (16)

Generated On: 20 Jul 2016 22:28:45

Tobacco plug kit number	T1993
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Tobacco plug vial number	16
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Level	0 
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Observation	
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Picture File Name	T1993_16_L7AC.JPG
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Date of analysis DD/MMM/YYYY	18 JUL 2014
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (17)

Generated On: 20 Jul 2016 22:28:45

Tobacco plug kit number	T1993
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Tobacco plug vial number	17
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Level	0 
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Observation	
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Picture File Name	T1993_17_RU4R.JPG
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Date of analysis DD/MMM/YYYY	18 JUL 2014
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (18)

Generated On: 20 Jul 2016 22:28:45

Tobacco plug kit number	T1993
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Tobacco plug vial number	18
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Level	0 
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Observation	<hr/>
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Picture File Name	T1993_18_XXMD.JPG
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Date of analysis DD/MMM/YYYY	18 JUL 2014
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (19)

Generated On: 20 Jul 2016 22:28:45

Tobacco plug kit number	T1993
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Tobacco plug vial number	19
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Level	0 
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Observation	
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Picture File Name	T1993_19_9KW5.JPG
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Date of analysis DD/MMM/YYYY	18 JUL 2014
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (20)

Generated On: 20 Jul 2016 22:28:45

Tobacco plug kit number	T1993
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Tobacco plug vial number	20
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Level	0 <input checked="" type="radio"/>
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Observation	
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Picture File Name	T1993_20_0JM7.JPG
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Date of analysis DD/MMM/YYYY	18 JUL 2014
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (1)

Generated On: 20 Jul 2016 22:28:45

Tobacco plug kit number	T2096
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Tobacco plug vial number	01
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Level	0 
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Observation	
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Picture File Name	T2096_01_T39Y.JPG
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Date of analysis DD/MMM/YYYY	18 JUL 2014
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (2)

Generated On: 20 Jul 2016 22:28:45

Tobacco plug kit number	T2096
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Tobacco plug vial number	02
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Level	0 
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Observation	
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Picture File Name	T2096_02_06B6.JPG
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Date of analysis DD/MMM/YYYY	18 JUL 2014
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (3)

Generated On: 20 Jul 2016 22:28:45

Tobacco plug kit number	T2096
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Tobacco plug vial number	03
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Level	0 
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Observation	<hr/>
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Picture File Name	T2096_03_MQGA.JPG
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Date of analysis DD/MMM/YYYY	18 JUL 2014
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (4)

Generated On: 20 Jul 2016 22:28:45

Tobacco plug kit number	T2096
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Tobacco plug vial number	04
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Level	0 <input checked="" type="radio"/>
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Observation	
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Picture File Name	T2096_04_DAQ0.JPG
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Date of analysis DD/MMM/YYYY	18 JUL 2014
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (5)

Generated On: 20 Jul 2016 22:28:45

Tobacco plug kit number	T2096
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Tobacco plug vial number	05
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Level	0 <input checked="" type="radio"/>
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Observation	
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Picture File Name	T2096_05_P1M8.JPG
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Date of analysis DD/MMM/YYYY	18 JUL 2014
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (6)

Generated On: 20 Jul 2016 22:28:45

Tobacco plug kit number	T2096
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Tobacco plug vial number	06
--------------------------	----

Level	0 
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Observation	
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Picture File Name	T2096_06_WXQX.JPG
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Date of analysis DD/MMM/YYYY	18 JUL 2014
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**


Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (7)

Generated On: 20 Jul 2016 22:28:45

Tobacco plug kit number	T2096
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Tobacco plug vial number	07
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Level	0 
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Observation	<hr/>
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Picture File Name	T2096_07_75ST.JPG
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Date of analysis DD/MMM/YYYY	18 JUL 2014
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (8)

Generated On: 20 Jul 2016 22:28:45

Tobacco plug kit number	T2096
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Tobacco plug vial number	08
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Level	0 <input checked="" type="radio"/>
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Observation	
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Picture File Name	T2096_08_NDPI.JPG
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Date of analysis DD/MMM/YYYY	18 JUL 2014
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (9)

Generated On: 20 Jul 2016 22:28:45

Tobacco plug kit number	T2096
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Tobacco plug vial number	09
--------------------------	----

Level	0 
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Observation	
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Picture File Name	T2096_09_GYF7.JPG
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Date of analysis DD/MMM/YYYY	18 JUL 2014
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (10)

Generated On: 20 Jul 2016 22:28:45

Tobacco plug kit number	T2096
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Tobacco plug vial number	10
--------------------------	----

Level	0 
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Observation	
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Picture File Name	T2096_10_3Q6V.JPG
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Date of analysis DD/MMM/YYYY	18 JUL 2014
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (11)

Generated On: 20 Jul 2016 22:28:45

Tobacco plug kit number	T2096
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Tobacco plug vial number	11
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Level	0 
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Observation	<hr/>
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Picture File Name	T2096_11_9UC9.JPG
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Date of analysis DD/MMM/YYYY	18 JUL 2014
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (12)

Generated On: 20 Jul 2016 22:28:45

Tobacco plug kit number	T2096
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Tobacco plug vial number	12
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Level	0 
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Observation	
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Picture File Name	T2096_12_800X.JPG
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Date of analysis DD/MMM/YYYY	18 JUL 2014
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (13)

Generated On: 20 Jul 2016 22:28:45

Tobacco plug kit number	T2096
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Tobacco plug vial number	13
--------------------------	----

Level	0 
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Observation	
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Picture File Name	T2096_13_L1JQ.JPG
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Date of analysis DD/MMM/YYYY	18 JUL 2014
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (14)

Generated On: 20 Jul 2016 22:28:45

Tobacco plug kit number	T2096
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Tobacco plug vial number	14
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Level	0 
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Observation	<hr/>
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Picture File Name	T2096_14_CLV4.JPG
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Date of analysis DD/MMM/YYYY	18 JUL 2014
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (15)

Generated On: 20 Jul 2016 22:28:45

Tobacco plug kit number	T2096
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Tobacco plug vial number	15
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Level	0 <input type="radio"/>
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Observation	
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Picture File Name	T2096_15_H5D8.JPG
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Date of analysis DD/MMM/YYYY	18 JUL 2014
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (16)

Generated On: 20 Jul 2016 22:28:45

Tobacco plug kit number	T2096
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Tobacco plug vial number	16
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Level	0 
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Observation	<hr/>
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Picture File Name	T2096_16_RT4W.JPG
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Date of analysis DD/MMM/YYYY	18 JUL 2014
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (17)

Generated On: 20 Jul 2016 22:28:45

Tobacco plug kit number	T2096
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Tobacco plug vial number	17
--------------------------	----

Level	0 
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Observation	
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Picture File Name	T2096_17_6CGC.JPG
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Date of analysis DD/MMM/YYYY	18 JUL 2014
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (18)

Generated On: 20 Jul 2016 22:28:45

Tobacco plug kit number	T2096
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Tobacco plug vial number	18
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Level	0 
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Observation	<hr/>
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Picture File Name	T2096_18_G3PJ.JPG
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Date of analysis DD/MMM/YYYY	18 JUL 2014
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (19)

Generated On: 20 Jul 2016 22:28:45

Tobacco plug kit number	T2096
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Tobacco plug vial number	19
--------------------------	----

Level	0 
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Observation	
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Picture File Name	T2096_19_4UEO.JPG
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Date of analysis DD/MMM/YYYY	18 JUL 2014
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (20)

Generated On: 20 Jul 2016 22:28:45

Tobacco plug kit number	T2096
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Tobacco plug vial number	20
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Level	0 
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Observation	<hr/>
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Picture File Name	T2096_20_XZKS.JPG
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Date of analysis DD/MMM/YYYY	18 JUL 2014
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (21)

Generated On: 20 Jul 2016 22:28:45

Tobacco plug kit number	T2096
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Tobacco plug vial number	21
--------------------------	----

Level	0 
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Observation	
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Picture File Name	T2096_21_VD1T.JPG
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Date of analysis DD/MMM/YYYY	18 JUL 2014
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**


Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (22)

Generated On: 20 Jul 2016 22:28:45

Tobacco plug kit number	T2096
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Tobacco plug vial number	22
--------------------------	----

Level	0 
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Observation	
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Picture File Name	T2096_22_82Z7.JPG
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Date of analysis DD/MMM/YYYY	18 JUL 2014
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**


Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (23)

Generated On: 20 Jul 2016 22:28:45

Tobacco plug kit number	T2096
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Tobacco plug vial number	23
--------------------------	----

Level	0 
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Observation	
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Picture File Name	T2096_23_8DBJ.JPG
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Date of analysis DD/MMM/YYYY	18 JUL 2014
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (1)

Generated On: 20 Jul 2016 22:28:45

Tobacco plug kit number	T2100
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Tobacco plug vial number	01
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Level	0 
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Observation	
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Picture File Name	T2100_01_YF8Q.JPG
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Date of analysis DD/MMM/YYYY	18 JUL 2014
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (2)

Generated On: 20 Jul 2016 22:28:45

Tobacco plug kit number	T2100
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Tobacco plug vial number	02
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Level	0 
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Observation	
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Picture File Name	T2100_02_GJHK.JPG
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Date of analysis DD/MMM/YYYY	18 JUL 2014
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (3)

Generated On: 20 Jul 2016 22:28:45

Tobacco plug kit number	T2100
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Tobacco plug vial number	03
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Level	0 
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Observation	
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Picture File Name	T2100_03_ZU53.JPG
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Date of analysis DD/MMM/YYYY	18 JUL 2014
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (4)

Generated On: 20 Jul 2016 22:28:45

Tobacco plug kit number	T2100
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Tobacco plug vial number	04
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Level	0 
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Observation	
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Picture File Name	T2100_04_JHGM.JPG
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Date of analysis DD/MMM/YYYY	18 JUL 2014
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (5)

Generated On: 20 Jul 2016 22:28:45

Tobacco plug kit number	T2100
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Tobacco plug vial number	05
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Level	0 <input checked="" type="radio"/>
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Observation	
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Picture File Name	T2100_05_3DIM.JPG
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Date of analysis DD/MMM/YYYY	18 JUL 2014
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (6)

Generated On: 20 Jul 2016 22:28:45

Tobacco plug kit number	T2100
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Tobacco plug vial number	06
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Level	0 
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Observation	<hr/>
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Picture File Name	T2100_06_J7NI.JPG
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Date of analysis DD/MMM/YYYY	18 JUL 2014
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (7)

Generated On: 20 Jul 2016 22:28:45

Tobacco plug kit number	T2100
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Tobacco plug vial number	07
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Level	0 
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Observation	
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Picture File Name	T2100_07_931G.JPG
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Date of analysis DD/MMM/YYYY	18 JUL 2014
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (8)

Generated On: 20 Jul 2016 22:28:45

Tobacco plug kit number	T2100
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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	T2100_08_PEFM.JPG
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Date of analysis DD/MMM/YYYY	18 JUL 2014
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (9)

Generated On: 20 Jul 2016 22:28:45

Tobacco plug kit number	T2100
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Tobacco plug vial number	09
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Level	0 
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Observation	
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Picture File Name	T2100_09_NCM7.JPG
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Date of analysis DD/MMM/YYYY	18 JUL 2014
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (10)

Generated On: 20 Jul 2016 22:28:45

Tobacco plug kit number	T2100
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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	T2100_10_C6K5.JPG
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Date of analysis DD/MMM/YYYY	18 JUL 2014
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (11)

Generated On: 20 Jul 2016 22:28:45

Tobacco plug kit number	T2100
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Tobacco plug vial number	11
--------------------------	----

Level	0 
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Observation	
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Picture File Name	T2100_11_ZAIW.JPG
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Date of analysis DD/MMM/YYYY	18 JUL 2014
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (12)

Generated On: 20 Jul 2016 22:28:45

Tobacco plug kit number	T2100
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Tobacco plug vial number	12
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Level	0 
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Observation	<hr/>
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Picture File Name	T2100_12_292V.JPG
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Date of analysis DD/MMM/YYYY	18 JUL 2014
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (13)

Generated On: 20 Jul 2016 22:28:45

Tobacco plug kit number	T2100
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Tobacco plug vial number	13
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Level	0 <input checked="" type="radio"/>
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Observation	
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Picture File Name	T2100_13_UT0I.JPG
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Date of analysis DD/MMM/YYYY	18 JUL 2014
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (14)

Generated On: 20 Jul 2016 22:28:45

Tobacco plug kit number	T2100
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Tobacco plug vial number	14
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Level	0 
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Observation	
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Picture File Name	T2100_14_5ICN.JPG
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Date of analysis DD/MMM/YYYY	18 JUL 2014
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (15)

Generated On: 20 Jul 2016 22:28:45

Tobacco plug kit number	T2100
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Tobacco plug vial number	15
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Level	0 
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Observation	<hr/>
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Picture File Name	T2100_15_5K74.JPG
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Date of analysis DD/MMM/YYYY	18 JUL 2014
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (16)

Generated On: 20 Jul 2016 22:28:45

Tobacco plug kit number	T2100
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Tobacco plug vial number	16
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Level	0 <input checked="" type="radio"/>
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Observation	
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Picture File Name	T2100_16_EHRU.JPG
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Date of analysis DD/MMM/YYYY	18 JUL 2014
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (17)

Generated On: 20 Jul 2016 22:28:45

Tobacco plug kit number	T2100
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Tobacco plug vial number	17
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Level	0 
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Observation	<hr/>
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Picture File Name	T2100_17_VQ66.JPG
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Date of analysis DD/MMM/YYYY	18 JUL 2014
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (18)

Generated On: 20 Jul 2016 22:28:45

Tobacco plug kit number	T2100
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Tobacco plug vial number	18
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Level	0 
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Observation	
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Picture File Name	T2100_18_264T.JPG
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Date of analysis DD/MMM/YYYY	18 JUL 2014
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (19)

Generated On: 20 Jul 2016 22:28:45

Tobacco plug kit number	T2100
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Tobacco plug vial number	19
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Level	0 
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Observation	<hr/>
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Picture File Name	T2100_19_1VEB.JPG
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Date of analysis DD/MMM/YYYY	18 JUL 2014
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (20)

Generated On: 20 Jul 2016 22:28:45

Tobacco plug kit number	T2100
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Tobacco plug vial number	20
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Level	0 
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Observation	<hr/>
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Picture File Name	T2100_20_KZDR.JPG
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Date of analysis DD/MMM/YYYY	18 JUL 2014
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (21)

Generated On: 20 Jul 2016 22:28:45

Tobacco plug kit number	T2100
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Tobacco plug vial number	21
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Level	0 
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Observation	<hr/>
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Picture File Name	T2100_21_PBIA.JPG
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Date of analysis DD/MMM/YYYY	18 JUL 2014
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (1)

Generated On: 20 Jul 2016 22:28:45

Tobacco plug kit number	T2104
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Tobacco plug vial number	01
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Level	0 
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Observation	
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Picture File Name	T2104_01_BSYS.JPG
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Date of analysis DD/MMM/YYYY	18 JUL 2014
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**


Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (2)

Generated On: 20 Jul 2016 22:28:45

Tobacco plug kit number	T2104
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Tobacco plug vial number	02
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Level	0 
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Observation	
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Picture File Name	T2104_02_SG2L.JPG
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Date of analysis DD/MMM/YYYY	18 JUL 2014
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (3)

Generated On: 20 Jul 2016 22:28:45

Tobacco plug kit number	T2104
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Tobacco plug vial number	03
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Level	0 
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Observation	
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Picture File Name	T2104_03_GYED.JPG
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Date of analysis DD/MMM/YYYY	18 JUL 2014
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (4)

Generated On: 20 Jul 2016 22:28:45

Tobacco plug kit number	T2104
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Tobacco plug vial number	04
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Level	0 
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Observation	<hr/>
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Picture File Name	T2104_04_JBK8.JPG
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Date of analysis DD/MMM/YYYY	18 JUL 2014
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (5)

Generated On: 20 Jul 2016 22:28:45

Tobacco plug kit number	T2104
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Tobacco plug vial number	05
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Level	0 <input checked="" type="radio"/>
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Observation	
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Picture File Name	T2104_05_2QLI.JPG
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Date of analysis DD/MMM/YYYY	18 JUL 2014
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (6)

Generated On: 20 Jul 2016 22:28:45

Tobacco plug kit number	T2104
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Tobacco plug vial number	06
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Level	0 
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Observation	
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Picture File Name	T2104_06_CM08.JPG
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Date of analysis DD/MMM/YYYY	18 JUL 2014
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (7)

Generated On: 20 Jul 2016 22:28:45

Tobacco plug kit number	T2104
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Tobacco plug vial number	07
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Level	0 
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Observation	<hr/>
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Picture File Name	T2104_07_ATLE.JPG
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Date of analysis DD/MMM/YYYY	18 JUL 2014
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (8)

Generated On: 20 Jul 2016 22:28:45

Tobacco plug kit number	T2104
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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	T2104_08_NV30.JPG
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Date of analysis DD/MMM/YYYY	18 JUL 2014
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (9)

Generated On: 20 Jul 2016 22:28:45

Tobacco plug kit number	T2104
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Tobacco plug vial number	09
--------------------------	----

Level	0 
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Observation	
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Picture File Name	T2104_09_N36T.JPG
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Date of analysis DD/MMM/YYYY	18 JUL 2014
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (10)

Generated On: 20 Jul 2016 22:28:45

Tobacco plug kit number	T2104
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Tobacco plug vial number	10
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Level	0 
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Observation	
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Picture File Name	T2104_10_E1W6.JPG
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Date of analysis DD/MMM/YYYY	18 JUL 2014
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (11)

Generated On: 20 Jul 2016 22:28:45

Tobacco plug kit number	T2104
-------------------------	-------

Tobacco plug vial number	11
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Level	0 
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Observation	<hr/>
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Picture File Name	T2104_11_WWGA.JPG
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Date of analysis DD/MMM/YYYY	18 JUL 2014
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (12)

Generated On: 20 Jul 2016 22:28:45

Tobacco plug kit number	T2104
-------------------------	-------

Tobacco plug vial number	12
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Level	0 
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Observation	<hr/>
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Picture File Name	T2104_12_RNHS.JPG
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Date of analysis DD/MMM/YYYY	18 JUL 2014
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (13)

Generated On: 20 Jul 2016 22:28:45

Tobacco plug kit number	T2104
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Tobacco plug vial number	13
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Level	0 
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Observation	
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Picture File Name	T2104_13_ZNZ6.JPG
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Date of analysis DD/MMM/YYYY	18 JUL 2014
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (14)

Generated On: 20 Jul 2016 22:28:45

Tobacco plug kit number	T2104
-------------------------	-------

Tobacco plug vial number	14
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Level	0 
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Observation	<hr/>
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Picture File Name	T2104_14_LJ9K.JPG
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Date of analysis DD/MMM/YYYY	18 JUL 2014
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (15)

Generated On: 20 Jul 2016 22:28:45

Tobacco plug kit number	T2104
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Tobacco plug vial number	15
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Level	0 
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Observation	<hr/>
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Picture File Name	T2104_15_LEG1.JPG
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Date of analysis DD/MMM/YYYY	18 JUL 2014
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (16)

Generated On: 20 Jul 2016 22:28:45

Tobacco plug kit number	T2104
-------------------------	-------

Tobacco plug vial number	16
--------------------------	----

Level	0 
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Observation	
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Picture File Name	T2104_16_O12T.JPG
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Date of analysis DD/MMM/YYYY	18 JUL 2014
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (17)

Generated On: 20 Jul 2016 22:28:45

Tobacco plug kit number	T2104
-------------------------	-------

Tobacco plug vial number	17
--------------------------	----

Level	0 
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Observation	
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Picture File Name	T2104_17_3ZS4.JPG
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Date of analysis DD/MMM/YYYY	18 JUL 2014
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (18)

Generated On: 20 Jul 2016 22:28:45

Tobacco plug kit number	T2104
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Tobacco plug vial number	18
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Level	0 
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Observation	<hr/>
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Picture File Name	T2104_18_AT97.JPG
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Date of analysis DD/MMM/YYYY	18 JUL 2014
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (19)

Generated On: 20 Jul 2016 22:28:45

Tobacco plug kit number	T2104
-------------------------	-------

Tobacco plug vial number	19
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Level	0 
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Observation	<hr/>
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Picture File Name	T2104_19_GPS8.JPG
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Date of analysis DD/MMM/YYYY	18 JUL 2014
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (20)

Generated On: 20 Jul 2016 22:28:45

Tobacco plug kit number	T2104
-------------------------	-------

Tobacco plug vial number	20
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Level	0 
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Observation	<hr/>
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Picture File Name	T2104_20_8N79.JPG
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Date of analysis DD/MMM/YYYY	18 JUL 2014
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (21)

Generated On: 20 Jul 2016 22:28:45

Tobacco plug kit number	T2104
-------------------------	-------

Tobacco plug vial number	21
--------------------------	----

Level	0 
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Observation	
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Picture File Name	T2104_21_JNUX.JPG
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Date of analysis DD/MMM/YYYY	18 JUL 2014
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (22)

Generated On: 20 Jul 2016 22:28:45

Tobacco plug kit number	T2104
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Tobacco plug vial number	22
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Level	1 
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Observation	
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Picture File Name	T2104_22_7G9C.JPG
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Date of analysis DD/MMM/YYYY	18 JUL 2014
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (23)

Generated On: 20 Jul 2016 22:28:45

Tobacco plug kit number	T2104
-------------------------	-------

Tobacco plug vial number	23
--------------------------	----

Level	0 
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Observation	
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Picture File Name	T2104_23_8DQH.JPG
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Date of analysis DD/MMM/YYYY	18 JUL 2014
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (24)

Generated On: 20 Jul 2016 22:28:45

Tobacco plug kit number	T2104
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Tobacco plug vial number	24
--------------------------	----

Level	0 
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Observation	
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Picture File Name	T2104_24_X1U4.JPG
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Date of analysis DD/MMM/YYYY	18 JUL 2014
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (1)

Generated On: 20 Jul 2016 22:28:45

Tobacco plug kit number	T2014
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Tobacco plug vial number	01
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Level	0 <input checked="" type="radio"/>
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Observation	
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Picture File Name	T2014_01_79DB.JPG
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Date of analysis DD/MMM/YYYY	18 JUL 2014
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (2)

Generated On: 20 Jul 2016 22:28:45

Tobacco plug kit number	T2014
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Tobacco plug vial number	02
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Level	0 <input checked="" type="radio"/>
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Observation	
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Picture File Name	T2014_02_8T8E.JPG
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Date of analysis DD/MMM/YYYY	18 JUL 2014
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (3)

Generated On: 20 Jul 2016 22:28:45

Tobacco plug kit number	T2014
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Tobacco plug vial number	03
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Level	0 
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Observation	
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Picture File Name	T2014_03_YL9J.JPG
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Date of analysis DD/MMM/YYYY	18 JUL 2014
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (4)

Generated On: 20 Jul 2016 22:28:45

Tobacco plug kit number	T2014
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Tobacco plug vial number	04
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Level	0 <input checked="" type="radio"/>
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Observation	
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Picture File Name	T2014_04_UJOL.JPG
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Date of analysis DD/MMM/YYYY	18 JUL 2014
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (5)

Generated On: 20 Jul 2016 22:28:45

Tobacco plug kit number	T2014
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Tobacco plug vial number	05
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Level	0 <input checked="" type="radio"/>
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Observation	
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Picture File Name	T2014_05_N0Z0.JPG
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Date of analysis DD/MMM/YYYY	18 JUL 2014
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (6)

Generated On: 20 Jul 2016 22:28:45

Tobacco plug kit number	T2014
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Tobacco plug vial number	06
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Level	0 <input checked="" type="radio"/>
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Observation	
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Picture File Name	T2014_06_PNT8.JPG
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Date of analysis DD/MMM/YYYY	18 JUL 2014
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (7)

Generated On: 20 Jul 2016 22:28:45

Tobacco plug kit number	T2014
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Tobacco plug vial number	07
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Level	0 
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Observation	
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Picture File Name	T2014_07_6Y4W.JPG
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Date of analysis DD/MMM/YYYY	18 JUL 2014
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (8)

Generated On: 20 Jul 2016 22:28:45

Tobacco plug kit number	T2014
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Tobacco plug vial number	08
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Level	0 
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Observation	
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Picture File Name	T2014_08_7VE5.JPG
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Date of analysis DD/MMM/YYYY	18 JUL 2014
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (9)

Generated On: 20 Jul 2016 22:28:45

Tobacco plug kit number	T2014
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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	T2014_09_CUNF.JPG
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Date of analysis DD/MMM/YYYY	18 JUL 2014
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (10)

Generated On: 20 Jul 2016 22:28:45

Tobacco plug kit number	T2014
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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	T2014_10_EBSH.JPG
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Date of analysis DD/MMM/YYYY	18 JUL 2014
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (11)

Generated On: 20 Jul 2016 22:28:45

Tobacco plug kit number	T2014
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Tobacco plug vial number	11
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Level	0 <input checked="" type="radio"/>
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Observation	
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Picture File Name	T2014_11_I53I.JPG
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Date of analysis DD/MMM/YYYY	18 JUL 2014
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (12)

Generated On: 20 Jul 2016 22:28:45

Tobacco plug kit number	T2014
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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	T2014_12_AS9W.JPG
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Date of analysis DD/MMM/YYYY	18 JUL 2014
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (13)

Generated On: 20 Jul 2016 22:28:45

Tobacco plug kit number	T2014
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Tobacco plug vial number	13
--------------------------	----

Level	0 <input checked="" type="radio"/>
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Observation	
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Picture File Name	T2014_13_7JUW.JPG
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Date of analysis DD/MMM/YYYY	18 JUL 2014
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (14)

Generated On: 20 Jul 2016 22:28:45

Tobacco plug kit number	T2014
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Tobacco plug vial number	14
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Level	0 <input type="radio"/>
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Observation	
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Picture File Name	T2014_14_A6FW.JPG
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Date of analysis DD/MMM/YYYY	18 JUL 2014
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (1)

Generated On: 20 Jul 2016 22:28:45

Tobacco plug kit number	T2040
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Tobacco plug vial number	01
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Level	0 <input checked="" type="radio"/>
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Observation	
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Picture File Name	T2040_01_MOLW.JPG
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Date of analysis DD/MMM/YYYY	25 JUL 2014
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (2)

Generated On: 20 Jul 2016 22:28:45

Tobacco plug kit number	T2040
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Tobacco plug vial number	02
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Level	0 
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Observation	<hr/>
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Picture File Name	T2040_02_1LLT.JPG
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Date of analysis DD/MMM/YYYY	25 JUL 2014
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (3)

Generated On: 20 Jul 2016 22:28:45

Tobacco plug kit number	T2040
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Tobacco plug vial number	03
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Level	0 <input type="radio"/>
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Observation	
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Picture File Name	T2040_03_QHG4.JPG
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Date of analysis DD/MMM/YYYY	25 JUL 2014
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (4)

Generated On: 20 Jul 2016 22:28:45

Tobacco plug kit number	T2040
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Tobacco plug vial number	04
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Level	0 <input checked="" type="radio"/>
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Observation	
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Picture File Name	T2040_04_INIA.JPG
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Date of analysis DD/MMM/YYYY	25 JUL 2014
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (5)

Generated On: 20 Jul 2016 22:28:45

Tobacco plug kit number	T2040
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Tobacco plug vial number	05
--------------------------	----

Level	0 <input checked="" type="radio"/>
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Observation	
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Picture File Name	T2040_05_9N0N.JPG
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Date of analysis DD/MMM/YYYY	25 JUL 2014
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (6)

Generated On: 20 Jul 2016 22:28:45

Tobacco plug kit number	T2040
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Tobacco plug vial number	06
--------------------------	----

Level	0 
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Observation	
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Picture File Name	T2040_06_W8A4.JPG
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Date of analysis DD/MMM/YYYY	25 JUL 2014
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (7)

Generated On: 20 Jul 2016 22:28:45

Tobacco plug kit number	T2040
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Tobacco plug vial number	07
--------------------------	----

Level	0 
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Observation	
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Picture File Name	T2040_07_J16U.JPG
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Date of analysis DD/MMM/YYYY	25 JUL 2014
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (8)

Generated On: 20 Jul 2016 22:28:45

Tobacco plug kit number	T2040
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Tobacco plug vial number	08
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Level	0 <input checked="" type="radio"/>
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Observation	
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Picture File Name	T2040_08_UMCZ.JPG
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Date of analysis DD/MMM/YYYY	25 JUL 2014
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (9)

Generated On: 20 Jul 2016 22:28:45

Tobacco plug kit number	T2040
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Tobacco plug vial number	09
--------------------------	----

Level	0 
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Observation	
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Picture File Name	T2040_09_VC2F.JPG
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Date of analysis DD/MMM/YYYY	25 JUL 2014
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (10)

Generated On: 20 Jul 2016 22:28:45

Tobacco plug kit number	T2040
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Tobacco plug vial number	10
--------------------------	----

Level	0 <input checked="" type="radio"/>
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Observation	
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Picture File Name	T2040_10_UF1Z.JPG
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Date of analysis DD/MMM/YYYY	25 JUL 2014
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (11)

Generated On: 20 Jul 2016 22:28:45

Tobacco plug kit number	T2040
-------------------------	-------

Tobacco plug vial number	11
--------------------------	----

Level	0 
-------	---

Observation	<hr/>
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Picture File Name	T2040_11_TIY1.JPG
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Date of analysis DD/MMM/YYYY	25 JUL 2014
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (12)

Generated On: 20 Jul 2016 22:28:45

Tobacco plug kit number	T2040
-------------------------	-------

Tobacco plug vial number	12
--------------------------	----

Level	0 <input type="radio"/>
-------	-------------------------

Observation	
-------------	--

Picture File Name	T2040_12_RVK9.JPG
-------------------	-------------------

Date of analysis DD/MMM/YYYY	25 JUL 2014
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (13)

Generated On: 20 Jul 2016 22:28:45

Tobacco plug kit number	T2040
-------------------------	-------

Tobacco plug vial number	13
--------------------------	----

Level	0 <input checked="" type="radio"/>
-------	------------------------------------

Observation	
-------------	--

Picture File Name	T2040_13_U124.JPG
-------------------	-------------------

Date of analysis DD/MMM/YYYY	25 JUL 2014
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (14)

Generated On: 20 Jul 2016 22:28:45

Tobacco plug kit number	T2040
-------------------------	-------

Tobacco plug vial number	14
--------------------------	----

Level	0 <input checked="" type="radio"/>
-------	------------------------------------

Observation	
-------------	--

Picture File Name	T2040_14_QSPO.JPG
-------------------	-------------------

Date of analysis DD/MMM/YYYY	25 JUL 2014
---------------------------------	-------------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (15)

Generated On: 20 Jul 2016 22:28:45

Tobacco plug kit number	T2040
-------------------------	-------

Tobacco plug vial number	15
--------------------------	----

Level	0 <input type="radio"/>
-------	-------------------------

Observation	
-------------	--

Picture File Name	T2040_15_CP2Q.JPG
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Date of analysis DD/MMM/YYYY	25 JUL 2014
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Product use diary(Paper)

Data signed: (hfarmer1) 30 Mar 2015 13:36:04

Generated On: 20 Jul 2016 22:28:45

Was paper questionnaire used?

No ☒

Reason not done

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Product Use

Form: Product use diary(Paper) (1)

Data signed: (hfarmer1) 30 Mar 2015 13:36:04

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Product Use

Form: Product use diary(Paper) (1)

Data signed: (hfarmer1) 30 Mar 2015 13:36:04

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Folder: Adverse Events

Form: Adverse Events Y/N

Data signed: (hfarmer1) 30 Mar 2015 13:36:04

Generated On: 20 Jul 2016 22:28:45

Was there any Adverse Event for this subject?

No ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Previous and Concomitant Medication

Form: Previous and Concomitant Medication Y/N

Data signed: (hfarmer1) 30 Mar 2015 13:36:04

Generated On: 20 Jul 2016 22:28:45

Has the subject taken previous or concomitant
medication?

No ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Device Events

Form: Device report - THS 2.2 menthol Cigarette Holder

Data signed: (hfarmer1) 30 Mar 2015 13:36:05

Generated On: 20 Jul 2016 22:28:45

Were there any events with the device?

Yes ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Device Events

Form: Device report - THS 2.2 menthol Cigarette Holder (1)

Data signed: (hfarmer1) 30 Mar 2015 13:36:05

Generated On: 20 Jul 2016 22:28:45

Were there any events with the device? Yes ☒

Event Log Number 1

Date of Device Event 07 APR 2014
DD/MMM/YYYY

Time of Device Event 10:59
hour:min 24-hour clock

Event Relates to Device Type: THS 2.2 CIGARETTE HOLDER

Unique Device Identifier Serial Number 1249157

Event Description CH heater broken (LED ☒
blinking red)

Other Describe _____

Severity of Event Major (cannot be resolved. ☒
Device needs to be
exchanged)

Adverse Event Relationship Is not related to AE ☒

If Related to AE, AE Number _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Device Events

Form: Device report - THS 2.2 menthol Cigarette Holder (1)

Data signed: (hfarmer1) 30 Mar 2015 13:36:05

Generated On: 20 Jul 2016 22:28:45

Solution Proposed:

Device Replaced ☒

If the device was replaced, New Device Serial Number:

1249352

Date of Device Event Closure
DD/MMM/YYYY

07 APR 2014

Time of Device Event Closure
hour:min 24-hour clock

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Device Events

Form: Device report - THS 2.2 menthol Cigarette Holder (2)

Data signed: (hfarmer1) 30 Mar 2015 13:36:05

Generated On: 20 Jul 2016 22:28:45

Were there any events with the device? Yes ☒

Event Log Number 2

Date of Device Event 28 APR 2014
DD/MMM/YYYY

Time of Device Event 02:05
hour:min 24-hour clock

Event Relates to Device Type: THS 2.2 CIGARETTE HOLDER

Unique Device Identifier Serial Number 1249404

Event Description CH does not charge when ☒
inserted into the Mobil unit

Other Describe _____

Severity of Event Major (cannot be resolved. ☒
Device needs to be
exchanged)

Adverse Event Relationship Is not related to AE ☒

If Related to AE, AE Number _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Device Events

Form: Device report - THS 2.2 menthol Cigarette Holder (2)

Data signed: (hfarmer1) 30 Mar 2015 13:36:05

Generated On: 20 Jul 2016 22:28:45

Solution Proposed:

Device Replaced ☒

If the device was replaced, New Device Serial Number:

1249096

Date of Device Event Closure
DD/MMM/YYYY

28 APR 2014

Time of Device Event Closure
hour:min 24-hour clock

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Device Events

Form: Device report - THS 2.2 menthol Cigarette Holder (3)

Data signed: (hfarmer1) 30 Mar 2015 13:36:05

Generated On: 20 Jul 2016 22:28:45

Were there any events with the device? Yes ☒

Event Log Number 3

Date of Device Event 28 APR 2014
DD/MMM/YYYY

Time of Device Event 02:05
hour:min 24-hour clock

Event Relates to Device Type: THS 2.2 CIGARETTE HOLDER

Unique Device Identifier Serial Number 1249352

Event Description CH does not charge when ☒
inserted into the Mobil unit

Other Describe _____

Severity of Event Major (cannot be resolved. ☒
Device needs to be
exchanged)

Adverse Event Relationship Is not related to AE ☒

If Related to AE, AE Number _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Device Events

Form: Device report - THS 2.2 menthol Cigarette Holder (3)

Data signed: (hfarmer1) 30 Mar 2015 13:36:05

Generated On: 20 Jul 2016 22:28:45

Solution Proposed:

Device Replaced ☒

If the device was replaced, New Device Serial Number:

1249452

Date of Device Event Closure
DD/MMM/YYYY

28 APR 2014

Time of Device Event Closure
hour:min 24-hour clock

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Device Events

Form: Device report - THS 2.2 menthol Cigarette Holder (4)

Data signed: (hfarmer1) 30 Mar 2015 13:36:05

Generated On: 20 Jul 2016 22:28:45

Were there any events with the device? Yes ☒

Event Log Number 4

Date of Device Event 03 JUN 2014
DD/MMM/YYYY

Time of Device Event 11:06
hour:min 24-hour clock

Event Relates to Device Type: THS 2.2 CIGARETTE HOLDER

Unique Device Identifier Serial Number 1249452

Event Description CH heater broken (LED ☒
blinking red)

Other Describe _____

Severity of Event Major (cannot be resolved. ☒
Device needs to be
exchanged)

Adverse Event Relationship Is not related to AE ☒

If Related to AE, AE Number _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Device Events

Form: Device report - THS 2.2 menthol Cigarette Holder (4)

Data signed: (hfarmer1) 30 Mar 2015 13:36:05

Generated On: 20 Jul 2016 22:28:45

Solution Proposed:

Device Replaced ☒

If the device was replaced, New Device Serial Number:

1249206

Date of Device Event Closure
DD/MMM/YYYY

03 JUN 2014

Time of Device Event Closure
hour:min 24-hour clock

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Device Events

Form: Device report - THS 2.2 menthol Charging Unit

Data signed: (hfarmer1) 30 Mar 2015 13:36:05

Generated On: 20 Jul 2016 22:28:45

Were there any events with the device?

Yes ☒

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Folder: Device Events

Form: Device report - THS 2.2 menthol Charging Unit (1)

Data signed: (hfarmer1) 30 Mar 2015 13:36:05

Generated On: 20 Jul 2016 22:28:45

Were there any events with the device? Yes ☒

Event Log Number 1

Date of Device Event 28 APR 2014
DD/MMM/YYYY

Time of Device Event 02:05
hour:min 24-hour clock

Event Relates to THS 2.2 CHARGING UNIT
Device Type:

Unique Device Identifier Serial Number 1318140

Event Description Other ☒

Other Describe IMPOSSIBLE TO RECHARGE
HOLDER IN THE CHARGER

Severity of Event Major (cannot be resolved. ☒
Device needs to be
exchanged)

Adverse Event Relationship Is not related to AE ☒

Solution Proposed: Device Replaced ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Device Events

Form: Device report - THS 2.2 menthol Charging Unit (1)

Data signed: (hfarmer1) 30 Mar 2015 13:36:05

Generated On: 20 Jul 2016 22:28:45

If the device was replaced, New Device Serial Number:	1318350
---	---------

Date of Device Event Closure DD/MMM/YYYY	28 APR 2014
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Time of Device Event Closure hour:min 24-hour clock	
--	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Device Inventory

Form: Device Inventory - THS 2.2 menthol Cigarette Holder (1)

Data signed: (hfarmer1) 30 Mar 2015 13:36:05

Generated On: 20 Jul 2016 22:28:45

Device Inventory	1
Log Number	

Date of Device Distribution	05 APR 2014
DD/MMM/YYYY	

Time of	07:28
Device Distribution	
hour:min 24-hour clock	

Device Type	THS 2.2 CIGARETTE HOLDER
-------------	--------------------------

Device Serial Number	1249404
----------------------	---------

Date of Device Collection	28 APR 2014
DD/MMM/YYYY	

Time of	
Device Collection	
hour:min 24-hour clock	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Device Inventory

Form: Device Inventory - THS 2.2 menthol Cigarette Holder (2)

Data signed: (hfarmer1) 30 Mar 2015 13:36:05

Generated On: 20 Jul 2016 22:28:45

Device Inventory	2
Log Number	

Date of Device Distribution	05 APR 2014
DD/MMM/YYYY	

Time of	07:28
Device Distribution	
hour:min 24-hour clock	

Device Type	THS 2.2 CIGARETTE HOLDER
-------------	--------------------------

Device Serial Number	1249157
----------------------	---------

Date of Device Collection	07 APR 2014
DD/MMM/YYYY	

Time of	
Device Collection	
hour:min 24-hour clock	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Device Inventory

Form: Device Inventory - THS 2.2 menthol Cigarette Holder (3)

Data signed: (hfarmer1) 30 Mar 2015 13:36:05

Generated On: 20 Jul 2016 22:28:45

Device Inventory	3
Log Number	

Date of Device Distribution	28 APR 2014
DD/MMM/YYYY	

Time of	
Device Distribution	
hour:min 24-hour clock	

Device Type	THS 2.2 CIGARETTE HOLDER
-------------	--------------------------

Device Serial Number	1249096
----------------------	---------

Date of Device Collection	04 JUN 2014
DD/MMM/YYYY	

Time of	09:30
Device Collection	
hour:min 24-hour clock	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Device Inventory

Form: Device Inventory - THS 2.2 menthol Cigarette Holder (4)

Data signed: (hfarmer1) 30 Mar 2015 13:36:05

Generated On: 20 Jul 2016 22:28:45

Device Inventory	4
Log Number	

Date of Device Distribution	28 APR 2014
DD/MMM/YYYY	

Time of	
Device Distribution	
hour:min 24-hour clock	

Device Type	THS 2.2 CIGARETTE HOLDER
-------------	--------------------------

Device Serial Number	1249452
----------------------	---------

Date of Device Collection	03 JUN 2014
DD/MMM/YYYY	

Time of	
Device Collection	
hour:min 24-hour clock	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Device Inventory

Form: Device Inventory - THS 2.2 menthol Cigarette Holder (5)

Data signed: (hfarmer1) 30 Mar 2015 13:36:05

Generated On: 20 Jul 2016 22:28:45

Device Inventory	05
Log Number	

Date of Device Distribution	07 APR 2014
DD/MMM/YYYY	

Time of	
Device Distribution	
hour:min 24-hour clock	

Device Type	THS 2.2 CIGARETTE HOLDER
-------------	--------------------------

Device Serial Number	1249352
----------------------	---------

Date of Device Collection	03 JUN 2014
DD/MMM/YYYY	

Time of	
Device Collection	
hour:min 24-hour clock	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Device Inventory

Form: Device Inventory - THS 2.2 menthol Charging Unit (1)

Data signed: (hfarmer1) 30 Mar 2015 13:36:05

Generated On: 20 Jul 2016 22:28:45

Device Inventory	1
Log Number	

Date of Device Distribution	05 APR 2014
DD/MMM/YYYY	

Time of	07:28
Device Distribution	
hour:min 24-hour clock	

Device Type	THS 2.2 CHARGING UNIT
-------------	-----------------------

Device Serial Number	1318140
----------------------	---------

Date of Device Collection	28 APR 2014
DD/MMM/YYYY	

Time of	
Device Collection	
hour:min 24-hour clock	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Folder: Device Inventory

Form: Device Inventory - THS 2.2 menthol Charging Unit (2)

Data signed: (hfarmer1) 30 Mar 2015 13:36:05

Generated On: 20 Jul 2016 22:28:45

Device Inventory	2
Log Number	

Date of Device Distribution	28 APR 2014
DD/MMM/YYYY	

Time of	
Device Distribution	
hour:min 24-hour clock	

Device Type	THS 2.2 CHARGING UNIT
-------------	-----------------------

Device Serial Number	1318350
----------------------	---------

Date of Device Collection	04 JUN 2014
DD/MMM/YYYY	

Time of	09:30
Device Collection	
hour:min 24-hour clock	

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Form: Product use diary (1)

Data signed: (hfarmer1) 30 Mar 2015 13:33:01

Generated On: 20 Jul 2016 22:28:45

Date of Birth	(b) (6)
Date of completion DD/MMM/YYYY	2014 APR 10
Time of completion hh:mm	21:03
Date the questionnaire was completed for DD/MMM/YYYY	2014 APR 10
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?	13
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: 1252

Form: Product use diary (1)

Data signed: (hfarmer1) 30 Mar 2015 13:33:01

Generated On: 20 Jul 2016 22:28:45

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: 1252

Form: Product use diary (2)

Data signed: (hfarmer1) 30 Mar 2015 13:33:01

Generated On: 20 Jul 2016 22:28:45

Date of Birth	(b) (6)
Date of completion DD/MMM/YYYY	2014 APR 11
Time of completion hh:mm	18:03
Date the questionnaire was completed for DD/MMM/YYYY	2014 APR 11
Assessment Status	Completed <input checked="" type="radio"/>
What tobacco/nicotine product did you use today?	THS 2.2 and CC <input checked="" type="radio"/>
How many THS 2.2 tobacco sticks did you use today?	22
How many CC/ roll-your-own did you smoke today?	5
What NRT product did you used today?	Not Applicable <input checked="" type="radio"/>
How many times did you use an inhaler today?	-9
How many times did you use a nasal spray today?	-9
How many gums did you use today?	-9
How many lozenges did you use today?	-9

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Form: Product use diary (2)

Data signed: (hfarmer1) 30 Mar 2015 13:33:01

Generated On: 20 Jul 2016 22:28:45

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: 1252

Form: Product use diary (3)

Data signed: (hfarmer1) 30 Mar 2015 13:33:01

Generated On: 20 Jul 2016 22:28:45

Date of Birth	(b) (6)
Date of completion DD/MMM/YYYY	2014 APR 12
Time of completion hh:mm	20:01
Date the questionnaire was completed for DD/MMM/YYYY	2014 APR 12
Assessment Status	Completed <input checked="" type="radio"/>
What tobacco/nicotine product did you use today?	THS 2.2 <input checked="" type="radio"/>
How many THS 2.2 tobacco sticks did you use today?	33
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: 1252

Form: Product use diary (3)

Data signed: (hfarmer1) 30 Mar 2015 13:33:01

Generated On: 20 Jul 2016 22:28:45

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: 1252

Form: Product use diary (4)

Data signed: (hfarmer1) 30 Mar 2015 13:33:01

Generated On: 20 Jul 2016 22:28:45

Date of Birth	(b) (6)
Date of completion DD/MMM/YYYY	2014 APR 13
Time of completion hh:mm	20:01
Date the questionnaire was completed for DD/MMM/YYYY	2014 APR 13
Assessment Status	Completed <input checked="" type="radio"/>
What tobacco/nicotine product did you use today?	THS 2.2 <input checked="" type="radio"/>
How many THS 2.2 tobacco sticks did you use today?	47
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: 1252

Form: Product use diary (4)

Data signed: (hfarmer1) 30 Mar 2015 13:33:01

Generated On: 20 Jul 2016 22:28:45

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: 1252

Form: Product use diary (5)

Data signed: (hfarmer1) 30 Mar 2015 13:33:01

Generated On: 20 Jul 2016 22:28:45

Date of Birth	(b) (6)
Date of completion DD/MMM/YYYY	2014 APR 14
Time of completion hh:mm	21:01
Date the questionnaire was completed for DD/MMM/YYYY	2014 APR 14
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?	38
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: 1252

Form: Product use diary (5)

Data signed: (hfarmer1) 30 Mar 2015 13:33:01

Generated On: 20 Jul 2016 22:28:45

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: 1252

Form: Product use diary (6)

Data signed: (hfarmer1) 30 Mar 2015 13:33:01

Generated On: 20 Jul 2016 22:28:45

Date of Birth	(b) (6)
Date of completion DD/MMM/YYYY	2014 APR 15
Time of completion hh:mm	20:04
Date the questionnaire was completed for DD/MMM/YYYY	2014 APR 15
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?	49
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: 1252

Form: Product use diary (6)

Data signed: (hfarmer1) 30 Mar 2015 13:33:01

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Form: Product use diary (7)

Data signed: (hfarmer1) 30 Mar 2015 13:33:01

Generated On: 20 Jul 2016 22:28:45

Date of Birth	(b) (6)
Date of completion DD/MMM/YYYY	2014 APR 16
Time of completion hh:mm	20:01
Date the questionnaire was completed for DD/MMM/YYYY	2014 APR 16
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?	51
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: 1252

Form: Product use diary (7)

Data signed: (hfarmer1) 30 Mar 2015 13:33:01

Generated On: 20 Jul 2016 22:28:45

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: 1252

Form: Product use diary (8)

Data signed: (hfarmer1) 30 Mar 2015 13:33:01

Generated On: 20 Jul 2016 22:28:45

Date of Birth

(b) (6)

Date of completion
DD/MMM/YYYY

2014 APR 17

Time of completion
hh:mm

20:01

Date the questionnaire was completed for
DD/MMM/YYYY

2014 APR 17

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?

46

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: 1252

Form: Product use diary (8)

Data signed: (hfarmer1) 30 Mar 2015 13:33:01

Generated On: 20 Jul 2016 22:28:45

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: 1252

Form: Product use diary (9)

Data signed: (hfarmer1) 30 Mar 2015 13:33:01

Generated On: 20 Jul 2016 22:28:45

Date of Birth	(b) (6)
Date of completion DD/MMM/YYYY	2014 APR 18
Time of completion hh:mm	20:01
Date the questionnaire was completed for DD/MMM/YYYY	2014 APR 18
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?	34
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: 1252

Form: Product use diary (9)

Data signed: (hfarmer1) 30 Mar 2015 13:33:01

Generated On: 20 Jul 2016 22:28:45

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: 1252

Form: Product use diary (10)

Data signed: (hfarmer1) 30 Mar 2015 13:33:01

Generated On: 20 Jul 2016 22:28:45

Date of Birth	(b) (6)
Date of completion DD/MMM/YYYY	2014 APR 19
Time of completion hh:mm	20:01
Date the questionnaire was completed for DD/MMM/YYYY	2014 APR 19
Assessment Status	Completed <input checked="" type="radio"/>
What tobacco/nicotine product did you use today?	THS 2.2 and CC <input checked="" type="radio"/>
How many THS 2.2 tobacco sticks did you use today?	34
How many CC/ roll-your-own did you smoke today?	3
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: 1252

Form: Product use diary (10)

Data signed: (hfarmer1) 30 Mar 2015 13:33:01

Generated On: 20 Jul 2016 22:28:45

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: 1252

Form: Product use diary (11)

Data signed: (hfarmer1) 30 Mar 2015 13:33:01

Generated On: 20 Jul 2016 22:28:45

Date of Birth	(b) (6)
Date of completion DD/MMM/YYYY	2014 APR 20
Time of completion hh:mm	20:01
Date the questionnaire was completed for DD/MMM/YYYY	2014 APR 20
Assessment Status	Completed <input checked="" type="radio"/>
What tobacco/nicotine product did you use today?	THS 2.2 and CC <input checked="" type="radio"/>
How many THS 2.2 tobacco sticks did you use today?	36
How many CC/ roll-your-own did you smoke today?	3
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: 1252

Form: Product use diary (11)

Data signed: (hfarmer1) 30 Mar 2015 13:33:01

Generated On: 20 Jul 2016 22:28:45

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: 1252

Form: Product use diary (12)

Data signed: (hfarmer1) 30 Mar 2015 13:33:01

Generated On: 20 Jul 2016 22:28:45

Date of Birth

(b) (6)

Date of completion
DD/MMM/YYYY

2014 APR 21

Time of completion
hh:mm

20:01

Date the questionnaire was completed for
DD/MMM/YYYY

2014 APR 21

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?

42

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: 1252

Form: Product use diary (12)

Data signed: (hfarmer1) 30 Mar 2015 13:33:01

Generated On: 20 Jul 2016 22:28:45

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: 1252

Form: Product use diary (13)

Data signed: (hfarmer1) 30 Mar 2015 13:33:01

Generated On: 20 Jul 2016 22:28:45

Date of Birth

(b) (6)

Date of completion
DD/MMM/YYYY

2014 APR 22

Time of completion
hh:mm

20:03

Date the questionnaire was completed for
DD/MMM/YYYY

2014 APR 22

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?

68

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: 1252

Form: Product use diary (13)

Data signed: (hfarmer1) 30 Mar 2015 13:33:01

Generated On: 20 Jul 2016 22:28:45

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: 1252

Form: Product use diary (14)

Data signed: (hfarmer1) 30 Mar 2015 13:33:01

Generated On: 20 Jul 2016 22:28:45

Date of Birth	(b) (6)
Date of completion DD/MMM/YYYY	2014 APR 23
Time of completion hh:mm	20:01
Date the questionnaire was completed for DD/MMM/YYYY	2014 APR 23
Assessment Status	Completed <input checked="" type="radio"/>
What tobacco/nicotine product did you use today?	THS 2.2 <input checked="" type="radio"/>
How many THS 2.2 tobacco sticks did you use today?	35
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: 1252

Form: Product use diary (14)

Data signed: (hfarmer1) 30 Mar 2015 13:33:01

Generated On: 20 Jul 2016 22:28:45

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: 1252

Form: Product use diary (15)

Data signed: (hfarmer1) 30 Mar 2015 13:33:01

Generated On: 20 Jul 2016 22:28:45

Date of Birth

(b) (6)

Date of completion
DD/MMM/YYYY

2014 APR 24

Time of completion
hh:mm

20:02

Date the questionnaire was completed for
DD/MMM/YYYY

2014 APR 24

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?

48

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: 1252

Form: Product use diary (15)

Data signed: (hfarmer1) 30 Mar 2015 13:33:01

Generated On: 20 Jul 2016 22:28:45

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: 1252

Form: Product use diary (16)

Data signed: (hfarmer1) 30 Mar 2015 13:33:01

Generated On: 20 Jul 2016 22:28:45

Date of Birth

(b) (6)

Date of completion
DD/MMM/YYYY

2014 APR 25

Time of completion
hh:mm

20:08

Date the questionnaire was completed for
DD/MMM/YYYY

2014 APR 25

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?

49

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: 1252

Form: Product use diary (16)

Data signed: (hfarmer1) 30 Mar 2015 13:33:01

Generated On: 20 Jul 2016 22:28:45

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: 1252

Form: Product use diary (17)

Data signed: (hfarmer1) 30 Mar 2015 13:33:01

Generated On: 20 Jul 2016 22:28:45

Date of Birth

(b) (6)

Date of completion
DD/MMM/YYYY

2014 APR 26

Time of completion
hh:mm

21:06

Date the questionnaire was completed for
DD/MMM/YYYY

2014 APR 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?

35

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: 1252

Form: Product use diary (17)

Data signed: (hfarmer1) 30 Mar 2015 13:33:01

Generated On: 20 Jul 2016 22:28:45

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: 1252

Form: Product use diary (18)

Data signed: (hfarmer1) 30 Mar 2015 13:33:01

Generated On: 20 Jul 2016 22:28:45

Date of Birth	(b) (6)
Date of completion DD/MMM/YYYY	2014 APR 27
Time of completion hh:mm	20:02
Date the questionnaire was completed for DD/MMM/YYYY	2014 APR 27
Assessment Status	Completed <input checked="" type="radio"/>
What tobacco/nicotine product did you use today?	THS 2.2 <input checked="" type="radio"/>
How many THS 2.2 tobacco sticks did you use today?	29
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: 1252**

Form: Product use diary (18)

Data signed: (hfarmer1) 30 Mar 2015 13:33:01

Generated On: 20 Jul 2016 22:28:45

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: 1252

Form: Product use diary (19)

Data signed: (hfarmer1) 30 Mar 2015 13:33:01

Generated On: 20 Jul 2016 22:28:45

Date of Birth

(b) (6)

Date of completion
DD/MMM/YYYY

2014 APR 28

Time of completion
hh:mm

20:02

Date the questionnaire was completed for
DD/MMM/YYYY

2014 APR 28

Assessment Status

Completed ☒

What tobacco/nicotine product did you use today?

CC ☒

How many THS 2.2 tobacco sticks did you use today?

-9

How many CC/ roll-your-own did you smoke today?

10

What NRT product did you used today?

Not Applicable ☒

How many times did you use an inhaler today?

-9

How many times did you use a nasal spray today?

-9

How many gums did you use today?

-9

How many lozenges did you use today?

-9

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Form: Product use diary (19)

Data signed: (hfarmer1) 30 Mar 2015 13:33:01

Generated On: 20 Jul 2016 22:28:45

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: 1252

Form: Product use diary (20)

Data signed: (hfarmer1) 30 Mar 2015 13:33:01

Generated On: 20 Jul 2016 22:28:45

Date of Birth	(b) (6)
Date of completion DD/MMM/YYYY	2014 APR 29
Time of completion hh:mm	20:00
Date the questionnaire was completed for DD/MMM/YYYY	2014 APR 29
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?	26
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: 1252

Form: Product use diary (20)

Data signed: (hfarmer1) 30 Mar 2015 13:33:01

Generated On: 20 Jul 2016 22:28:45

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: 1252

Form: Product use diary (21)

Data signed: (hfarmer1) 30 Mar 2015 13:33:01

Generated On: 20 Jul 2016 22:28:45

Date of Birth

(b) (6)

Date of completion
DD/MMM/YYYY

2014 APR 30

Time of completion
hh:mm

20:03

Date the questionnaire was completed for
DD/MMM/YYYY

2014 APR 30

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?

37

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: 1252

Form: Product use diary (21)

Data signed: (hfarmer1) 30 Mar 2015 13:33:01

Generated On: 20 Jul 2016 22:28:45

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: 1252

Form: Product use diary (22)

Data signed: (hfarmer1) 30 Mar 2015 13:33:01

Generated On: 20 Jul 2016 22:28:45

Date of Birth	(b) (6)
Date of completion DD/MMM/YYYY	2014 MAY 01
Time of completion hh:mm	20:01
Date the questionnaire was completed for DD/MMM/YYYY	2014 MAY 01
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?	45
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: 1252

Form: Product use diary (22)

Data signed: (hfarmer1) 30 Mar 2015 13:33:01

Generated On: 20 Jul 2016 22:28:45

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: 1252

Form: Product use diary (23)

Data signed: (hfarmer1) 30 Mar 2015 13:33:01

Generated On: 20 Jul 2016 22:28:45

Date of Birth	(b) (6)
Date of completion DD/MMM/YYYY	2014 MAY 02
Time of completion hh:mm	20:02
Date the questionnaire was completed for DD/MMM/YYYY	2014 MAY 02
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?	41
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: 1252

Form: Product use diary (23)

Data signed: (hfarmer1) 30 Mar 2015 13:33:01

Generated On: 20 Jul 2016 22:28:45

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: 1252

Form: Product use diary (24)

Data signed: (hfarmer1) 30 Mar 2015 13:33:01

Generated On: 20 Jul 2016 22:28:45

Date of Birth	(b) (6)
Date of completion DD/MMM/YYYY	2014 MAY 03
Time of completion hh:mm	20:03
Date the questionnaire was completed for DD/MMM/YYYY	2014 MAY 03
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?	48
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: 1252

Form: Product use diary (24)

Data signed: (hfarmer1) 30 Mar 2015 13:33:01

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Form: Product use diary (25)

Data signed: (hfarmer1) 30 Mar 2015 13:33:01

Generated On: 20 Jul 2016 22:28:45

Date of Birth

(b) (6)

Date of completion
DD/MMM/YYYY

2014 MAY 04

Time of completion
hh:mm

20:06

Date the questionnaire was completed for
DD/MMM/YYYY

2014 MAY 04

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?

10

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: 1252

Form: Product use diary (25)

Data signed: (hfarmer1) 30 Mar 2015 13:33:01

Generated On: 20 Jul 2016 22:28:45

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: 1252

Form: Product use diary (26)

Data signed: (hfarmer1) 30 Mar 2015 13:33:01

Generated On: 20 Jul 2016 22:28:45

Date of Birth	(b) (6)
Date of completion DD/MMM/YYYY	2014 MAY 05
Time of completion hh:mm	20:01
Date the questionnaire was completed for DD/MMM/YYYY	2014 MAY 05
Assessment Status	Completed <input checked="" type="radio"/>
What tobacco/nicotine product did you use today?	THS 2.2 and CC <input checked="" type="radio"/>
How many THS 2.2 tobacco sticks did you use today?	16
How many CC/ roll-your-own did you smoke today?	1
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: 1252

Form: Product use diary (26)

Data signed: (hfarmer1) 30 Mar 2015 13:33:01

Generated On: 20 Jul 2016 22:28:45

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: 1252

Form: Product use diary (27)

Data signed: (hfarmer1) 30 Mar 2015 13:33:01

Generated On: 20 Jul 2016 22:28:45

Date of Birth

(b) (6)

Date of completion
DD/MMM/YYYY

2014 MAY 06

Time of completion
hh:mm

20:01

Date the questionnaire was completed for
DD/MMM/YYYY

2014 MAY 06

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?

40

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: 1252

Form: Product use diary (27)

Data signed: (hfarmer1) 30 Mar 2015 13:33:01

Generated On: 20 Jul 2016 22:28:45

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: 1252

Form: Product use diary (28)

Data signed: (hfarmer1) 30 Mar 2015 13:33:01

Generated On: 20 Jul 2016 22:28:45

Date of Birth	(b) (6)
Date of completion DD/MMM/YYYY	2014 MAY 07
Time of completion hh:mm	20:00
Date the questionnaire was completed for DD/MMM/YYYY	2014 MAY 07
Assessment Status	Completed <input checked="" type="radio"/>
What tobacco/nicotine product did you use today?	THS 2.2 <input checked="" type="radio"/>
How many THS 2.2 tobacco sticks did you use today?	35
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: 1252

Form: Product use diary (28)

Data signed: (hfarmer1) 30 Mar 2015 13:33:01

Generated On: 20 Jul 2016 22:28:45

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: 1252

Form: Product use diary (29)

Data signed: (hfarmer1) 30 Mar 2015 13:33:01

Generated On: 20 Jul 2016 22:28:45

Date of Birth	(b) (6)
Date of completion DD/MMM/YYYY	2014 MAY 08
Time of completion hh:mm	20:01
Date the questionnaire was completed for DD/MMM/YYYY	2014 MAY 08
Assessment Status	Completed <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?	38
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: 1252

Form: Product use diary (29)

Data signed: (hfarmer1) 30 Mar 2015 13:33:01

Generated On: 20 Jul 2016 22:28:45

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: 1252

Form: Product use diary (30)

Data signed: (hfarmer1) 30 Mar 2015 13:33:01

Generated On: 20 Jul 2016 22:28:45

Date of Birth

(b) (6)

Date of completion
DD/MMM/YYYY

2014 MAY 09

Time of completion
hh:mm

20:01

Date the questionnaire was completed for
DD/MMM/YYYY

2014 MAY 09

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?

40

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: 1252

Form: Product use diary (30)

Data signed: (hfarmer1) 30 Mar 2015 13:33:01

Generated On: 20 Jul 2016 22:28:45

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: 1252

Form: Product use diary (31)

Data signed: (hfarmer1) 30 Mar 2015 13:33:01

Generated On: 20 Jul 2016 22:28:45

Date of Birth	(b) (6)
Date of completion DD/MMM/YYYY	2014 MAY 10
Time of completion hh:mm	22:01
Date the questionnaire was completed for DD/MMM/YYYY	2014 MAY 10
Assessment Status	Completed <input checked="" type="radio"/>
What tobacco/nicotine product did you use today?	THS 2.2 <input checked="" type="radio"/>
How many THS 2.2 tobacco sticks did you use today?	33
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: 1252

Form: Product use diary (31)

Data signed: (hfarmer1) 30 Mar 2015 13:33:01

Generated On: 20 Jul 2016 22:28:45

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: 1252

Form: Product use diary (32)

Data signed: (hfarmer1) 30 Mar 2015 13:33:01

Generated On: 20 Jul 2016 22:28:45

Date of Birth	(b) (6)
Date of completion DD/MMM/YYYY	2014 MAY 11
Time of completion hh:mm	22:01
Date the questionnaire was completed for DD/MMM/YYYY	2014 MAY 11
Assessment Status	Completed <input checked="" type="radio"/>
What tobacco/nicotine product did you use today?	THS 2.2 <input checked="" type="radio"/>
How many THS 2.2 tobacco sticks did you use today?	43
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: 1252

Form: Product use diary (32)

Data signed: (hfarmer1) 30 Mar 2015 13:33:01

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Form: Product use diary (33)

Data signed: (hfarmer1) 30 Mar 2015 13:33:01

Generated On: 20 Jul 2016 22:28:45

Date of Birth	(b) (6)
Date of completion DD/MMM/YYYY	2014 MAY 12
Time of completion hh:mm	20:01
Date the questionnaire was completed for DD/MMM/YYYY	2014 MAY 12
Assessment Status	Completed <input checked="" type="radio"/>
What tobacco/nicotine product did you use today?	THS 2.2 <input checked="" type="radio"/>
How many THS 2.2 tobacco sticks did you use today?	28
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: 1252

Form: Product use diary (33)

Data signed: (hfarmer1) 30 Mar 2015 13:33:01

Generated On: 20 Jul 2016 22:28:45

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: 1252

Form: Product use diary (34)

Data signed: (hfarmer1) 30 Mar 2015 13:33:01

Generated On: 20 Jul 2016 22:28:45

Date of Birth	(b) (6)
Date of completion DD/MMM/YYYY	2014 MAY 13
Time of completion hh:mm	20:02
Date the questionnaire was completed for DD/MMM/YYYY	2014 MAY 13
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?	43
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: 1252

Form: Product use diary (34)

Data signed: (hfarmer1) 30 Mar 2015 13:33:01

Generated On: 20 Jul 2016 22:28:45

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: 1252

Form: Product use diary (35)

Data signed: (hfarmer1) 30 Mar 2015 13:33:01

Generated On: 20 Jul 2016 22:28:45

Date of Birth

(b) (6)

Date of completion
DD/MMM/YYYY

2014 MAY 14

Time of completion
hh:mm

21:01

Date the questionnaire was completed for
DD/MMM/YYYY

2014 MAY 14

Assessment Status

Completed ☒

What tobacco/nicotine product did you use today?

Electronic cigarette ☒

How many THS 2.2 tobacco sticks did you use today?

-9

How many CC/ roll-your-own did you smoke today?

-9

What NRT product did you used today?

Not Applicable ☒

How many times did you use an inhaler today?

-9

How many times did you use a nasal spray today?

-9

How many gums did you use today?

-9

How many lozenges did you use today?

-9

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Form: Product use diary (35)

Data signed: (hfarmer1) 30 Mar 2015 13:33:01

Generated On: 20 Jul 2016 22:28:45

How many patches did you use today?	-9
-------------------------------------	----

How many times did you use other NRT products today not listed previously?	-9
--	----

What other tobacco product did you used today?	Not Applicable <input type="radio"/>
--	--------------------------------------

How many times did you use chewable/smokeless tobacco today?	-9
--	----

How many cigars/cigarillos did you smoke today?	-9
---	----

How many times did you smoke a pipe today?	-9
--	----

How many times did you use a tobacco product today not listed previously?	-9
---	----

How many times did you use an electronic cigarette today?	48
---	----

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Form: Product use diary (36)

Data signed: (hfarmer1) 30 Mar 2015 13:33:01

Generated On: 20 Jul 2016 22:28:45

Date of Birth

(b) (6)

Date of completion
DD/MMM/YYYY

2014 MAY 15

Time of completion
hh:mm

20:01

Date the questionnaire was completed for
DD/MMM/YYYY

2014 MAY 15

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?

38

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: 1252

Form: Product use diary (36)

Data signed: (hfarmer1) 30 Mar 2015 13:33:01

Generated On: 20 Jul 2016 22:28:45

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: 1252

Form: Product use diary (37)

Data signed: (hfarmer1) 30 Mar 2015 13:33:01

Generated On: 20 Jul 2016 22:28:45

Date of Birth

(b) (6)

Date of completion
DD/MMM/YYYY

2014 MAY 16

Time of completion
hh:mm

20:01

Date the questionnaire was completed for
DD/MMM/YYYY

2014 MAY 16

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?

37

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: 1252

Form: Product use diary (37)

Data signed: (hfarmer1) 30 Mar 2015 13:33:01

Generated On: 20 Jul 2016 22:28:45

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: 1252

Form: Product use diary (38)

Data signed: (hfarmer1) 30 Mar 2015 13:33:01

Generated On: 20 Jul 2016 22:28:45

Date of Birth	(b) (6)
Date of completion DD/MMM/YYYY	2014 MAY 17
Time of completion hh:mm	20:00
Date the questionnaire was completed for DD/MMM/YYYY	2014 MAY 17
Assessment Status	Completed <input checked="" type="radio"/>
What tobacco/nicotine product did you use today?	THS 2.2 <input checked="" type="radio"/>
How many THS 2.2 tobacco sticks did you use today?	40
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: 1252

Form: Product use diary (38)

Data signed: (hfarmer1) 30 Mar 2015 13:33:01

Generated On: 20 Jul 2016 22:28:45

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: 1252

Form: Product use diary (39)

Data signed: (hfarmer1) 30 Mar 2015 13:33:01

Generated On: 20 Jul 2016 22:28:45

Date of Birth	(b) (6)
Date of completion DD/MMM/YYYY	2014 MAY 18
Time of completion hh:mm	20:02
Date the questionnaire was completed for DD/MMM/YYYY	2014 MAY 18
Assessment Status	Completed <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?	42
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: 1252

Form: Product use diary (39)

Data signed: (hfarmer1) 30 Mar 2015 13:33:01

Generated On: 20 Jul 2016 22:28:45

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: 1252

Form: Product use diary (40)

Data signed: (hfarmer1) 30 Mar 2015 13:33:01

Generated On: 20 Jul 2016 22:28:45

Date of Birth	(b) (6)
Date of completion DD/MMM/YYYY	2014 MAY 19
Time of completion hh:mm	20:01
Date the questionnaire was completed for DD/MMM/YYYY	2014 MAY 19
Assessment Status	Completed <input checked="" type="radio"/>
What tobacco/nicotine product did you use today?	THS 2.2 <input checked="" type="radio"/>
How many THS 2.2 tobacco sticks did you use today?	34
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: 1252

Form: Product use diary (40)

Data signed: (hfarmer1) 30 Mar 2015 13:33:01

Generated On: 20 Jul 2016 22:28:45

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: 1252

Form: Product use diary (41)

Data signed: (hfarmer1) 30 Mar 2015 13:33:01

Generated On: 20 Jul 2016 22:28:45

Date of Birth	(b) (6)
Date of completion DD/MMM/YYYY	2014 MAY 20
Time of completion hh:mm	20:01
Date the questionnaire was completed for DD/MMM/YYYY	2014 MAY 20
Assessment Status	Completed <input checked="" type="radio"/>
What tobacco/nicotine product did you use today?	THS 2.2 <input checked="" type="radio"/>
How many THS 2.2 tobacco sticks did you use today?	37
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: 1252

Form: Product use diary (41)

Data signed: (hfarmer1) 30 Mar 2015 13:33:01

Generated On: 20 Jul 2016 22:28:45

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: 1252

Form: Product use diary (42)

Data signed: (hfarmer1) 30 Mar 2015 13:33:01

Generated On: 20 Jul 2016 22:28:45

Date of Birth	(b) (6)
Date of completion DD/MMM/YYYY	2014 MAY 21
Time of completion hh:mm	20:01
Date the questionnaire was completed for DD/MMM/YYYY	2014 MAY 21
Assessment Status	Completed
What tobacco/nicotine product did you use today?	THS 2.2
How many THS 2.2 tobacco sticks did you use today?	37
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: 1252

Form: Product use diary (42)

Data signed: (hfarmer1) 30 Mar 2015 13:33:01

Generated On: 20 Jul 2016 22:28:45

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: 1252

Form: Product use diary (43)

Data signed: (hfarmer1) 30 Mar 2015 13:33:01

Generated On: 20 Jul 2016 22:28:45

Date of Birth

(b) (6)

Date of completion
DD/MMM/YYYY

2014 MAY 22

Time of completion
hh:mm

20:01

Date the questionnaire was completed for
DD/MMM/YYYY

2014 MAY 22

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?

37

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: 1252

Form: Product use diary (43)

Data signed: (hfarmer1) 30 Mar 2015 13:33:01

Generated On: 20 Jul 2016 22:28:45

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: 1252

Form: Product use diary (44)

Data signed: (hfarmer1) 30 Mar 2015 13:33:01

Generated On: 20 Jul 2016 22:28:45

Date of Birth

(b) (6)

Date of completion
DD/MMM/YYYY

2014 MAY 23

Time of completion
hh:mm

20:01

Date the questionnaire was completed for
DD/MMM/YYYY

2014 MAY 23

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?

46

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: 1252

Form: Product use diary (44)

Data signed: (hfarmer1) 30 Mar 2015 13:33:01

Generated On: 20 Jul 2016 22:28:45

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: 1252

Form: Product use diary (45)

Data signed: (hfarmer1) 30 Mar 2015 13:33:01

Generated On: 20 Jul 2016 22:28:45

Date of Birth	(b) (6)
Date of completion DD/MMM/YYYY	2014 MAY 24
Time of completion hh:mm	20:01
Date the questionnaire was completed for DD/MMM/YYYY	2014 MAY 24
Assessment Status	Completed <input checked="" type="radio"/>
What tobacco/nicotine product did you use today?	THS 2.2 <input checked="" type="radio"/>
How many THS 2.2 tobacco sticks did you use today?	36
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: 1252

Form: Product use diary (45)

Data signed: (hfarmer1) 30 Mar 2015 13:33:01

Generated On: 20 Jul 2016 22:28:45

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: 1252

Form: Product use diary (46)

Data signed: (hfarmer1) 30 Mar 2015 13:33:01

Generated On: 20 Jul 2016 22:28:45

Date of Birth	(b) (6)
Date of completion DD/MMM/YYYY	2014 MAY 25
Time of completion hh:mm	20:01
Date the questionnaire was completed for DD/MMM/YYYY	2014 MAY 25
Assessment Status	Completed <input checked="" type="radio"/>
What tobacco/nicotine product did you use today?	THS 2.2 <input checked="" type="radio"/>
How many THS 2.2 tobacco sticks did you use today?	42
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: 1252

Form: Product use diary (46)

Data signed: (hfarmer1) 30 Mar 2015 13:33:01

Generated On: 20 Jul 2016 22:28:45

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: 1252

Form: Product use diary (47)

Data signed: (hfarmer1) 30 Mar 2015 13:33:01

Generated On: 20 Jul 2016 22:28:45

Date of Birth	(b) (6)
Date of completion DD/MMM/YYYY	2014 MAY 26
Time of completion hh:mm	20:01
Date the questionnaire was completed for DD/MMM/YYYY	2014 MAY 26
Assessment Status	Completed <input checked="" type="radio"/>
What tobacco/nicotine product did you use today?	THS 2.2 <input checked="" type="radio"/>
How many THS 2.2 tobacco sticks did you use today?	35
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: 1252

Form: Product use diary (47)

Data signed: (hfarmer1) 30 Mar 2015 13:33:01

Generated On: 20 Jul 2016 22:28:45

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: 1252

Form: Product use diary (48)

Data signed: (hfarmer1) 30 Mar 2015 13:33:01

Generated On: 20 Jul 2016 22:28:45

Date of Birth	(b) (6)
Date of completion DD/MMM/YYYY	2014 MAY 27
Time of completion hh:mm	21:01
Date the questionnaire was completed for DD/MMM/YYYY	2014 MAY 27
Assessment Status	Completed <input checked="" type="radio"/>
What tobacco/nicotine product did you use today?	THS 2.2 and CC <input checked="" type="radio"/>
How many THS 2.2 tobacco sticks did you use today?	26
How many CC/ roll-your-own did you smoke today?	10
What NRT product did you used today?	Not Applicable <input checked="" type="radio"/>
How many times did you use an inhaler today?	-9
How many times did you use a nasal spray today?	-9
How many gums did you use today?	-9
How many lozenges did you use today?	-9

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1252

Form: Product use diary (48)

Data signed: (hfarmer1) 30 Mar 2015 13:33:01

Generated On: 20 Jul 2016 22:28:45

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: 1252

Form: Product use diary (49)

Data signed: (hfarmer1) 30 Mar 2015 13:33:01

Generated On: 20 Jul 2016 22:28:45

Date of Birth	(b) (6)
Date of completion DD/MMM/YYYY	2014 MAY 28
Time of completion hh:mm	23:02
Date the questionnaire was completed for DD/MMM/YYYY	2014 MAY 28
Assessment Status	Completed <input checked="" type="radio"/>
What tobacco/nicotine product did you use today?	THS 2.2 <input checked="" type="radio"/>
How many THS 2.2 tobacco sticks did you use today?	36
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: 1252

Form: Product use diary (49)

Data signed: (hfarmer1) 30 Mar 2015 13:33:01

Generated On: 20 Jul 2016 22:28:45

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: 1252

Form: Product use diary (50)

Data signed: (hfarmer1) 30 Mar 2015 13:33:01

Generated On: 20 Jul 2016 22:28:45

Date of Birth	(b) (6)
Date of completion DD/MMM/YYYY	2014 MAY 29
Time of completion hh:mm	20:01
Date the questionnaire was completed for DD/MMM/YYYY	2014 MAY 29
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?	30
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: 1252

Form: Product use diary (50)

Data signed: (hfarmer1) 30 Mar 2015 13:33:01

Generated On: 20 Jul 2016 22:28:45

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: 1252

Form: Product use diary (51)

Data signed: (hfarmer1) 30 Mar 2015 13:33:01

Generated On: 20 Jul 2016 22:28:45

Date of Birth	(b) (6)
Date of completion DD/MMM/YYYY	2014 MAY 30
Time of completion hh:mm	20:01
Date the questionnaire was completed for DD/MMM/YYYY	2014 MAY 30
Assessment Status	Completed <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?	33
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: 1252

Form: Product use diary (51)

Data signed: (hfarmer1) 30 Mar 2015 13:33:01

Generated On: 20 Jul 2016 22:28:45

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: 1252

Form: Product use diary (52)

Data signed: (hfarmer1) 30 Mar 2015 13:33:01

Generated On: 20 Jul 2016 22:28:45

Date of Birth	(b) (6)
Date of completion DD/MMM/YYYY	2014 MAY 31
Time of completion hh:mm	22:02
Date the questionnaire was completed for DD/MMM/YYYY	2014 MAY 31
Assessment Status	Completed <input checked="" type="radio"/>
What tobacco/nicotine product did you use today?	THS 2.2 <input checked="" type="radio"/>
How many THS 2.2 tobacco sticks did you use today?	21
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: 1252

Form: Product use diary (52)

Data signed: (hfarmer1) 30 Mar 2015 13:33:01

Generated On: 20 Jul 2016 22:28:45

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: 1252

Form: Product use diary (53)

Data signed: (hfarmer1) 30 Mar 2015 13:33:01

Generated On: 20 Jul 2016 22:28:45

Date of Birth	(b) (6)
Date of completion DD/MMM/YYYY	2014 JUN 02
Time of completion hh:mm	20:01
Date the questionnaire was completed for DD/MMM/YYYY	2014 JUN 02
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?	32
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: 1252

Form: Product use diary (53)

Data signed: (hfarmer1) 30 Mar 2015 13:33:01

Generated On: 20 Jul 2016 22:28:45

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: 1252

Form: Product use diary (54)

Data signed: (hfarmer1) 30 Mar 2015 13:33:01

Generated On: 20 Jul 2016 22:28:45

Date of Birth	(b) (6)
Date of completion DD/MMM/YYYY	2014 JUN 03
Time of completion hh:mm	20:01
Date the questionnaire was completed for DD/MMM/YYYY	2014 JUN 03
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?	13
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: 1252

Form: Product use diary (54)

Data signed: (hfarmer1) 30 Mar 2015 13:33:01

Generated On: 20 Jul 2016 22:28:45

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: 1252

Form: Product use diary (55)

Data signed: (hfarmer1) 30 Mar 2015 13:33:01

Generated On: 20 Jul 2016 22:28:45

Date of Birth

(b) (6)

Date of completion
DD/MMM/YYYY

2014 JUN 04

Time of completion
hh:mm

20:02

Date the questionnaire was completed for
DD/MMM/YYYY

2014 JUN 04

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?

32

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: 1252

Form: Product use diary (55)

Data signed: (hfarmer1) 30 Mar 2015 13:33:01

Generated On: 20 Jul 2016 22:28:45

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: 1252

Form: Product use diary (56)

Data signed: (hfarmer1) 30 Mar 2015 13:33:01

Generated On: 20 Jul 2016 22:28:45

Date of Birth	(b) (6)
Date of completion DD/MMM/YYYY	2014 JUN 06
Time of completion hh:mm	09:01
Date the questionnaire was completed for DD/MMM/YYYY	2014 JUN 05
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?	36
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: 1252

Form: Product use diary (56)

Data signed: (hfarmer1) 30 Mar 2015 13:33:01

Generated On: 20 Jul 2016 22:28:45

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: 1252

Form: Product use diary (57)

Data signed: (hfarmer1) 30 Mar 2015 13:33:01

Generated On: 20 Jul 2016 22:28:45

Date of Birth	(b) (6)
Date of completion DD/MMM/YYYY	2014 JUN 06
Time of completion hh:mm	20:01
Date the questionnaire was completed for DD/MMM/YYYY	2014 JUN 06
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?	33
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: 1252

Form: Product use diary (57)

Data signed: (hfarmer1) 30 Mar 2015 13:33:01

Generated On: 20 Jul 2016 22:28:45

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: 1252

Form: Product use diary (58)

Data signed: (hfarmer1) 30 Mar 2015 13:33:01

Generated On: 20 Jul 2016 22:28:45

Date of Birth	(b) (6)
Date of completion DD/MMM/YYYY	2014 JUN 07
Time of completion hh:mm	21:02
Date the questionnaire was completed for DD/MMM/YYYY	2014 JUN 07
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?	51
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: 1252

Form: Product use diary (58)

Data signed: (hfarmer1) 30 Mar 2015 13:33:01

Generated On: 20 Jul 2016 22:28:45

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: 1252

Form: Product use diary (59)

Data signed: (hfarmer1) 30 Mar 2015 13:33:01

Generated On: 20 Jul 2016 22:28:45

Date of Birth

(b) (6)

Date of completion
DD/MMM/YYYY

2014 JUN 08

Time of completion
hh:mm

20:01

Date the questionnaire was completed for
DD/MMM/YYYY

2014 JUN 08

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?

35

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: 1252

Form: Product use diary (59)

Data signed: (hfarmer1) 30 Mar 2015 13:33:01

Generated On: 20 Jul 2016 22:28:45

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: 1252

Form: Product use diary (60)

Data signed: (hfarmer1) 30 Mar 2015 13:33:01

Generated On: 20 Jul 2016 22:28:45

Date of Birth

(b) (6)

Date of completion
DD/MMM/YYYY

2014 JUN 09

Time of completion
hh:mm

20:01

Date the questionnaire was completed for
DD/MMM/YYYY

2014 JUN 09

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?

49

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: 1252

Form: Product use diary (60)

Data signed: (hfarmer1) 30 Mar 2015 13:33:01

Generated On: 20 Jul 2016 22:28:45

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: 1252**

Form: End of study

Data signed: (hfarmer1) 30 Mar 2015 13:32:59

Generated On: 20 Jul 2016 22:28:45

End of study date

02 JUL 2014
DD/MMM/YYYY

Has the subject completed the study ?

No ☒

If No, please specify the reason:

Lost To Follow-up ☒

Details:

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1252**

Form: Consent Withdrawal

Data signed: (hfarmer1) 30 Mar 2015 13:33:00

Generated On: 20 Jul 2016 22:28:45

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