

Subject Case Report Forms

1077 (Prod: Covance Clinical Development Services, Daytona Beach, Florida)

Generated On: 20 Jul 2016 12:37:46

All time stamps listed in this document are displayed in GMT

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Form: Subject

Data signed: (hfarmer1) 26 Mar 2015 15:20:46

Generated On: 20 Jul 2016 12:37:46

Screening number	1077
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Site number	DAY
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Subject Status

Form: Subject Status

Data signed: (hfarmer1) 26 Mar 2015 15:20:49

Generated On: 20 Jul 2016 12:37:46

Date of 'Screen Failed' Event

Date of 'Discontinued From
Enrollment' Event

Randomization Date

13 FEB 2014
DD/MMM/YYYY

Randomization Time

13:11
hour:min 24-hour clock

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Screening

Form: Date of Visit

Data signed: (hfarmer1) 26 Mar 2015 15:20:55

Generated On: 20 Jul 2016 12:37:46

Date of Visit

16 JAN 2014
DD/MMM/YYYY

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Screening

Form: Additional Informed Consent

Data signed: (hfarmer1) 26 Mar 2015 15:20:49

Generated On: 20 Jul 2016 12:37:46

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

Yes ☒

Consent Date

16 JAN 2014
DD/MMM/YYYY

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

Yes ☒

Consent Date

16 JAN 2014
DD/MMM/YYYY

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Screening

Form: Inclusion Criteria

Data signed: (hfarmer1) 26 Mar 2015 15:20:50

Generated On: 20 Jul 2016 12:37:46

*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: 1077**

Folder: Screening

Form: Inclusion Criteria (1)

Data signed: (hfarmer1) 26 Mar 2015 15:20:50

Generated On: 20 Jul 2016 12:37:46

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

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

*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: 1077**

Folder: Screening

Form: Inclusion Criteria (2)

Data signed: (hfarmer1) 26 Mar 2015 15:20:50

Generated On: 20 Jul 2016 12:37:46

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

*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: 1077

Folder: Screening

Form: Inclusion Criteria (3)

Data signed: (hfarmer1) 26 Mar 2015 15:20:50

Generated On: 20 Jul 2016 12:37:46

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: 1077

Folder: Screening

Form: Inclusion Criteria (4)

Data signed: (hfarmer1) 26 Mar 2015 15:20:50

Generated On: 20 Jul 2016 12:37:46

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

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Screening

Form: Inclusion Criteria (5)

Data signed: (hfarmer1) 26 Mar 2015 15:20:50

Generated On: 20 Jul 2016 12:37:46

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

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Screening

Form: Inclusion Criteria (6)

Data signed: (hfarmer1) 26 Mar 2015 15:20:50

Generated On: 20 Jul 2016 12:37:46

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

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Screening

Form: Exclusion Criteria

Data signed: (hfarmer1) 26 Mar 2015 15:20:50

Generated On: 20 Jul 2016 12:37:46

*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: 1077**

Folder: Screening

Form: Exclusion Criteria (1)

Data signed: (hfarmer1) 26 Mar 2015 15:20:50

Generated On: 20 Jul 2016 12:37:46

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: 1077

Folder: Screening

Form: Exclusion Criteria (2)

Data signed: (hfarmer1) 26 Mar 2015 15:20:50

Generated On: 20 Jul 2016 12:37:46

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

*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: 1077

Folder: Screening

Form: Exclusion Criteria (3)

Data signed: (hfarmer1) 26 Mar 2015 15:20:50

Generated On: 20 Jul 2016 12:37:46

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: 1077

Folder: Screening

Form: Exclusion Criteria (4)

Data signed: (hfarmer1) 26 Mar 2015 15:20:50

Generated On: 20 Jul 2016 12:37:46

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

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Screening

Form: Exclusion Criteria (5)

Data signed: (hfarmer1) 26 Mar 2015 15:20:50

Generated On: 20 Jul 2016 12:37:46

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: 1077**

Folder: Screening

Form: Exclusion Criteria (6)

Data signed: (hfarmer1) 26 Mar 2015 15:20:50

Generated On: 20 Jul 2016 12:37:46

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

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: 1077**

Folder: Screening

Form: Exclusion Criteria (7)

Data signed: (hfarmer1) 26 Mar 2015 15:20:50

Generated On: 20 Jul 2016 12:37:46

Exclusion Criterion Number	7
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Exclusion Criterion	The subject has a body mass index (BMI) <18.5 or ≥35 kg/m2.
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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: 1077**

Folder: Screening

Form: Exclusion Criteria (8)

Data signed: (hfarmer1) 26 Mar 2015 15:20:50

Generated On: 20 Jul 2016 12:37:46

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.
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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: 1077**

Folder: Screening

Form: Exclusion Criteria (9)

Data signed: (hfarmer1) 26 Mar 2015 15:20:50

Generated On: 20 Jul 2016 12:37:46

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

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

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1077

Folder: Screening

Form: Exclusion Criteria (10)

Data signed: (hfarmer1) 26 Mar 2015 15:20:50

Generated On: 20 Jul 2016 12:37:46

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

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: 1077**

Folder: Screening

Form: Exclusion Criteria (11)

Data signed: (hfarmer1) 26 Mar 2015 15:20:50

Generated On: 20 Jul 2016 12:37:46

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: 1077**

Folder: Screening

Form: Exclusion Criteria (12)

Data signed: (hfarmer1) 26 Mar 2015 15:20:50

Generated On: 20 Jul 2016 12:37:46

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: 1077**

Folder: Screening

Form: Exclusion Criteria (13)

Data signed: (hfarmer1) 26 Mar 2015 15:20:50

Generated On: 20 Jul 2016 12:37:46

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: 1077**

Folder: Screening

Form: Exclusion Criteria (14)

Data signed: (hfarmer1) 26 Mar 2015 15:20:50

Generated On: 20 Jul 2016 12:37:46

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

Exclusion Criterion	The subject has a positive urine drug test. <input checked="" type="radio"/>
---------------------	--

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: 1077**

Folder: Screening

Form: Exclusion Criteria (15)

Data signed: (hfarmer1) 26 Mar 2015 15:20:50

Generated On: 20 Jul 2016 12:37:46

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

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Screening

Form: Exclusion Criteria (16)

Data signed: (hfarmer1) 26 Mar 2015 15:20:50

Generated On: 20 Jul 2016 12:37:46

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: 1077**

Folder: Screening

Form: Exclusion Criteria (17)

Data signed: (hfarmer1) 26 Mar 2015 15:20:50

Generated On: 20 Jul 2016 12:37:46

Exclusion Criterion Number	18
----------------------------	----

Exclusion Criterion	The subject is a current or former employee of the tobacco industry or of their first-degree relatives (parent, sibling, child).
---------------------	--

Result	No <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: 1077**

Folder: Screening

Form: Exclusion Criteria (18)

Data signed: (hfarmer1) 26 Mar 2015 15:20:50

Generated On: 20 Jul 2016 12:37:46

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

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

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

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Screening

Form: Exclusion Criteria (19)

Data signed: (hfarmer1) 26 Mar 2015 15:20:50

Generated On: 20 Jul 2016 12:37:46

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

Exclusion Criterion	The subject has participated in a clinical study within 3 months prior to the Screening Visit.
---------------------	--

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: 1077**

Folder: Screening

Form: Exclusion Criteria (20)

Data signed: (hfarmer1) 26 Mar 2015 15:20:50

Generated On: 20 Jul 2016 12:37:46

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

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: 1077**

Folder: Screening

Form: Exclusion Criteria (21)

Data signed: (hfarmer1) 26 Mar 2015 15:20:50

Generated On: 20 Jul 2016 12:37:46

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

Exclusion Criterion	For women only : Subject does not agree to use an acceptable method of effective contraception	<input type="radio"/>
---------------------	---	-----------------------

Result	NA	<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: 1077**

Folder: Screening

Form: Demographics

Data signed: (hfarmer1) 26 Mar 2015 15:20:49

Generated On: 20 Jul 2016 12:37:46

Date of Birth

(b) (6)

Sex

Male ☒

Race

White ☒

Other, specify _____

Ethnicity

Not Hispanic ☒

Date the Subject signed the Informed Consent

16 JAN 2014
DD/MMM/YYYY

Time the Subject signed the Informed Consent

10:18
hour:min 24-hour clock

Age(Derived)

48

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Screening

Form: Medical History/Concomitant Disease

Data signed: (hcoleman1) 18 Jun 2015 20:00:06

Generated On: 20 Jul 2016 12:37:46

Date of collection

16 JAN 2014
DD/MMM/YYYY

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

Yes ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Screening

Form: Medical History/Concomitant Disease (1)

Data signed: (hcoleman1) 18 Jun 2015 20:00:06

Generated On: 20 Jul 2016 12:37:46

Date of collection	16 JAN 2014 DD/MMM/YYYY
--------------------	----------------------------

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

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

Diagnosis Description	DENTAL EXTRACTIONS SURGERY, VARIOUS LOCATIONS
-----------------------	---

Onset Date DD/MMM/YYYY	UN UNK 2003
---------------------------	-------------

Stop Date DD/MMM/YYYY	UN DEC 2003
--------------------------	-------------

Ongoing?	False
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Screening

Form: Medical History/Concomitant Disease (2)

Data signed: (hcoleman1) 18 Jun 2015 20:00:06

Generated On: 20 Jul 2016 12:37:46

Date of collection	16 JAN 2014 DD/MMM/YYYY
--------------------	----------------------------

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

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

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

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

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

Ongoing?	True
----------	------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Screening

Form: Medical History/Concomitant Disease (3)

Data signed: (hcoleman1) 18 Jun 2015 20:00:06

Generated On: 20 Jul 2016 12:37:46

Date of collection	16 JAN 2014 DD/MMM/YYYY
--------------------	----------------------------

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

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

Diagnosis Description	BROKEN WRIST, CASTING
-----------------------	-----------------------

Onset Date DD/MMM/YYYY	UN UNK 1971
---------------------------	-------------

Stop Date DD/MMM/YYYY	UN UNK 1971
--------------------------	-------------

Ongoing?	False
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Screening

Form: Medical History/Concomitant Disease (4)

Data signed: (hcoleman1) 18 Jun 2015 20:00:06

Generated On: 20 Jul 2016 12:37:46

Date of collection	16 JAN 2014 DD/MMM/YYYY
--------------------	----------------------------

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

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

Diagnosis Description	BROKEN WRIST, CASTING
-----------------------	-----------------------

Onset Date DD/MMM/YYYY	UN UNK 1974
---------------------------	-------------

Stop Date DD/MMM/YYYY	UN UNK 1974
--------------------------	-------------

Ongoing?	False
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Screening

Form: Medical History/Concomitant Disease (5)

Data signed: (hcoleman1) 18 Jun 2015 20:00:06

Generated On: 20 Jul 2016 12:37:46

Date of collection

16 JAN 2014
DD/MMM/YYYY

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

Yes ☒

Number

5

Diagnosis Description

MULTIPLE TEETH HAVE
CAVITIES, MILD

Onset Date
DD/MMM/YYYY

UN UNK 2003

Stop Date
DD/MMM/YYYY

Ongoing?

True

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Screening

Form: Vital Signs<Screening/<

Data signed: (hfarmer1) 26 Mar 2015 15:20:55

Generated On: 20 Jul 2016 12:37:46

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

16 JAN 2014
DD/MMM/YYYY

Time of assessment

12:18
hour:min 24-hour clock

Pulse rate

53
beats per minute

Respiratory rate

16
breaths per minute

Blood Pressure (systolic)

123
mmHg

Blood Pressure (diastolic)

88
mmHg

Vital Signs Position of Subject

Supine ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Screening

Form: Physical Examination

Data signed: (hfarmer1) 26 Mar 2015 15:20:52

Generated On: 20 Jul 2016 12:37:46

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

16 JAN 2014
DD/MMM/YYYY

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Screening

Form: Physical Examination (1)

Data signed: (hfarmer1) 26 Mar 2015 15:20:52

Generated On: 20 Jul 2016 12:37:46

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of assessment 16 JAN 2014
DD/MMM/YYYY

System General Appearance ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Screening

Form: Physical Examination (2)

Data signed: (hfarmer1) 26 Mar 2015 15:20:52

Generated On: 20 Jul 2016 12:37:46

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

16 JAN 2014
DD/MMM/YYYY

System

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

Outcome

Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done

False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Screening

Form: Physical Examination (3)

Data signed: (hfarmer1) 26 Mar 2015 15:20:52

Generated On: 20 Jul 2016 12:37:46

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of assessment 16 JAN 2014
DD/MMM/YYYY

System Thyroid Gland ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Screening

Form: Physical Examination (4)

Data signed: (hfarmer1) 26 Mar 2015 15:20:52

Generated On: 20 Jul 2016 12:37:46

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

16 JAN 2014
DD/MMM/YYYY

System

Heart ☒

Outcome

Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done

False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Screening

Form: Physical Examination (5)

Data signed: (hfarmer1) 26 Mar 2015 15:20:52

Generated On: 20 Jul 2016 12:37:46

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of assessment 16 JAN 2014
DD/MMM/YYYY

System Chest ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Screening

Form: Physical Examination (6)

Data signed: (hfarmer1) 26 Mar 2015 15:20:52

Generated On: 20 Jul 2016 12:37:46

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of assessment 16 JAN 2014
DD/MMM/YYYY

System Lungs ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Screening

Form: Physical Examination (7)

Data signed: (hfarmer1) 26 Mar 2015 15:20:52

Generated On: 20 Jul 2016 12:37:46

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

16 JAN 2014
DD/MMM/YYYY

System

Gastrointestinal ☒

Outcome

Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done

False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Screening

Form: Physical Examination (8)

Data signed: (hfarmer1) 26 Mar 2015 15:20:52

Generated On: 20 Jul 2016 12:37:46

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of assessment 16 JAN 2014
DD/MMM/YYYY

System Cardiovascular System ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Screening

Form: Physical Examination (9)

Data signed: (hfarmer1) 26 Mar 2015 15:20:52

Generated On: 20 Jul 2016 12:37:46

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of assessment 16 JAN 2014
DD/MMM/YYYY

System Neurologic ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Screening

Form: Physical Examination (10)

Data signed: (hfarmer1) 26 Mar 2015 15:20:52

Generated On: 20 Jul 2016 12:37:46

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of assessment 16 JAN 2014
DD/MMM/YYYY

System Skin ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Screening

Form: Physical Examination (11)

Data signed: (hfarmer1) 26 Mar 2015 15:20:52

Generated On: 20 Jul 2016 12:37:46

Was the physical examination performed? Yes ☐

If No, please specify the reason: _____

Date of assessment 16 JAN 2014
DD/MMM/YYYY

System Back ☐

Outcome Normal ☐

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Screening

Form: Physical Examination (12)

Data signed: (hfarmer1) 26 Mar 2015 15:20:52

Generated On: 20 Jul 2016 12:37:46

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of assessment 16 JAN 2014
DD/MMM/YYYY

System Musculoskeletal ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Screening

Form: Physical Examination (13)

Data signed: (hfarmer1) 26 Mar 2015 15:20:52

Generated On: 20 Jul 2016 12:37:46

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of assessment 16 JAN 2014
DD/MMM/YYYY

System Abdomen ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Screening

Form: Physical Examination (14)

Data signed: (hfarmer1) 26 Mar 2015 15:20:52

Generated On: 20 Jul 2016 12:37:46

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of assessment 16 JAN 2014
DD/MMM/YYYY

System Dentition ☒

Outcome Abnormal ☒

Abnormal, please specify DECAVED 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: 1077**

Folder: Screening

Form: Physical Examination (15)

Data signed: (hfarmer1) 26 Mar 2015 15:20:52

Generated On: 20 Jul 2016 12:37:46

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

16 JAN 2014
DD/MMM/YYYY

System

Other ☒

Other, Specify _____

Outcome _____

Abnormal, please specify _____

Clinically significant _____

Not Done

True

Not Done; please specify the reason: _____

NOT EXAMINED

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Screening

Form: Physical Examination (16)

Data signed: (hfarmer1) 26 Mar 2015 15:20:52

Generated On: 20 Jul 2016 12:37:46

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

16 JAN 2014
DD/MMM/YYYY

System

Other ☒

Other, Specify _____

Outcome _____

Abnormal, please specify _____

Clinically significant _____

Not Done

True

Not Done; please specify the reason: _____

NOT EXAMINED

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Screening

Form: Physical Examination (17)

Data signed: (hfarmer1) 26 Mar 2015 15:20:52

Generated On: 20 Jul 2016 12:37:46

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

16 JAN 2014
DD/MMM/YYYY

System

Other ☒

Other, Specify _____

Outcome _____

Abnormal, please specify _____

Clinically significant _____

Not Done

True

Not Done; please specify the reason: _____

NOT EXAMINED

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Screening

Form: Physical Examination (18)

Data signed: (hfarmer1) 26 Mar 2015 15:20:52

Generated On: 20 Jul 2016 12:37:46

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

16 JAN 2014
DD/MMM/YYYY

System

Other ☒

Other, Specify _____

Outcome _____

Abnormal, please specify _____

Clinically significant _____

Not Done

True

Not Done; please specify the reason: _____

NOT EXAMINED

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Screening

Form: Physical Examination (19)

Data signed: (hfarmer1) 26 Mar 2015 15:20:52

Generated On: 20 Jul 2016 12:37:46

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

16 JAN 2014
DD/MMM/YYYY

System

Other ☒

Other, Specify _____

Outcome _____

Abnormal, please specify _____

Clinically significant _____

Not Done

True

Not Done; please specify the reason: _____

NOT EXAMINED

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Screening

Form: Advice on the risk of smoking and debriefing

Data signed: (hfarmer1) 26 Mar 2015 15:20:55

Generated On: 20 Jul 2016 12:37:46

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: 1077**

Folder: Screening

Form: Identification of Current Cigarette Brand

Data signed: (hfarmer1) 26 Mar 2015 15:20:55

Generated On: 20 Jul 2016 12:37:46

Date

16 JAN 2014
DD/MMM/YYYY

Brand name

PALL MALL MENTHOL

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Screening

Form: THS 2.2 menthol product demonstration

Data signed: (hfarmer1) 26 Mar 2015 15:20:55

Generated On: 20 Jul 2016 12:37:46

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: 1077**

Folder: Screening

Form: Smoking History

Data signed: (hfarmer1) 26 Mar 2015 15:20:55

Generated On: 20 Jul 2016 12:37:46

Date of Assessment

16 JAN 2014
DD/MMM/YYYY

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

No ☐

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

Yes ☐

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

>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: 1077**

Folder: Screening

Form: Weight and Height

Data signed: (hfarmer1) 26 Mar 2015 15:20:55

Generated On: 20 Jul 2016 12:37:46

Measurement(s) assessed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

16 JAN 2014
DD/MMM/YYYY

Weight

73.6
kg

Height

185
cm

BMI (Derived)

21.5
kg/m2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Screening

Form: ECG (12-Lead Standard)

Data signed: (hfarmer1) 26 Mar 2015 15:20:49

Generated On: 20 Jul 2016 12:37:46

Was the ECG performed? Yes ☒

If No, please specify the reason: _____

Date of assessment: 16 JAN 2014
DD/MMM/YYYY

Position Supine ☒

Heart Rate 52
beats per minute

QRS Interval 105
msec

QT Interval 439
msec

QTcB Interval 410
msec

QTcF Interval 419
msec

PR Interval 151
msec

Interpretation Normal ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Screening

Form: ECG (12-Lead Standard)

Data signed: (hfarmer1) 26 Mar 2015 15:20:49

Generated On: 20 Jul 2016 12:37:46

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: 1077**

Folder: Screening

Form: Spirometry (1)

Data signed: (hfarmer1) 26 Mar 2015 15:20:54

Generated On: 20 Jul 2016 12:37:46

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 16 JAN 2014
DD/MMM/YYYY

Time of assessment 13:19

Predicted FVC value 5.60
L

Best measured FVC value 5.71
L

Percent of predicted FVC value 102
%

Best measured FEV1 value 3.91
L

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Screening

Form: Spirometry (1)

Data signed: (hfarmer1) 26 Mar 2015 15:20:54

Generated On: 20 Jul 2016 12:37:46

Predicted FEV1 value	4.36 L
----------------------	-----------

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

Calculated ratio between FEV1/FVC	0.68
-----------------------------------	------

MEF 25/75 value	2.38 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: 1077**

Folder: Screening

Form: Spirometry (2)

Data signed: (hfarmer1) 26 Mar 2015 15:20:54

Generated On: 20 Jul 2016 12:37:46

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 16 JAN 2014
DD/MMM/YYYY

Time of assessment 13:43

Name of bronchodilator ALBUTEROL SULFATE

Dose 180 MCG

Predicted FVC value 5.60
L

Best measured FVC value 5.74
L

Percent of predicted FVC value 102
%

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Screening

Form: Spirometry (2)

Data signed: (hfarmer1) 26 Mar 2015 15:20:54

Generated On: 20 Jul 2016 12:37:46

Best measured FEV1 value	4.07 L
Predicted FEV1 value	4.36 L
Percent of predicted FEV1 value	93 %
Calculated ratio between FEV1/FVC	0.71
MEF 25/75 value	2.78 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: 1077**

Folder: Screening

Form: Chest X-Ray

Data signed: (hfarmer1) 26 Mar 2015 15:20:55

Generated On: 20 Jul 2016 12:37:46

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

Yes ☒

If No, please specify the reason: _____

Date of assessment

28 JAN 2014
DD/MMM/YYYY

System

Chest ☒

Interpretation

Normal ☒

Clinically significant _____

Abnormal, please specify: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Screening

Form: Haematology

Data signed: (hfarmer1) 26 Mar 2015 15:20:51

Generated On: 20 Jul 2016 12:37:46

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: 1077**

Folder: Screening

Form: Clinical Chemistry

Data signed: (hfarmer1) 26 Mar 2015 15:20:51

Generated On: 20 Jul 2016 12:37:46

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: 1077**

Folder: Screening

Form: Urine analysis

Data signed: (hfarmer1) 26 Mar 2015 15:20:51

Generated On: 20 Jul 2016 12:37:46

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: 1077**

Folder: Screening

Form: Serology for HIV and Hepatitis B and C

Data signed: (hfarmer1) 26 Mar 2015 15:20:51

Generated On: 20 Jul 2016 12:37:46

Category

Serology ☒

Not Done

False

If Not Done, please specify the reason:

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1077

Folder: Screening

Form: Urine Drug Screen

Data signed: (hfarmer1) 26 Mar 2015 15:20:51

Generated On: 20 Jul 2016 12:37:46

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

If Not Done, please specify the reason: _____

Date of sample collection	16 JAN 2014 DD/MMM/YYYY
---------------------------	----------------------------

Time of sample collection	11:15 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: 1077

Folder: Screening

Form: Urine Drug Screen (4)

Data signed: (hfarmer1) 26 Mar 2015 15:20:51

Generated On: 20 Jul 2016 12:37:46

Drug type	Result
Cannabinoids	Negative
Cocaine	Negative
Opiates	Negative

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Screening

Form: Alcohol Test

Data signed: (hfarmer1) 26 Mar 2015 15:20:51

Generated On: 20 Jul 2016 12:37:46

Was the alcohol test performed? Yes ☒

If No, please specify the reason: _____

Method used Breath test ☒

Date of assessment 16 JAN 2014
DD/MMM/YYYY

Time of assessment 12:23
hour:min 24-hour clock

Result Negative ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Screening

Form: Urine Cotinine Test

Data signed: (hfarmer1) 26 Mar 2015 15:20:51

Generated On: 20 Jul 2016 12:37:46

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

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

If Not Done, please specify the reason: _____

Date of Sample Collection	16 JAN 2014 DD/MMM/YYYY
---------------------------	----------------------------

Time of Sample Collection	11:15 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: 1077**

Folder: Screening

Form: Lab-BU-LabCorp CHEMISTRY(16 JAN 2014)

Data signed: (hfarmer1) 26 Mar 2015 15:20:55

Generated On: 20 Jul 2016 12:37:46

Experiment Type

CHEMISTRY

Date of Sample Collection
YYYY/MM/DD

16 JAN 2014

Please document clinically relevant abnormalities in the AE form

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Screening

Form: Lab-BU-LabCorp CHEMISTRY(16 JAN 2014)

Data signed: (hfarmer1) 26 Mar 2015 15:20:55

Generated On: 20 Jul 2016 12:37:46

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

Date of Sample Collection YYYY/MM/DD	16 JAN 2014
---	-------------

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

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

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

Time of Sample Collection	13:04
---------------------------	-------

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

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

Result	83
--------	----

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

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

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

Flag	
------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Screening

Form: Lab-BU-LabCorp CHEMISTRY(16 JAN 2014)

Data signed: (hfarmer1) 26 Mar 2015 15:20:55

Generated On: 20 Jul 2016 12:37:46

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

01657100030

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Screening

Form: Lab-BU-LabCorp (2)

Data signed: (hfarmer1) 26 Mar 2015 15:20:55

Generated On: 20 Jul 2016 12:37:46

Experiment Type	CHEMISTRY
Date of Sample Collection YYYY/MM/DD	16 JAN 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Male <input checked="" type="radio"/>
Time of Sample Collection	13:04
Analyte Name	BUN
Code	001040
Result	11
Unit	MG/DL
Lower limit	6
Upper limit	24
Flag	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Screening

Form: Lab-BU-LabCorp (2)

Data signed: (hfarmer1) 26 Mar 2015 15:20:55

Generated On: 20 Jul 2016 12:37:46

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

01657100030

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Screening

Form: Lab-BU-LabCorp (3)

Data signed: (hfarmer1) 26 Mar 2015 15:20:55

Generated On: 20 Jul 2016 12:37:46

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

Date of Sample Collection YYYY/MM/DD	16 JAN 2014
---	-------------

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

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

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

Time of Sample Collection	13:04
---------------------------	-------

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

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

Result	181
--------	-----

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

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

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

Flag	
------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Screening

Form: Lab-BU-LabCorp (3)

Data signed: (hfarmer1) 26 Mar 2015 15:20:55

Generated On: 20 Jul 2016 12:37:46

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

01657100030

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Screening

Form: Lab-BU-LabCorp (4)

Data signed: (hfarmer1) 26 Mar 2015 15:20:55

Generated On: 20 Jul 2016 12:37:46

Experiment Type	CHEMISTRY
Date of Sample Collection YYYY/MM/DD	16 JAN 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Male <input checked="" type="radio"/>
Time of Sample Collection	13:04
Analyte Name	PROTEIN, TOTAL, SERUM
Code	001073
Result	6.9
Unit	G/DL
Lower limit	6.0
Upper limit	8.5
Flag	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Screening

Form: Lab-BU-LabCorp (4)

Data signed: (hfarmer1) 26 Mar 2015 15:20:55

Generated On: 20 Jul 2016 12:37:46

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

01657100030

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Screening

Form: Lab-BU-LabCorp (5)

Data signed: (hfarmer1) 26 Mar 2015 15:20:55

Generated On: 20 Jul 2016 12:37:46

Experiment Type

CHEMISTRY

Date of Sample Collection
YYYY/MM/DD

16 JAN 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male ☒

Time of Sample Collection

13:04

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: 1077**

Folder: Screening

Form: Lab-BU-LabCorp (5)

Data signed: (hfarmer1) 26 Mar 2015 15:20:55

Generated On: 20 Jul 2016 12:37:46

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

01657100030

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Screening

Form: Lab-BU-LabCorp (6)

Data signed: (hfarmer1) 26 Mar 2015 15:20:55

Generated On: 20 Jul 2016 12:37:46

Experiment Type	CHEMISTRY
Date of Sample Collection YYYY/MM/DD	16 JAN 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Male <input checked="" type="radio"/>
Time of Sample Collection	13:04
Analyte Name	BILIRUBIN, TOTAL
Code	001099
Result	0.4
Unit	MG/DL
Lower limit	0.0
Upper limit	1.2
Flag	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Screening

Form: Lab-BU-LabCorp (6)

Data signed: (hfarmer1) 26 Mar 2015 15:20:55

Generated On: 20 Jul 2016 12:37:46

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

01657100030

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Screening

Form: Lab-BU-LabCorp (7)

Data signed: (hfarmer1) 26 Mar 2015 15:20:55

Generated On: 20 Jul 2016 12:37:46

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

Date of Sample Collection YYYY/MM/DD	16 JAN 2014
---	-------------

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

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

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

Time of Sample Collection	13:04
---------------------------	-------

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

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

Result	88
--------	----

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

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

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

Flag	
------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Screening

Form: Lab-BU-LabCorp (7)

Data signed: (hfarmer1) 26 Mar 2015 15:20:55

Generated On: 20 Jul 2016 12:37:46

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

01657100030

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Screening

Form: Lab-BU-LabCorp (8)

Data signed: (hfarmer1) 26 Mar 2015 15:20:55

Generated On: 20 Jul 2016 12:37:46

Experiment Type	CHEMISTRY
Date of Sample Collection YYYY/MM/DD	16 JAN 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Male <input checked="" type="radio"/>
Time of Sample Collection	13:04
Analyte Name	LDH
Code	001115
Result	169
Unit	IU/L
Lower limit	0
Upper limit	225
Flag	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Screening

Form: Lab-BU-LabCorp (8)

Data signed: (hfarmer1) 26 Mar 2015 15:20:55

Generated On: 20 Jul 2016 12:37:46

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

01657100030

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Screening

Form: Lab-BU-LabCorp (9)

Data signed: (hfarmer1) 26 Mar 2015 15:20:55

Generated On: 20 Jul 2016 12:37:46

Experiment Type	CHEMISTRY
Date of Sample Collection YYYY/MM/DD	16 JAN 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Male <input checked="" type="radio"/>
Time of Sample Collection	13:04
Analyte Name	AST (SGOT)
Code	001123
Result	21
Unit	IU/L
Lower limit	0
Upper limit	40
Flag	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Screening

Form: Lab-BU-LabCorp (9)

Data signed: (hfarmer1) 26 Mar 2015 15:20:55

Generated On: 20 Jul 2016 12:37:46

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

01657100030

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Screening

Form: Lab-BU-LabCorp (10)

Data signed: (hfarmer1) 26 Mar 2015 15:20:55

Generated On: 20 Jul 2016 12:37:46

Experiment Type	CHEMISTRY
Date of Sample Collection YYYY/MM/DD	16 JAN 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Male <input checked="" type="radio"/>
Time of Sample Collection	13:04
Analyte Name	TRIGLYCERIDES
Code	001172
Result	219
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: 1077**

Folder: Screening

Form: Lab-BU-LabCorp (10)

Data signed: (hfarmer1) 26 Mar 2015 15:20:55

Generated On: 20 Jul 2016 12:37:46

Clinically Significant?

No ☒

Comment

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

01657100030

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Screening

Form: Lab-BU-LabCorp (11)

Data signed: (hfarmer1) 26 Mar 2015 15:20:55

Generated On: 20 Jul 2016 12:37:46

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

Date of Sample Collection YYYY/MM/DD	16 JAN 2014
---	-------------

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

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

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

Time of Sample Collection	13:04
---------------------------	-------

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

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

Result	4.2
--------	-----

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

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

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

Flag	
------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Screening

Form: Lab-BU-LabCorp (11)

Data signed: (hfarmer1) 26 Mar 2015 15:20:55

Generated On: 20 Jul 2016 12:37:46

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

01657100030

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Screening

Form: Lab-BU-LabCorp (12)

Data signed: (hfarmer1) 26 Mar 2015 15:20:55

Generated On: 20 Jul 2016 12:37:46

Experiment Type	CHEMISTRY
Date of Sample Collection YYYY/MM/DD	16 JAN 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Male <input checked="" type="radio"/>
Time of Sample Collection	13:04
Analyte Name	SODIUM, SERUM
Code	001198
Result	141
Unit	MMOL/L
Lower limit	134
Upper limit	144
Flag	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Screening

Form: Lab-BU-LabCorp (12)

Data signed: (hfarmer1) 26 Mar 2015 15:20:55

Generated On: 20 Jul 2016 12:37:46

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

01657100030

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Screening

Form: Lab-BU-LabCorp (13)

Data signed: (hfarmer1) 26 Mar 2015 15:20:55

Generated On: 20 Jul 2016 12:37:46

Experiment Type

CHEMISTRY

Date of Sample Collection
YYYY/MM/DD

16 JAN 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male ☒

Time of Sample Collection

13:04

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: 1077**

Folder: Screening

Form: Lab-BU-LabCorp (13)

Data signed: (hfarmer1) 26 Mar 2015 15:20:55

Generated On: 20 Jul 2016 12:37:46

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

01657100030

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Screening

Form: Lab-BU-LabCorp (14)

Data signed: (hfarmer1) 26 Mar 2015 15:20:55

Generated On: 20 Jul 2016 12:37:46

Experiment Type	CHEMISTRY
Date of Sample Collection YYYY/MM/DD	16 JAN 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Male <input checked="" type="radio"/>
Time of Sample Collection	13:04
Analyte Name	CREATININE, SERUM
Code	001370
Result	0.85
Unit	MG/DL
Lower limit	0.76
Upper limit	1.27
Flag	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Screening

Form: Lab-BU-LabCorp (14)

Data signed: (hfarmer1) 26 Mar 2015 15:20:55

Generated On: 20 Jul 2016 12:37:46

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

01657100030

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Screening

Form: Lab-BU-LabCorp (15)

Data signed: (hfarmer1) 26 Mar 2015 15:20:55

Generated On: 20 Jul 2016 12:37:46

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

Date of Sample Collection YYYY/MM/DD	16 JAN 2014
---	-------------

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

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

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

Time of Sample Collection	13:04
---------------------------	-------

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

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

Result	13
--------	----

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

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

Upper limit	44
-------------	----

Flag	
------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Screening

Form: Lab-BU-LabCorp (15)

Data signed: (hfarmer1) 26 Mar 2015 15:20:55

Generated On: 20 Jul 2016 12:37:46

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

01657100030

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Screening

Form: Lab-BU-LabCorp (16)

Data signed: (hfarmer1) 26 Mar 2015 15:20:55

Generated On: 20 Jul 2016 12:37:46

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

Date of Sample Collection YYYY/MM/DD	16 JAN 2014
---	-------------

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

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

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

Time of Sample Collection	13:04
---------------------------	-------

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

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

Result	9
--------	---

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

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

Upper limit	65
-------------	----

Flag	
------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Screening

Form: Lab-BU-LabCorp (16)

Data signed: (hfarmer1) 26 Mar 2015 15:20:55

Generated On: 20 Jul 2016 12:37:46

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

01657100030

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Screening

Form: Lab-BU-LabCorp (17)

Data signed: (hfarmer1) 26 Mar 2015 15:20:55

Generated On: 20 Jul 2016 12:37:46

Experiment Type

CHEMISTRY

Date of Sample Collection
YYYY/MM/DD

16 JAN 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male ☒

Time of Sample Collection

13:04

Analyte Name

HEP C VIRUS AB

Code

140683

Result

<0.1

Unit

S/CO RATIO

Lower limit

0.0

Upper limit

0.9

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Screening

Form: Lab-BU-LabCorp (17)

Data signed: (hfarmer1) 26 Mar 2015 15:20:55

Generated On: 20 Jul 2016 12:37:46

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

01657100030

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Screening

Form: Lab-BU-LabCorp SEROLOGY(16 JAN 2014)

Data signed: (hfarmer1) 26 Mar 2015 15:20:56

Generated On: 20 Jul 2016 12:37:46

Experiment Type

SEROLOGY

Date of Sample Collection
YYYY/MM/DD

16 JAN 2014

Please document clinically relevant abnormalities in the AE form

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Screening

Form: Lab-BU-LabCorp SEROLOGY(16 JAN 2014)

Data signed: (hfarmer1) 26 Mar 2015 15:20:56

Generated On: 20 Jul 2016 12:37:46

Experiment Type

SEROLOGY

Date of Sample Collection
YYYY/MM/DD

16 JAN 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male ☒

Time of Sample Collection

13:04

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: 1077**

Folder: Screening

Form: Lab-BU-LabCorp SEROLOGY(16 JAN 2014)

Data signed: (hfarmer1) 26 Mar 2015 15:20:56

Generated On: 20 Jul 2016 12:37:46

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

01657100030

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Screening

Form: Lab-BU-LabCorp (2)

Data signed: (hfarmer1) 26 Mar 2015 15:20:56

Generated On: 20 Jul 2016 12:37:46

Experiment Type

SEROLOGY

Date of Sample Collection
YYYY/MM/DD

16 JAN 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male ☒

Time of Sample Collection

13:04

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: 1077**

Folder: Screening

Form: Lab-BU-LabCorp (2)

Data signed: (hfarmer1) 26 Mar 2015 15:20:56

Generated On: 20 Jul 2016 12:37:46

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

01657100030

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Screening

Form: Lab-BU-LabCorp (3)

Data signed: (hfarmer1) 26 Mar 2015 15:20:56

Generated On: 20 Jul 2016 12:37:46

Experiment Type	SEROLOGY
Date of Sample Collection YYYY/MM/DD	16 JAN 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Male <input checked="" type="radio"/>
Time of Sample Collection	13:04
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: 1077**

Folder: Screening

Form: Lab-BU-LabCorp (3)

Data signed: (hfarmer1) 26 Mar 2015 15:20:56

Generated On: 20 Jul 2016 12:37:46

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

01657100030

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Screening

Form: Lab-BU-LabCorp HEMATOLOGY(16 JAN 2014)

Data signed: (hfarmer1) 26 Mar 2015 15:20:57

Generated On: 20 Jul 2016 12:37:46

Experiment Type

HEMATOLOGY

Date of Sample Collection
YYYY/MM/DD

16 JAN 2014

Please document clinically relevant abnormalities in the AE form

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Screening

Form: Lab-BU-LabCorp HEMATOLOGY(16 JAN 2014)

Data signed: (hfarmer1) 26 Mar 2015 15:20:57

Generated On: 20 Jul 2016 12:37:46

Experiment Type	HEMATOLOGY
Date of Sample Collection YYYY/MM/DD	16 JAN 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Male <input checked="" type="radio"/>
Time of Sample Collection	13:04
Analyte Name	WBC
Code	005025
Result	7.4
Unit	X10E3/UL
Lower limit	3.4
Upper limit	10.8
Flag	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Screening

Form: Lab-BU-LabCorp HEMATOLOGY(16 JAN 2014)

Data signed: (hfarmer1) 26 Mar 2015 15:20:57

Generated On: 20 Jul 2016 12:37:46

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

01657100030

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Screening

Form: Lab-BU-LabCorp (2)

Data signed: (hfarmer1) 26 Mar 2015 15:20:57

Generated On: 20 Jul 2016 12:37:46

Experiment Type

HEMATOLOGY

Date of Sample Collection
YYYY/MM/DD

16 JAN 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male ☒

Time of Sample Collection

13:04

Analyte Name

RBC

Code

005033

Result

4.69

Unit

X10E6/UL

Lower limit

4.14

Upper limit

5.80

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Screening

Form: Lab-BU-LabCorp (2)

Data signed: (hfarmer1) 26 Mar 2015 15:20:57

Generated On: 20 Jul 2016 12:37:46

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

01657100030

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Screening

Form: Lab-BU-LabCorp (3)

Data signed: (hfarmer1) 26 Mar 2015 15:20:57

Generated On: 20 Jul 2016 12:37:46

Experiment Type

HEMATOLOGY

Date of Sample Collection
YYYY/MM/DD

16 JAN 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male ☒

Time of Sample Collection

13:04

Analyte Name

HEMOGLOBIN

Code

005041

Result

14.5

Unit

G/DL

Lower limit

12.6

Upper limit

17.7

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Screening

Form: Lab-BU-LabCorp (3)

Data signed: (hfarmer1) 26 Mar 2015 15:20:57

Generated On: 20 Jul 2016 12:37:46

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

01657100030

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Screening

Form: Lab-BU-LabCorp (4)

Data signed: (hfarmer1) 26 Mar 2015 15:20:57

Generated On: 20 Jul 2016 12:37:46

Experiment Type

HEMATOLOGY

Date of Sample Collection
YYYY/MM/DD

16 JAN 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male ☒

Time of Sample Collection

13:04

Analyte Name

HEMATOCRIT

Code

005058

Result

41.6

Unit

%

Lower limit

37.5

Upper limit

51.0

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Screening

Form: Lab-BU-LabCorp (4)

Data signed: (hfarmer1) 26 Mar 2015 15:20:57

Generated On: 20 Jul 2016 12:37:46

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

01657100030

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Screening

Form: Lab-BU-LabCorp (5)

Data signed: (hfarmer1) 26 Mar 2015 15:20:57

Generated On: 20 Jul 2016 12:37:46

Experiment Type

HEMATOLOGY

Date of Sample Collection
YYYY/MM/DD

16 JAN 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male ☒

Time of Sample Collection

13:04

Analyte Name

MCV

Code

015065

Result

89

Unit

FL

Lower limit

79

Upper limit

97

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Screening

Form: Lab-BU-LabCorp (5)

Data signed: (hfarmer1) 26 Mar 2015 15:20:57

Generated On: 20 Jul 2016 12:37:46

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

01657100030

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Screening

Form: Lab-BU-LabCorp (6)

Data signed: (hfarmer1) 26 Mar 2015 15:20:57

Generated On: 20 Jul 2016 12:37:46

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

Date of Sample Collection YYYY/MM/DD	16 JAN 2014
---	-------------

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

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

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

Time of Sample Collection	13:04
---------------------------	-------

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

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

Result	30.9
--------	------

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

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

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

Flag	
------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Screening

Form: Lab-BU-LabCorp (6)

Data signed: (hfarmer1) 26 Mar 2015 15:20:57

Generated On: 20 Jul 2016 12:37:46

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

01657100030

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Screening

Form: Lab-BU-LabCorp (7)

Data signed: (hfarmer1) 26 Mar 2015 15:20:57

Generated On: 20 Jul 2016 12:37:46

Experiment Type

HEMATOLOGY

Date of Sample Collection
YYYY/MM/DD

16 JAN 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male ☒

Time of Sample Collection

13:04

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: 1077**

Folder: Screening

Form: Lab-BU-LabCorp (7)

Data signed: (hfarmer1) 26 Mar 2015 15:20:57

Generated On: 20 Jul 2016 12:37:46

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

01657100030

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Screening

Form: Lab-BU-LabCorp (8)

Data signed: (hfarmer1) 26 Mar 2015 15:20:57

Generated On: 20 Jul 2016 12:37:46

Experiment Type

HEMATOLOGY

Date of Sample Collection
YYYY/MM/DD

16 JAN 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male ☒

Time of Sample Collection

13:04

Analyte Name

NEUTROPHILS

Code

015107

Result

58

Unit

%

Lower limit

40

Upper limit

74

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Screening

Form: Lab-BU-LabCorp (8)

Data signed: (hfarmer1) 26 Mar 2015 15:20:57

Generated On: 20 Jul 2016 12:37:46

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

01657100030

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Screening

Form: Lab-BU-LabCorp (9)

Data signed: (hfarmer1) 26 Mar 2015 15:20:57

Generated On: 20 Jul 2016 12:37:46

Experiment Type

HEMATOLOGY

Date of Sample Collection
YYYY/MM/DD

16 JAN 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male ☒

Time of Sample Collection

13:04

Analyte Name

LYMPHS

Code

015123

Result

29

Unit

%

Lower limit

14

Upper limit

46

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Screening

Form: Lab-BU-LabCorp (9)

Data signed: (hfarmer1) 26 Mar 2015 15:20:57

Generated On: 20 Jul 2016 12:37:46

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

01657100030

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Screening

Form: Lab-BU-LabCorp (10)

Data signed: (hfarmer1) 26 Mar 2015 15:20:57

Generated On: 20 Jul 2016 12:37:46

Experiment Type

HEMATOLOGY

Date of Sample Collection
YYYY/MM/DD

16 JAN 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male ☒

Time of Sample Collection

13:04

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: 1077**

Folder: Screening

Form: Lab-BU-LabCorp (10)

Data signed: (hfarmer1) 26 Mar 2015 15:20:57

Generated On: 20 Jul 2016 12:37:46

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

01657100030

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Screening

Form: Lab-BU-LabCorp (11)

Data signed: (hfarmer1) 26 Mar 2015 15:20:57

Generated On: 20 Jul 2016 12:37:46

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

Date of Sample Collection YYYY/MM/DD	16 JAN 2014
---	-------------

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

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

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

Time of Sample Collection	13:04
---------------------------	-------

Analyte Name	EOS
--------------	-----

Code	015149
------	--------

Result	4
--------	---

Unit	%
------	---

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

Upper limit	5
-------------	---

Flag	
------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Screening

Form: Lab-BU-LabCorp (11)

Data signed: (hfarmer1) 26 Mar 2015 15:20:57

Generated On: 20 Jul 2016 12:37:46

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

01657100030

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Screening

Form: Lab-BU-LabCorp (12)

Data signed: (hfarmer1) 26 Mar 2015 15:20:57

Generated On: 20 Jul 2016 12:37:46

Experiment Type

HEMATOLOGY

Date of Sample Collection
YYYY/MM/DD

16 JAN 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male ☒

Time of Sample Collection

13:04

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: 1077**

Folder: Screening

Form: Lab-BU-LabCorp (12)

Data signed: (hfarmer1) 26 Mar 2015 15:20:57

Generated On: 20 Jul 2016 12:37:46

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

01657100030

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Screening

Form: Lab-BU-LabCorp (13)

Data signed: (hfarmer1) 26 Mar 2015 15:20:57

Generated On: 20 Jul 2016 12:37:46

Experiment Type

HEMATOLOGY

Date of Sample Collection
YYYY/MM/DD

16 JAN 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male ☒

Time of Sample Collection

13:04

Analyte Name

PLATELETS

Code

015172

Result

276

Unit

X10E3/UL

Lower limit

155

Upper limit

379

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Screening

Form: Lab-BU-LabCorp (13)

Data signed: (hfarmer1) 26 Mar 2015 15:20:57

Generated On: 20 Jul 2016 12:37:46

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

01657100030

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Screening

Form: Lab-BU-LabCorp (14)

Data signed: (hfarmer1) 26 Mar 2015 15:20:57

Generated On: 20 Jul 2016 12:37:46

Experiment Type

HEMATOLOGY

Date of Sample Collection
YYYY/MM/DD

16 JAN 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male ☒

Time of Sample Collection

13:04

Analyte Name

NEUTROPHILS (ABSOLUTE)

Code

015909

Result

4.2

Unit

X10E3/UL

Lower limit

1.4

Upper limit

7.0

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Screening

Form: Lab-BU-LabCorp (14)

Data signed: (hfarmer1) 26 Mar 2015 15:20:57

Generated On: 20 Jul 2016 12:37:46

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

01657100030

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Screening

Form: Lab-BU-LabCorp (15)

Data signed: (hfarmer1) 26 Mar 2015 15:20:57

Generated On: 20 Jul 2016 12:37:46

Experiment Type

HEMATOLOGY

Date of Sample Collection
YYYY/MM/DD

16 JAN 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male ☒

Time of Sample Collection

13:04

Analyte Name

LYMPHS (ABSOLUTE)

Code

015917

Result

2.1

Unit

X10E3/UL

Lower limit

0.7

Upper limit

3.1

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Screening

Form: Lab-BU-LabCorp (15)

Data signed: (hfarmer1) 26 Mar 2015 15:20:57

Generated On: 20 Jul 2016 12:37:46

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

01657100030

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Screening

Form: Lab-BU-LabCorp (16)

Data signed: (hfarmer1) 26 Mar 2015 15:20:57

Generated On: 20 Jul 2016 12:37:46

Experiment Type

HEMATOLOGY

Date of Sample Collection
YYYY/MM/DD

16 JAN 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male ☒

Time of Sample Collection

13:04

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: 1077**

Folder: Screening

Form: Lab-BU-LabCorp (16)

Data signed: (hfarmer1) 26 Mar 2015 15:20:57

Generated On: 20 Jul 2016 12:37:46

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

01657100030

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1077

Folder: Screening

Form: Lab-BU-LabCorp (17)

Data signed: (hfarmer1) 26 Mar 2015 15:20:57

Generated On: 20 Jul 2016 12:37:46

Experiment Type

HEMATOLOGY

Date of Sample Collection
YYYY/MM/DD

16 JAN 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male ☒

Time of Sample Collection

13:04

Analyte Name

EOS (ABSOLUTE)

Code

015933

Result

0.3

Unit

X10E3/UL

Lower limit

0.0

Upper limit

0.4

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Screening

Form: Lab-BU-LabCorp (17)

Data signed: (hfarmer1) 26 Mar 2015 15:20:57

Generated On: 20 Jul 2016 12:37:46

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

01657100030

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Screening

Form: Lab-BU-LabCorp (18)

Data signed: (hfarmer1) 26 Mar 2015 15:20:57

Generated On: 20 Jul 2016 12:37:46

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

Date of Sample Collection YYYY/MM/DD	16 JAN 2014
---	-------------

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

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

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

Time of Sample Collection	13:04
---------------------------	-------

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: 1077**

Folder: Screening

Form: Lab-BU-LabCorp (18)

Data signed: (hfarmer1) 26 Mar 2015 15:20:57

Generated On: 20 Jul 2016 12:37:46

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

01657100030

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Screening

Form: Lab-BU-LabCorp URINALYSIS(16 JAN 2014)

Data signed: (hfarmer1) 26 Mar 2015 15:20:58

Generated On: 20 Jul 2016 12:37:46

Experiment Type

URINALYSIS

Date of Sample Collection
YYYY/MM/DD

16 JAN 2014

Please document clinically relevant abnormalities in the AE form

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Screening

Form: Lab-BU-LabCorp URINALYSIS(16 JAN 2014)

Data signed: (hfarmer1) 26 Mar 2015 15:20:58

Generated On: 20 Jul 2016 12:37:46

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

Date of Sample Collection YYYY/MM/DD	16 JAN 2014
---	-------------

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

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

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

Time of Sample Collection	11:43
---------------------------	-------

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

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

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

Unit	
------	--

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

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

Flag	
------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Screening

Form: Lab-BU-LabCorp URINALYSIS(16 JAN 2014)

Data signed: (hfarmer1) 26 Mar 2015 15:20:58

Generated On: 20 Jul 2016 12:37:46

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: 1077**

Folder: Screening

Form: Lab-BU-LabCorp (2)

Data signed: (hfarmer1) 26 Mar 2015 15:20:58

Generated On: 20 Jul 2016 12:37:46

Experiment Type	URINALYSIS
Date of Sample Collection YYYY/MM/DD	16 JAN 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Male <input checked="" type="radio"/>
Time of Sample Collection	11:43
Analyte Name	PH
Code	13078
Result	7
Unit	
Lower limit	5
Upper limit	8
Flag	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Screening

Form: Lab-BU-LabCorp (2)

Data signed: (hfarmer1) 26 Mar 2015 15:20:58

Generated On: 20 Jul 2016 12:37:46

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: 1077**

Folder: Screening

Form: Lab-BU-LabCorp (3)

Data signed: (hfarmer1) 26 Mar 2015 15:20:58

Generated On: 20 Jul 2016 12:37:46

Experiment Type

URINALYSIS

Date of Sample Collection
YYYY/MM/DD

16 JAN 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male ☒

Time of Sample Collection

11:43

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: 1077**

Folder: Screening

Form: Lab-BU-LabCorp (3)

Data signed: (hfarmer1) 26 Mar 2015 15:20:58

Generated On: 20 Jul 2016 12:37:46

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: 1077**

Folder: Screening

Form: Lab-BU-LabCorp (4)

Data signed: (hfarmer1) 26 Mar 2015 15:20:58

Generated On: 20 Jul 2016 12:37:46

Experiment Type

URINALYSIS

Date of Sample Collection
YYYY/MM/DD

16 JAN 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male ☒

Time of Sample Collection

11:43

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: 1077**

Folder: Screening

Form: Lab-BU-LabCorp (4)

Data signed: (hfarmer1) 26 Mar 2015 15:20:58

Generated On: 20 Jul 2016 12:37:46

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: 1077**

Folder: Screening

Form: Lab-BU-LabCorp (5)

Data signed: (hfarmer1) 26 Mar 2015 15:20:58

Generated On: 20 Jul 2016 12:37:46

Experiment Type

URINALYSIS

Date of Sample Collection
YYYY/MM/DD

16 JAN 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male ☒

Time of Sample Collection

11:43

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: 1077**

Folder: Screening

Form: Lab-BU-LabCorp (5)

Data signed: (hfarmer1) 26 Mar 2015 15:20:58

Generated On: 20 Jul 2016 12:37:46

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: 1077**

Folder: Screening

Form: Lab-BU-LabCorp (6)

Data signed: (hfarmer1) 26 Mar 2015 15:20:58

Generated On: 20 Jul 2016 12:37:46

Experiment Type

URINALYSIS

Date of Sample Collection
YYYY/MM/DD

16 JAN 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male

Time of Sample Collection

11:43

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: 1077**

Folder: Screening

Form: Lab-BU-LabCorp (6)

Data signed: (hfarmer1) 26 Mar 2015 15:20:58

Generated On: 20 Jul 2016 12:37:46

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: 1077**

Folder: Screening

Form: Lab-BU-LabCorp (7)

Data signed: (hfarmer1) 26 Mar 2015 15:20:58

Generated On: 20 Jul 2016 12:37:46

Experiment Type

URINALYSIS

Date of Sample Collection
YYYY/MM/DD

16 JAN 2014

Subject Number

Date of Birth

(b) (6)

Gender

Male ☒

Time of Sample Collection

11:43

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: 1077**

Folder: Screening

Form: Lab-BU-LabCorp (7)

Data signed: (hfarmer1) 26 Mar 2015 15:20:58

Generated On: 20 Jul 2016 12:37:46

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: 1077**

Folder: Screening

Form: FTND Questionnaire

Generated On: 20 Jul 2016 12:37:46

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

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

Date of assessment	2014 JAN 16
DD/MMM/YYYY	DD/MMM/YYYY

Time of assessment	13:56
	hour:min 24-hour clock

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

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

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

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

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

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

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

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1077

Folder: Screening

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

Data signed: (hfarmer1) 26 Mar 2015 15:20:55

Generated On: 20 Jul 2016 12:37:46

Was paper questionnaire used? Yes ☒

Reason not done _____

Type PROCHASKA STAGE OF
CHANGE QUESTIONNAIRE:
INTENTION TO QUIT
SMOKING

Date of assessment 16 JAN 2014
DD/MMM/YYYY

Time of assessment 10:35
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: 1077**

Folder: Admission (Day -2)

Form: Date of Visit

Data signed: (hfarmer1) 26 Mar 2015 15:21:01

Generated On: 20 Jul 2016 12:37:46

Date of Visit

11 FEB 2014
DD/MMM/YYYY

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Admission (Day -2)

Form: Inclusion Criteria

Data signed: (hfarmer1) 26 Mar 2015 15:20:59

Generated On: 20 Jul 2016 12:37:46

*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: 1077

Folder: Admission (Day -2)

Form: Inclusion Criteria (1)

Data signed: (hfarmer1) 26 Mar 2015 15:20:59

Generated On: 20 Jul 2016 12:37:46

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: 1077

Folder: Admission (Day -2)

Form: Inclusion Criteria (2)

Data signed: (hfarmer1) 26 Mar 2015 15:20:59

Generated On: 20 Jul 2016 12:37:46

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: 1077

Folder: Admission (Day -2)

Form: Inclusion Criteria (3)

Data signed: (hfarmer1) 26 Mar 2015 15:20:59

Generated On: 20 Jul 2016 12:37:46

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: 1077

Folder: Admission (Day -2)

Form: Inclusion Criteria (4)

Data signed: (hfarmer1) 26 Mar 2015 15:20:59

Generated On: 20 Jul 2016 12:37:46

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: 1077**

Folder: Admission (Day -2)

Form: Exclusion Criteria

Data signed: (hfarmer1) 26 Mar 2015 15:20:59

Generated On: 20 Jul 2016 12:37:46

*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: 1077

Folder: Admission (Day -2)

Form: Exclusion Criteria (1)

Data signed: (hfarmer1) 26 Mar 2015 15:20:59

Generated On: 20 Jul 2016 12:37:46

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: 1077

Folder: Admission (Day -2)

Form: Exclusion Criteria (2)

Data signed: (hfarmer1) 26 Mar 2015 15:20:59

Generated On: 20 Jul 2016 12:37:46

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: 1077

Folder: Admission (Day -2)

Form: Exclusion Criteria (3)

Data signed: (hfarmer1) 26 Mar 2015 15:20:59

Generated On: 20 Jul 2016 12:37:46

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

Exclusion Criterion	The subject has a body mass index (BMI) <18.5 or ≥35 kg/m2.	<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: 1077

Folder: Admission (Day -2)

Form: Exclusion Criteria (4)

Data signed: (hfarmer1) 26 Mar 2015 15:20:59

Generated On: 20 Jul 2016 12:37:46

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: 1077

Folder: Admission (Day -2)

Form: Exclusion Criteria (5)

Data signed: (hfarmer1) 26 Mar 2015 15:20:59

Generated On: 20 Jul 2016 12:37:46

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: 1077

Folder: Admission (Day -2)

Form: Exclusion Criteria (6)

Data signed: (hfarmer1) 26 Mar 2015 15:20:59

Generated On: 20 Jul 2016 12:37:46

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

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

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

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

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1077

Folder: Admission (Day -2)

Form: Exclusion Criteria (7)

Data signed: (hfarmer1) 26 Mar 2015 15:20:59

Generated On: 20 Jul 2016 12:37:46

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: 1077

Folder: Admission (Day -2)

Form: Exclusion Criteria (8)

Data signed: (hfarmer1) 26 Mar 2015 15:20:59

Generated On: 20 Jul 2016 12:37:46

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: 1077**

Folder: Admission (Day -2)

Form: Exclusion Criteria (9)

Data signed: (hfarmer1) 26 Mar 2015 15:20:59

Generated On: 20 Jul 2016 12:37:46

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: 1077

Folder: Admission (Day -2)

Form: Exclusion Criteria (10)

Data signed: (hfarmer1) 26 Mar 2015 15:20:59

Generated On: 20 Jul 2016 12:37:46

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: 1077**

Folder: Admission (Day -2)

Form: Exclusion Criteria (11)

Data signed: (hfarmer1) 26 Mar 2015 15:20:59

Generated On: 20 Jul 2016 12:37:46

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: 1077

Folder: Admission (Day -2)

Form: Exclusion Criteria (12)

Data signed: (hfarmer1) 26 Mar 2015 15:20:59

Generated On: 20 Jul 2016 12:37:46

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: 1077**

Folder: Admission (Day -2)

Form: Exclusion Criteria (13)

Data signed: (hfarmer1) 26 Mar 2015 15:20:59

Generated On: 20 Jul 2016 12:37:46

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: 1077**

Folder: Admission (Day -2)

Form: Exclusion Criteria (14)

Data signed: (hfarmer1) 26 Mar 2015 15:20:59

Generated On: 20 Jul 2016 12:37:46

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: 1077**

Folder: Admission (Day -2)

Form: Vital Signs

Data signed: (hfarmer1) 26 Mar 2015 15:21:01

Generated On: 20 Jul 2016 12:37:46

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 13:12
hour:min 24-hour clock

Pulse rate 55
beats per minute

Respiratory rate 14
breaths per minute

Blood Pressure (systolic) 120
mmHg

Blood Pressure (diastolic) 81
mmHg

Vital Signs Position of Subject Supine ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Admission (Day -2)

Form: Product preference

Data signed: (hfarmer1) 26 Mar 2015 15:21:00

Generated On: 20 Jul 2016 12:37:46

Which Product Arm would you prefer to be randomized
to:

THS 2.2 menthol ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Admission (Day -2)

Form: Advice on the risk of smoking and debriefing

Data signed: (hfarmer1) 26 Mar 2015 15:21:01

Generated On: 20 Jul 2016 12:37:46

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: 1077**

Folder: Admission (Day -2)

Form: Physical Examination

Data signed: (hcoleman1) 18 Jun 2015 20:00:07

Generated On: 20 Jul 2016 12:37:46

Was the physical examination performed?

Yes ☒

If No, please specify the reason:

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Admission (Day -2)

Form: Physical Examination (1)

Data signed: (hcoleman1) 18 Jun 2015 20:00:07

Generated On: 20 Jul 2016 12:37:46

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: 1077**

Folder: Admission (Day -2)

Form: Physical Examination (2)

Data signed: (hcoleman1) 18 Jun 2015 20:00:07

Generated On: 20 Jul 2016 12:37:46

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: 1077

Folder: Admission (Day -2)

Form: Physical Examination (3)

Data signed: (hcoleman1) 18 Jun 2015 20:00:07

Generated On: 20 Jul 2016 12:37:46

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: 1077**

Folder: Admission (Day -2)

Form: Physical Examination (4)

Data signed: (hcoleman1) 18 Jun 2015 20:00:07

Generated On: 20 Jul 2016 12:37:46

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: 1077**

Folder: Admission (Day -2)

Form: Physical Examination (5)

Data signed: (hcoleman1) 18 Jun 2015 20:00:07

Generated On: 20 Jul 2016 12:37:46

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: 1077**

Folder: Admission (Day -2)

Form: Physical Examination (6)

Data signed: (hcoleman1) 18 Jun 2015 20:00:07

Generated On: 20 Jul 2016 12:37:46

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: 1077**

Folder: Admission (Day -2)

Form: Physical Examination (7)

Data signed: (hcoleman1) 18 Jun 2015 20:00:07

Generated On: 20 Jul 2016 12:37:46

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: 1077**

Folder: Admission (Day -2)

Form: Physical Examination (8)

Data signed: (hcoleman1) 18 Jun 2015 20:00:07

Generated On: 20 Jul 2016 12:37:46

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: 1077**

Folder: Admission (Day -2)

Form: Physical Examination (9)

Data signed: (hcoleman1) 18 Jun 2015 20:00:07

Generated On: 20 Jul 2016 12:37:46

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: 1077**

Folder: Admission (Day -2)

Form: Physical Examination (10)

Data signed: (hcoleman1) 18 Jun 2015 20:00:07

Generated On: 20 Jul 2016 12:37:46

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: 1077**

Folder: Admission (Day -2)

Form: Physical Examination (11)

Data signed: (hcoleman1) 18 Jun 2015 20:00:07

Generated On: 20 Jul 2016 12:37:46

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: 1077**

Folder: Admission (Day -2)

Form: Physical Examination (12)

Data signed: (hcoleman1) 18 Jun 2015 20:00:07

Generated On: 20 Jul 2016 12:37:46

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

System Musculoskeletal ☒

Outcome Abnormal ☒

Abnormal, please specify ABRASION LEFT GREAT TOE

Clinically significant No ☒

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Admission (Day -2)

Form: Physical Examination (13)

Data signed: (hcoleman1) 18 Jun 2015 20:00:07

Generated On: 20 Jul 2016 12:37:46

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: 1077**

Folder: Admission (Day -2)

Form: Physical Examination (14)

Data signed: (hcoleman1) 18 Jun 2015 20:00:07

Generated On: 20 Jul 2016 12:37:46

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

System Dentition ☒

Outcome Abnormal ☒

Abnormal, please specify DEAYING AMD 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: 1077**

Folder: Admission (Day -2)

Form: Physical Examination (15)

Data signed: (hcoleman1) 18 Jun 2015 20:00:07

Generated On: 20 Jul 2016 12:37:46

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: 1077**

Folder: Admission (Day -2)

Form: Physical Examination (16)

Data signed: (hcoleman1) 18 Jun 2015 20:00:07

Generated On: 20 Jul 2016 12:37:46

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: 1077**

Folder: Admission (Day -2)

Form: Physical Examination (17)

Data signed: (hcoleman1) 18 Jun 2015 20:00:07

Generated On: 20 Jul 2016 12:37:46

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: 1077**

Folder: Admission (Day -2)

Form: Physical Examination (18)

Data signed: (hcoleman1) 18 Jun 2015 20:00:07

Generated On: 20 Jul 2016 12:37:46

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: 1077**

Folder: Admission (Day -2)

Form: Physical Examination (19)

Data signed: (hcoleman1) 18 Jun 2015 20:00:07

Generated On: 20 Jul 2016 12:37:46

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: 1077**

Folder: Admission (Day -2)

Form: Identification of Current Cigarette Brand

Data signed: (hfarmer1) 26 Mar 2015 15:21:00

Generated On: 20 Jul 2016 12:37:46

Brand name

PALL MALL MENTHOL 100'S

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1077

Folder: Admission (Day -2)

Form: THS 2.2 menthol product test

Data signed: (hfarmer1) 26 Mar 2015 15:21:01

Generated On: 20 Jul 2016 12:37:46

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: 1077

Folder: Admission (Day -2)

Form: Smoking History

Data signed: (hfarmer1) 26 Mar 2015 15:21:00

Generated On: 20 Jul 2016 12:37:46

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: 1077**

Folder: Admission (Day -2)

Form: Weight

Data signed: (hfarmer1) 26 Mar 2015 15:21:01

Generated On: 20 Jul 2016 12:37:46

Measurement(s) assessed?

Yes ☒

If No, please specify the reason: _____

Time of assessment

12:58
hour:min 24-hour clock

Weight

74.7
kg

Waist circumference

97
cm

BMI

21.8

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1077

Folder: Admission (Day -2)

Form: Urine Drug Screen

Data signed: (hfarmer1) 26 Mar 2015 15:20:59

Generated On: 20 Jul 2016 12:37:46

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

If Not Done, please specify the reason: _____

Time of sample collection	12:09
	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: 1077

Folder: Admission (Day -2)

Form: Urine Drug Screen (6)

Data signed: (hfarmer1) 26 Mar 2015 15:20:59

Generated On: 20 Jul 2016 12:37:46

Drug type	Result
Opiates	Negative

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Admission (Day -2)

Form: Alcohol Test

Data signed: (hfarmer1) 26 Mar 2015 15:20:59

Generated On: 20 Jul 2016 12:37:46

Was the alcohol test performed? Yes ☒

If No, please specify the reason: _____

Method used Breath test ☒

Time of assessment 12:25
hour:min 24-hour clock

Result Negative ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Admission (Day -2)

Form: CO Breath Test

Data signed: (hfarmer1) 26 Mar 2015 15:20:58

Generated On: 20 Jul 2016 12:37:46

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

If Not Done, please specify the reason: _____

Actual Time of Assessment	12:27
	hour:min 24-hour clock

Result	10
	ppm

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Admission (Day -2)

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

Data signed: (hfarmer1) 26 Mar 2015 15:21:00

Generated On: 20 Jul 2016 12:37:46

Was paper questionnaire used? Yes ☒

Reason not done _____

Type PROCHASKA STAGE OF
CHANGE QUESTIONNAIRE:
INTENTION TO QUIT
SMOKING

Date of assessment 11 FEB 2014
DD/MMM/YYYY

Time of assessment 13:21
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: 1077**

Folder: Baseline (Day -1)

Form: Date of Visit

Data signed: (hfarmer1) 26 Mar 2015 15:21:03

Generated On: 20 Jul 2016 12:37:46

Date of Visit

12 FEB 2014
DD/MMM/YYYY

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day -1)

Form: Vital Signs

Data signed: (hfarmer1) 26 Mar 2015 15:21:03

Generated On: 20 Jul 2016 12:37:46

Were Vitals Signs assessed?

Yes ☒

If No, please specify the reason: _____

Has the subject smoked within 15 minutes prior to
assessment

No ☒

Time of assessment

09:44
hour:min 24-hour clock

Pulse rate

69
beats per minute

Respiratory rate

16
breaths per minute

Blood Pressure (systolic)

118
mmHg

Blood Pressure (diastolic)

76
mmHg

Vital Signs Position of Subject

Supine ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day -1)

Form: CoHb Blood Sample

Data signed: (hfarmer1) 26 Mar 2015 15:21:01

Generated On: 20 Jul 2016 12:37:46

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

If Not Done, please specify the reason: _____

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

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

Time hour:min 24-hour clock	20:05
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day -1)

Form: CO Breath Test (1)

Data signed: (hfarmer1) 26 Mar 2015 15:21:01

Generated On: 20 Jul 2016 12:37:46

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

If Not Done, please specify the reason: _____

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

Actual Time of Assessment hour:min 24-hour clock	06:35
---	-------

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day -1)

Form: CO Breath Test (2)

Data signed: (hfarmer1) 26 Mar 2015 15:21:01

Generated On: 20 Jul 2016 12:37:46

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

If Not Done, please specify the reason: _____

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

Actual Time of Assessment hour:min 24-hour clock	12:05
---	-------

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day -1)

Form: CO Breath Test (3)

Data signed: (hfarmer1) 26 Mar 2015 15:21:01

Generated On: 20 Jul 2016 12:37:46

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

If Not Done, please specify the reason: _____

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

Actual Time of Assessment hour:min 24-hour clock	16:10
---	-------

Result(ppm)	21
-------------	----

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day -1)

Form: CO Breath Test (4)

Data signed: (hfarmer1) 26 Mar 2015 15:21:01

Generated On: 20 Jul 2016 12:37:46

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	20:01
---	-------

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day -1)

Form: 4 hour urine collection

Data signed: (hfarmer1) 26 Mar 2015 15:21:03

Generated On: 20 Jul 2016 12:37:46

Start Time	09:59
	hour:min 24-hour clock

End Time	14:00
	hour:min 24-hour clock

Volume	476
	mL

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day -1)

Form: Sample Urine Collection (4 Hour collection)

Data signed: (hfarmer1) 26 Mar 2015 15:21:03

Generated On: 20 Jul 2016 12:37:46

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: 1077**

Folder: Baseline (Day -1)

Form: Lab_BU_COHB (1)

Data signed: (hfarmer1) 26 Mar 2015 15:21:04

Generated On: 20 Jul 2016 12:37:46

Sample Barcode	05115150000465
----------------	----------------

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

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

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

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

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

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

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

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

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

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

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

Date of Collection	2014-FEB-12
--------------------	-------------

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day -1)

Form: Lab_BU_COHB (1)

Data signed: (hfarmer1) 26 Mar 2015 15:21:04

Generated On: 20 Jul 2016 12:37:46

Start Day (24 hour urine only)

End Day (24 hour Urine Only)

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day -1)

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)

Data signed: (hfarmer1) 26 Mar 2015 15:21:03

Generated On: 20 Jul 2016 12:37:46

Date of Birth

(b) (6)

Date of assessment

2014 FEB 12

DD/MMM/YYYY

DD/MMM/YYYY

Time of assessment

20:09

hour:min 24-hour clock

Assessment Status

Completed ☒

1. Was smoking satisfying?

Quite a lot ☒

2. Did cigarettes taste good?

Quite a lot ☒

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

Moderately ☒

4. Did smoking calm you down?

Moderately ☒

5. Did smoking make you feel more awake?

Moderately ☒

6. Did smoking make you feel less irritable?

Moderately ☒

7. Did smoking help you concentrate?

Moderately ☒

8. Did smoking reduce your hunger for food?

Little ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day -1)

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)

Data signed: (hfarmer1) 26 Mar 2015 15:21:03

Generated On: 20 Jul 2016 12:37:46

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

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

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

12. Did you enjoy smoking? Extremely ☐

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day -1)

Form: Behavioral Risk Factor Surveillance System Questionnaire

Data signed: (hfarmer1) 26 Mar 2015 15:21:01

Generated On: 20 Jul 2016 12:37:46

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

Was paper questionnaire used?	Yes <input type="radio"/>
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Reason not done	<hr/>
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Date of assessment	12 FEB 2014 DD/MMM/YYYY
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Time of assessment	20:11 hour:min 24-hour clock
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Have you ever smoked 100 cigarettes or more in your life?	Yes <input type="radio"/>
---	---------------------------

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

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

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day -1)

Form: Behavioral Risk Factor Surveillance System Questionnaire

Data signed: (hfarmer1) 26 Mar 2015 15:21:01

Generated On: 20 Jul 2016 12:37:46

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: 1077

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ)

Data signed: (hfarmer1) 26 Mar 2015 15:21:02

Generated On: 20 Jul 2016 12:37:46

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

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

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

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

Time of assessment	20:14 hour:min 24-hour clock
--------------------	---------------------------------

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

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

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

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

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

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ)

Data signed: (hfarmer1) 26 Mar 2015 15:21:02

Generated On: 20 Jul 2016 12:37:46

Months

Days

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

Years 0 Years

Months 0 Months

Days 0 Days

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

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1077

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (1)

Data signed: (hfarmer1) 26 Mar 2015 15:21:02

Generated On: 20 Jul 2016 12:37:46

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

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

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

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

Time of assessment	20:14 hour:min 24-hour clock
--------------------	---------------------------------

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

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

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

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

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

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

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1077

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (1)

Data signed: (hfarmer1) 26 Mar 2015 15:21:02

Generated On: 20 Jul 2016 12:37:46

Months

Days

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

Years

0 Years

Months

0 Months

Days

0 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

15

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

Hand-rolled Cigarettes
per day

0

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (1)

Data signed: (hfarmer1) 26 Mar 2015 15:21:02

Generated On: 20 Jul 2016 12:37:46

8. On average, how many cigars do/did you smoke per
day? _____

Cigars _____ 0
per day

8. On average, how many pipes do/did you smoke per _____ None ☒
day?

Pipes _____
per day

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1077

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (2)

Data signed: (hfarmer1) 26 Mar 2015 15:21:02

Generated On: 20 Jul 2016 12:37:46

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

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

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

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

Time of assessment	20:14 hour:min 24-hour clock
--------------------	---------------------------------

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

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

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

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

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

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

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1077

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (2)

Data signed: (hfarmer1) 26 Mar 2015 15:21:02

Generated On: 20 Jul 2016 12:37:46

Months

Days

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

Years

0 Years

Months

0 Months

Days

0 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?

Hand-rolled Cigarettes
per day

0

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (2)

Data signed: (hfarmer1) 26 Mar 2015 15:21:02

Generated On: 20 Jul 2016 12:37:46

8. On average, how many cigars do/did you smoke per
day? _____

Cigars _____ 0
per day

8. On average, how many pipes do/did you smoke per _____ None ☒

Pipes _____
per day

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1077

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (3)

Data signed: (hfarmer1) 26 Mar 2015 15:21:02

Generated On: 20 Jul 2016 12:37:46

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

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

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

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

Time of assessment	20:14 hour:min 24-hour clock
--------------------	---------------------------------

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

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

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

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

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

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (3)

Data signed: (hfarmer1) 26 Mar 2015 15:21:02

Generated On: 20 Jul 2016 12:37:46

Months _____

Days _____

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

Years 0 Years

Months 0 Months

Days 0 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 20
per day

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

Hand-rolled Cigarettes 0
per day

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (3)

Data signed: (hfarmer1) 26 Mar 2015 15:21:02

Generated On: 20 Jul 2016 12:37:46

8. On average, how many cigars do/did you smoke per
day? _____

Cigars _____ 0
per day

8. On average, how many pipes do/did you smoke per _____ None ☒
day?

Pipes _____
per day

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1077

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (4)

Data signed: (hfarmer1) 26 Mar 2015 15:21:02

Generated On: 20 Jul 2016 12:37:46

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

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

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

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

Time of assessment	20:14 hour:min 24-hour clock
--------------------	---------------------------------

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

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

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

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

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

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

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1077

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (4)

Data signed: (hfarmer1) 26 Mar 2015 15:21:02

Generated On: 20 Jul 2016 12:37:46

Months

Days

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

Years

0 Years

Months

0 Months

Days

0 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?

Hand-rolled Cigarettes
per day

0

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (4)

Data signed: (hfarmer1) 26 Mar 2015 15:21:02

Generated On: 20 Jul 2016 12:37:46

8. On average, how many cigars do/did you smoke per
day? _____

Cigars _____ 0
per day

8. On average, how many pipes do/did you smoke per _____ None ☒

Pipes _____
per day

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1077

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (5)

Data signed: (hfarmer1) 26 Mar 2015 15:21:02

Generated On: 20 Jul 2016 12:37:46

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

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

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

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

Time of assessment	20:14 hour:min 24-hour clock
--------------------	---------------------------------

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

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

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

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

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

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (5)

Data signed: (hfarmer1) 26 Mar 2015 15:21:02

Generated On: 20 Jul 2016 12:37:46

Months

Days

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

Years

0 Years

Months


0 Months

Days

0 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?

Hand-rolled Cigarettes
per day

0

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (5)

Data signed: (hfarmer1) 26 Mar 2015 15:21:02

Generated On: 20 Jul 2016 12:37:46

8. On average, how many cigars do/did you smoke per
day? _____

Cigars _____ 0
per day

8. On average, how many pipes do/did you smoke per _____ None ☒

Pipes _____
per day

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1077

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (6)

Data signed: (hfarmer1) 26 Mar 2015 15:21:02

Generated On: 20 Jul 2016 12:37:46

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

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

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

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

Time of assessment	20:14 hour:min 24-hour clock
--------------------	---------------------------------

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

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

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

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

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

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (6)

Data signed: (hfarmer1) 26 Mar 2015 15:21:02

Generated On: 20 Jul 2016 12:37:46

Months

Days

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

Years

0 Years

Months

0 Months

Days

0 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?

Hand-rolled Cigarettes
per day

0

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (6)

Data signed: (hfarmer1) 26 Mar 2015 15:21:02

Generated On: 20 Jul 2016 12:37:46

8. On average, how many cigars do/did you smoke per
day? _____

Cigars _____ 0
per day

8. On average, how many pipes do/did you smoke per _____ None ☒

Pipes _____
per day

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1077

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (7)

Data signed: (hfarmer1) 26 Mar 2015 15:21:02

Generated On: 20 Jul 2016 12:37:46

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

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

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

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

Time of assessment	20:14 hour:min 24-hour clock
--------------------	---------------------------------

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

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

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

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

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

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (7)

Data signed: (hfarmer1) 26 Mar 2015 15:21:02

Generated On: 20 Jul 2016 12:37:46

Months

Days

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

Years 0 Years

Months 0 Months

Days 0 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?

Hand-rolled Cigarettes 0
per day

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day -1)

Form: Smoking Questionnaire (SQ) (7)

Data signed: (hfarmer1) 26 Mar 2015 15:21:02

Generated On: 20 Jul 2016 12:37:46

8. On average, how many cigars do/did you smoke per
day? _____

Cigars _____ 0
per day

8. On average, how many pipes do/did you smoke per _____ None ☒

Pipes _____
per day

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day -1)

Form: Supplemental Questions

Data signed: (hfarmer1) 26 Mar 2015 15:21:03

Generated On: 20 Jul 2016 12:37:46

Was paper questionnaire used?

Yes ☒

Reason not done

Date of Assessment

12 FEB 2014
DD/MMM/YYYY

Time of assessment

20:15

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

02 minutes

Comments (open-end)

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1077

Folder: Baseline (Day -1)

Form: Supplemental Questions (1)

Data signed: (hfarmer1) 26 Mar 2015 15:21:03

Generated On: 20 Jul 2016 12:37:46

Was paper questionnaire used? Yes ☐

Reason not done _____

Date of Assessment 12 FEB 2014
DD/MMM/YYYY

Time of assessment 20:15

1. How long it takes for the subject to complete the SQ 02 minutes

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

Answer Yes ☐

Comments (open-end) _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day -1)

Form: Supplemental Questions (2)

Data signed: (hfarmer1) 26 Mar 2015 15:21:03

Generated On: 20 Jul 2016 12:37:46

Was paper questionnaire used? Yes ☐

Reason not done _____

Date of Assessment 12 FEB 2014
DD/MMM/YYYY

Time of assessment 20:15

1. How long it takes for the subject to complete the SQ 02 minutes

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

Answer Yes ☐

Comments (open-end) _____

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1077

Folder: Baseline (Day -1)

Form: Supplemental Questions (3)

Data signed: (hfarmer1) 26 Mar 2015 15:21:03

Generated On: 20 Jul 2016 12:37:46

Was paper questionnaire used? Yes ☐

Reason not done _____

Date of Assessment 12 FEB 2014
DD/MMM/YYYY

Time of assessment 20:15

1. How long it takes for the subject to complete the SQ 02 minutes

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

Answer Yes ☐

Comments (open-end) _____

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1077

Folder: Baseline (Day -1)

Form: Supplemental Questions (4)

Data signed: (hfarmer1) 26 Mar 2015 15:21:03

Generated On: 20 Jul 2016 12:37:46

Was paper questionnaire used? Yes ☐

Reason not done _____

Date of Assessment 12 FEB 2014
DD/MMM/YYYY

Time of assessment 20:15

1. How long it takes for the subject to complete the SQ 02 minutes

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

Answer Yes ☐

Comments (open-end) _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day -1)

Form: Supplemental Questions (5)

Data signed: (hfarmer1) 26 Mar 2015 15:21:03

Generated On: 20 Jul 2016 12:37:46

Was paper questionnaire used? Yes ☐

Reason not done _____

Date of Assessment 12 FEB 2014
DD/MMM/YYYY

Time of assessment 20:15

1. How long it takes for the subject to complete the SQ 02 minutes

Question 6. Was the SQ ☐
self-explaining?

Answer Yes ☐

Comments (open-end) _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day -1)

Form: Supplemental Questions (6)

Data signed: (hfarmer1) 26 Mar 2015 15:21:03

Generated On: 20 Jul 2016 12:37:46

Was paper questionnaire used? Yes ☐

Reason not done _____

Date of Assessment 12 FEB 2014
DD/MMM/YYYY

Time of assessment 20:15

1. How long it takes for the subject to complete the SQ 02 minutes

Question 7. Was the SQ easy to use? ☐

Answer Yes ☐

Comments (open-end) _____

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1077

Folder: Baseline (Day -1)

Form: Questionnaire on smoking urges (QSU)

Data signed: (hfarmer1) 26 Mar 2015 15:21:03

Generated On: 20 Jul 2016 12:37:46

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

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

Date of assessment	2014 FEB 12
--------------------	-------------

DD/MMM/YYYY

Time of assessment	20:07
--------------------	-------

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	Somewhat disagree <input type="radio"/>
---	---

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

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

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

6. I have an urge for a cigarette	Somewhat agree <input type="radio"/>
-----------------------------------	--------------------------------------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day -1)

Form: Questionnaire on smoking urges (QSU)

Data signed: (hfarmer1) 26 Mar 2015 15:21:03

Generated On: 20 Jul 2016 12:37:46

7. A cigarette would taste good now Agree ☐

8. I would do almost anything for a cigarette now Somewhat agree ☐

9. Smoking would make me less depressed Somewhat disagree ☐

10. I am going to smoke as soon as possible Strongly agree ☐

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day -1)

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

Data signed: (hfarmer1) 26 Mar 2015 15:21:04

Generated On: 20 Jul 2016 12:37:46

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day -1)

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

Data signed: (hfarmer1) 26 Mar 2015 15:21:04

Generated On: 20 Jul 2016 12:37:46

Sample Barcode	05112450000375
Analyte	HPMA
Sample type	URINE
Result	.
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	-1
Celerion Study Number	AA99128-03
Date of Collection	2014-FEB-12
Timepoint-minutes	
Urine Start Day	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day -1)

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

Data signed: (hfarmer1) 26 Mar 2015 15:21:04

Generated On: 20 Jul 2016 12:37:46

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day -1)

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

Data signed: (hfarmer1) 26 Mar 2015 15:21:04

Generated On: 20 Jul 2016 12:37:46

Sample Barcode	05112450000375
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Analyte	CEMA
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Sample type	URINE
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Result	.
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Result Unit	NG/ML
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Lab Status	OTHER
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Sample comment	ANALYSIS NOT REQUIRED
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Detection method	LC-MS/MS
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Planned time point (Hour)	0
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Day of Visit	-1
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Celerion Study Number	AA99128-03
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Date of Collection	2014-FEB-12
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Timepoint-minutes	
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Urine Start Day	
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day -1)

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

Data signed: (hfarmer1) 26 Mar 2015 15:21:04

Generated On: 20 Jul 2016 12:37:46

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day -1)

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

Data signed: (hfarmer1) 26 Mar 2015 15:21:04

Generated On: 20 Jul 2016 12:37:46

Sample Barcode	05112450000375
Analyte	HBMA
Sample type	URINE
Result	.
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	-1
Celerion Study Number	AA99128-03
Date of Collection	2014-FEB-12
Timepoint-minutes	
Urine Start Day	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day -1)

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

Data signed: (hfarmer1) 26 Mar 2015 15:21:04

Generated On: 20 Jul 2016 12:37:46

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (NNN, NNAL)

Data signed: (hfarmer1) 26 Mar 2015 15:21:04

Generated On: 20 Jul 2016 12:37:46

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day -1)

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

Data signed: (hfarmer1) 26 Mar 2015 15:21:04

Generated On: 20 Jul 2016 12:37:46

Sample Barcode	05112460001459
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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	OTHER
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Sample comment	ANALYSIS NOT REQUIRED
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Detection method	LC-MS/MS
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Planned time point (Hour)	0
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Day of Visit	-1
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Celerion Study Number	AA99128-04
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Date of Collection	2014-FEB-12
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Timepoint-minutes	
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Urine Start Day	
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day -1)

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

Data signed: (hfarmer1) 26 Mar 2015 15:21:04

Generated On: 20 Jul 2016 12:37:46

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day -1)

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

Data signed: (hfarmer1) 26 Mar 2015 15:21:04

Generated On: 20 Jul 2016 12:37:46

Sample Barcode	05112460001459
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Analyte	NNN
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Sample type	URINE
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Result	.
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Result Unit	PG/ML
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Lab Status	OTHER
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Sample comment	ANALYSIS NOT REQUIRED
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Detection method	LC-MS/MS
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Planned time point (Hour)	0
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Day of Visit	-1
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Celerion Study Number	AA99128-04
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Date of Collection	2014-FEB-12
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Timepoint-minutes	
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Urine Start Day	
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day -1)

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

Data signed: (hfarmer1) 26 Mar 2015 15:21:04

Generated On: 20 Jul 2016 12:37:46

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (HEMA)

Data signed: (hfarmer1) 26 Mar 2015 15:21:04

Generated On: 20 Jul 2016 12:37:46

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (HEMA) (1)

Data signed: (hfarmer1) 26 Mar 2015 15:21:04

Generated On: 20 Jul 2016 12:37:46

Sample Barcode	05112470000364
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Analyte	HEMA
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Sample type	URINE
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Result	.
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Result Unit	NG/ML
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Lab Status	OTHER
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Sample comment	ANALYSIS NOT REQUIRED
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Detection method	LC-MS/MS
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Planned time point (Hour)	0
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Day of Visit	-1
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Celerion Study Number	AA99128-05
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Date of Collection	2014-FEB-12
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Timepoint-minutes	
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Urine Start Day	
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (HEMA) (1)

Data signed: (hfarmer1) 26 Mar 2015 15:21:04

Generated On: 20 Jul 2016 12:37:46

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day -1)

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

Data signed: (hfarmer1) 26 Mar 2015 15:21:04

Generated On: 20 Jul 2016 12:37:46

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day -1)

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

Data signed: (hfarmer1) 26 Mar 2015 15:21:04

Generated On: 20 Jul 2016 12:37:46

Sample Barcode	05112550000034
Analyte	COT
Sample type	URINE
Result	.
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	-1
Celerion Study Number	AA99128-13
Date of Collection	2014-FEB-12
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day -1)

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

Data signed: (hfarmer1) 26 Mar 2015 15:21:04

Generated On: 20 Jul 2016 12:37:46

Urine Start Day

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day -1)

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

Data signed: (hfarmer1) 26 Mar 2015 15:21:04

Generated On: 20 Jul 2016 12:37:46

Sample Barcode	05112550000034
Analyte	COT-GLUC
Sample type	URINE
Result	.
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	-1
Celerion Study Number	AA99128-13
Date of Collection	2014-FEB-12
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day -1)

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

Data signed: (hfarmer1) 26 Mar 2015 15:21:04

Generated On: 20 Jul 2016 12:37:46

Urine Start Day

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day -1)

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

Data signed: (hfarmer1) 26 Mar 2015 15:21:04

Generated On: 20 Jul 2016 12:37:46

Sample Barcode	05112550000034
Analyte	NIC
Sample type	URINE
Result	.
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	-1
Celerion Study Number	AA99128-13
Date of Collection	2014-FEB-12
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day -1)

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

Data signed: (hfarmer1) 26 Mar 2015 15:21:04

Generated On: 20 Jul 2016 12:37:46

Urine Start Day

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day -1)

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

Data signed: (hfarmer1) 26 Mar 2015 15:21:04

Generated On: 20 Jul 2016 12:37:46

Sample Barcode	05112550000034
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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	OTHER
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Sample comment	ANALYSIS NOT REQUIRED
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Detection method	LC-MS/MS
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Planned time point (Hour)	0
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Day of Visit	-1
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Celerion Study Number	AA99128-13
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Date of Collection	2014-FEB-12
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Timepoint-minutes	
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day -1)

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

Data signed: (hfarmer1) 26 Mar 2015 15:21:04

Generated On: 20 Jul 2016 12:37:46

Urine Start Day

Urine End Day

-1

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1077

Folder: Baseline (Day -1)

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

Data signed: (hfarmer1) 26 Mar 2015 15:21:04

Generated On: 20 Jul 2016 12:37:46

Sample Barcode	05112550000034
Analyte	THCOT
Sample type	URINE
Result	.
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	-1
Celerion Study Number	AA99128-13
Date of Collection	2014-FEB-12
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day -1)

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

Data signed: (hfarmer1) 26 Mar 2015 15:21:04

Generated On: 20 Jul 2016 12:37:46

Urine Start Day

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day -1)

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(6)**

Data signed: (hfarmer1) 26 Mar 2015 15:21:04

Generated On: 20 Jul 2016 12:37:46

Sample Barcode	05112550000034
Analyte	THCOT-GLUC
Sample type	URINE
Result	.
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	-1
Celerion Study Number	AA99128-13
Date of Collection	2014-FEB-12
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day -1)

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(6)**

Data signed: (hfarmer1) 26 Mar 2015 15:21:04

Generated On: 20 Jul 2016 12:37:46

Urine Start Day

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (3-OH BaP)

Data signed: (hfarmer1) 26 Mar 2015 15:21:04

Generated On: 20 Jul 2016 12:37:46

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (3-OH BaP) (1)

Data signed: (hfarmer1) 26 Mar 2015 15:21:04

Generated On: 20 Jul 2016 12:37:46

Sample Barcode	05112490000364
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Analyte	3-OH BAP
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Sample type	URINE
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Result	.
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Result Unit	FG/ML
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Lab Status	OTHER
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Sample comment	ANALYSIS NOT REQUIRED
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Detection method	LC-MS/MS
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Planned time point (Hour)	0
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Day of Visit	-1
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Celerion Study Number	AA99128-07
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Date of Collection	2014-FEB-12
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Timepoint-minutes	
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Urine Start Day	
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (3-OH BaP) (1)

Data signed: (hfarmer1) 26 Mar 2015 15:21:04

Generated On: 20 Jul 2016 12:37:46

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP)

Data signed: (hfarmer1) 26 Mar 2015 15:21:04

Generated On: 20 Jul 2016 12:37:46

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (1)

Data signed: (hfarmer1) 26 Mar 2015 15:21:04

Generated On: 20 Jul 2016 12:37:46

Sample Barcode	05112510000364
Analyte	1-NA
Sample type	URINE
Result	.
Result Unit	PG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	-1
Celerion Study Number	AA99128-09
Date of Collection	2014-FEB-12
Timepoint-minutes	
Urine Start Day	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (1)

Data signed: (hfarmer1) 26 Mar 2015 15:21:04

Generated On: 20 Jul 2016 12:37:46

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (2)

Data signed: (hfarmer1) 26 Mar 2015 15:21:04

Generated On: 20 Jul 2016 12:37:46

Sample Barcode	05112510000364
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Analyte	2-NA
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Sample type	URINE
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Result	.
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Result Unit	PG/ML
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Lab Status	OTHER
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Sample comment	ANALYSIS NOT REQUIRED
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Detection method	LC-MS/MS
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Planned time point (Hour)	0
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Day of Visit	-1
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Celerion Study Number	AA99128-09
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Date of Collection	2014-FEB-12
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Timepoint-minutes	
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Urine Start Day	
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (2)

Data signed: (hfarmer1) 26 Mar 2015 15:21:04

Generated On: 20 Jul 2016 12:37:46

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (3)

Data signed: (hfarmer1) 26 Mar 2015 15:21:04

Generated On: 20 Jul 2016 12:37:46

Sample Barcode	05112510000364
Analyte	4-ABP
Sample type	URINE
Result	.
Result Unit	PG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	-1
Celerion Study Number	AA99128-09
Date of Collection	2014-FEB-12
Timepoint-minutes	
Urine Start Day	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (3)

Data signed: (hfarmer1) 26 Mar 2015 15:21:04

Generated On: 20 Jul 2016 12:37:46

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (4)

Data signed: (hfarmer1) 26 Mar 2015 15:21:04

Generated On: 20 Jul 2016 12:37:46

Sample Barcode	05112510000364
Analyte	O-TOL
Sample type	URINE
Result	.
Result Unit	PG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	-1
Celerion Study Number	AA99128-09
Date of Collection	2014-FEB-12
Timepoint-minutes	
Urine Start Day	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (4)

Data signed: (hfarmer1) 26 Mar 2015 15:21:04

Generated On: 20 Jul 2016 12:37:46

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (11-dTXb2)

Data signed: (hfarmer1) 26 Mar 2015 15:21:04

Generated On: 20 Jul 2016 12:37:46

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (11-dTXb2) (1)

Data signed: (hfarmer1) 26 Mar 2015 15:21:04

Generated On: 20 Jul 2016 12:37:46

Sample Barcode	05112530000232
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Analyte	11-DTXB2
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Sample type	URINE
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Result	.
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Result Unit	PG/ML
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Lab Status	OTHER
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Sample comment	ANALYSIS NOT REQUIRED
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Detection method	LC-MS/MS
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Planned time point (Hour)	0
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Day of Visit	-1
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Celerion Study Number	AA99128-11
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Date of Collection	2014-FEB-12
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Timepoint-minutes	_____
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Urine Start Day	_____
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (11-dTXb2) (1)

Data signed: (hfarmer1) 26 Mar 2015 15:21:04

Generated On: 20 Jul 2016 12:37:46

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (iPF2a-III)

Data signed: (hfarmer1) 26 Mar 2015 15:21:04

Generated On: 20 Jul 2016 12:37:46

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (iPF2a-III) (1)

Data signed: (hfarmer1) 26 Mar 2015 15:21:04

Generated On: 20 Jul 2016 12:37:46

Sample Barcode	05112540000232
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Analyte	IPF2A-III
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Sample type	URINE
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Result	.
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Result Unit	PG/ML
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Lab Status	OTHER
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Sample comment	ANALYSIS NOT REQUIRED
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Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
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Day of Visit	-1
--------------	----

Celerion Study Number	AA99128-12
-----------------------	------------

Date of Collection	2014-FEB-12
--------------------	-------------

Timepoint-minutes	_____
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Urine Start Day	_____
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (iPF2a-III) (1)

Data signed: (hfarmer1) 26 Mar 2015 15:21:04

Generated On: 20 Jul 2016 12:37:46

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (1-OHP)

Data signed: (hfarmer1) 26 Mar 2015 15:21:05

Generated On: 20 Jul 2016 12:37:46

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (1-OHP) (1)

Data signed: (hfarmer1) 26 Mar 2015 15:21:05

Generated On: 20 Jul 2016 12:37:46

Sample Barcode	05115190001321
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Analyte	1-OHP
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Sample type	URINE
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Result	.
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Result Unit	PG/ML
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Lab Status	OTHER
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Sample comment	ANALYSIS NOT REQUIRED
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Detection method	LC-MS/MS
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Planned time point (Hour)	0
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Day of Visit	-1
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Celerion Study Number	AA99598-03
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Date of Collection	2014-FEB-12
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Timepoint-minutes	_____
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Urine Start Day	_____
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (1-OHP) (1)

Data signed: (hfarmer1) 26 Mar 2015 15:21:05

Generated On: 20 Jul 2016 12:37:46

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (SPMA, SBMA)

Data signed: (hfarmer1) 26 Mar 2015 15:21:04

Generated On: 20 Jul 2016 12:37:46

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (SPMA, SBMA) (1)

Data signed: (hfarmer1) 26 Mar 2015 15:21:04

Generated On: 20 Jul 2016 12:37:46

Sample Barcode	05115170001277
----------------	----------------

Analyte	SBMA
---------	------

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

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

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

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

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

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

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

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

Celerion Study Number	AA99598-01
-----------------------	------------

Date of Collection	2014-FEB-12
--------------------	-------------

Timepoint-minutes	_____
-------------------	-------

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (SPMA, SBMA) (1)

Data signed: (hfarmer1) 26 Mar 2015 15:21:04

Generated On: 20 Jul 2016 12:37:46

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (SPMA, SBMA) (2)

Data signed: (hfarmer1) 26 Mar 2015 15:21:04

Generated On: 20 Jul 2016 12:37:46

Sample Barcode	05115170001277
----------------	----------------

Analyte	SPMA
---------	------

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

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

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

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

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

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

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

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

Celerion Study Number	AA99598-01
-----------------------	------------

Date of Collection	2014-FEB-12
--------------------	-------------

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

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (SPMA, SBMA) (2)

Data signed: (hfarmer1) 26 Mar 2015 15:21:04

Generated On: 20 Jul 2016 12:37:46

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (MHBMA)

Data signed: (hfarmer1) 26 Mar 2015 15:21:04

Generated On: 20 Jul 2016 12:37:46

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (MHBMA) (1)

Data signed: (hfarmer1) 26 Mar 2015 15:21:04

Generated On: 20 Jul 2016 12:37:46

Sample Barcode	05115180001321
----------------	----------------

Analyte	MHBMA
---------	-------

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

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

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

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

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

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

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

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

Celerion Study Number	AA99598-02
-----------------------	------------

Date of Collection	2014-FEB-12
--------------------	-------------

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

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (MHBMA) (1)

Data signed: (hfarmer1) 26 Mar 2015 15:21:04

Generated On: 20 Jul 2016 12:37:46

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (Creatinine)

Data signed: (hfarmer1) 26 Mar 2015 15:21:05

Generated On: 20 Jul 2016 12:37:46

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (Creatinine) (1)

Data signed: (hfarmer1) 26 Mar 2015 15:21:05

Generated On: 20 Jul 2016 12:37:46

Sample Barcode	05115160000661
Analyte	CREATININE
Sample type	URINE
Result	.
Result Unit	MG/DL
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	SPECTROPHOTOMETRIC
Planned time point (Hour)	0
Day of Visit	-1
Celerion Study Number	AA99128-14
Date of Collection	2014-FEB-12
Timepoint-minutes	
Urine Start Day	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day -1)

Form: Biomarker-Urine (Creatinine) (1)

Data signed: (hfarmer1) 26 Mar 2015 15:21:05

Generated On: 20 Jul 2016 12:37:46

Urine End Day

-1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day 0)

Form: Date of Visit

Data signed: (hfarmer1) 26 Mar 2015 15:21:06

Generated On: 20 Jul 2016 12:37:46

Date of Visit

13 FEB 2014
DD/MMM/YYYY

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day 0)

Form: Randomization

Data signed: (hfarmer1) 26 Mar 2015 15:21:06

Generated On: 20 Jul 2016 12:37:46

Randomization number (4 digits)	2004
---------------------------------	------

Allocation Arm	SA <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: 1077**

Folder: Baseline (Day 0)

Form: Vital Signs

Data signed: (hfarmer1) 26 Mar 2015 15:21:06

Generated On: 20 Jul 2016 12:37:46

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 09:14
hour:min 24-hour clock

Pulse rate 56
beats per minute

Respiratory rate 14
breaths per minute

Blood Pressure (systolic) 113
mmHg

Blood Pressure (diastolic) 80
mmHg

Vital Signs Position of Subject Supine ☒

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1077

Folder: Baseline (Day 0)

Form: Gas Transfer

Data signed: (hcoleman1) 18 Jun 2015 20:00:07

Generated On: 20 Jul 2016 12:37:46

Was the Gas Transfer performed?

No ☒

If No, please specify the reason:

TEST PERFORMED BUT THEY
WERE NOT RESULTED

Category

Position

SITTING

Time of assessment

DLCO value

KCO value

DLCO/VA value

Interpretation

If Abnormal, Clinical Significance

If Not Clinically Significant or Clinically Significant, Please
specify the finding(s)

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1077

Folder: Baseline (Day 0)

Form: Lung Volume Measurements

Data signed: (hcoleman1) 18 Jun 2015 20:00:09

Generated On: 20 Jul 2016 12:37:46

Were the Lung Volume Measurements performed?

No ☐

If No, please specify the reason:

TEST PERFORMED BUT THEY
WERE NOT RESULTED

Category

Position

SITTING

Time of assessment

VC value

TLC value

IC value

FRC value

Interpretation

If Abnormal, Clinical Significance

If Not Clinically Significant or Clinically Significant, Please
specify the finding(s)

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day 0)

Form: Spirometry with a short-acting bronchodilator

Data signed: (hcoleman1) 18 Jun 2015 20:00:09

Generated On: 20 Jul 2016 12:37:46

Was the Spirometry with a short-acting bronchodilator
performed?

No ☒

If No, please specify the reason:

TEST PERFORMED BUT THEY
WERE NOT RESULTED

Category

With short-acting
bronchodilator ☒

Position

SITTING

Time of assessment

Name of bronchodilator

Dose

Predicted FVC value

Best measured FVC value

Percent of predicted FVC value

Best measured FEV1 value

Predicted FEV1 value

Percent of predicted FEV1 value

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day 0)

Form: Spirometry with a short-acting bronchodilator

Data signed: (hcoleman1) 18 Jun 2015 20:00:09

Generated On: 20 Jul 2016 12:37:46

Calculated ratio between FEV1/FVC

MEF 25/75 value

Interpretation

If Abnormal, Clinical Significance

If Not Clinically Significant or Clinically Significant, Please
specify the finding(s)

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day 0)

Form: Haematology

Data signed: (hfarmer1) 26 Mar 2015 15:21:05

Generated On: 20 Jul 2016 12:37:46

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: 1077**

Folder: Baseline (Day 0)

Form: Clinical Chemistry

Data signed: (hfarmer1) 26 Mar 2015 15:21:05

Generated On: 20 Jul 2016 12:37:46

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: 1077**

Folder: Baseline (Day 0)

Form: Urine analysis

Data signed: (hfarmer1) 26 Mar 2015 15:21:05

Generated On: 20 Jul 2016 12:37:46

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: 1077**

Folder: Baseline (Day 0)

Form: Plasma Nicotine Sample

Data signed: (hfarmer1) 26 Mar 2015 15:21:06

Generated On: 20 Jul 2016 12:37:46

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	13 FEB 2014
---------------------	-------------

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day 0)

Form: Plasma Cotinine Sample

Data signed: (hfarmer1) 26 Mar 2015 15:21:05

Generated On: 20 Jul 2016 12:37:46

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	13 FEB 2014
---------------------	-------------

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day 0)

Form: CoHb Blood Sample <D0> (1)

Data signed: (hfarmer1) 26 Mar 2015 15:21:05

Generated On: 20 Jul 2016 12:37:46

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	13 FEB 2014
---------------------	-------------

Timepoint	Prior to gas transfer assessment and prior to product use <input checked="" type="radio"/>
-----------	--

Time hour:min 24-hour clock	05:15
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day 0)

Form: CoHb Blood Sample <D0> (2)

Data signed: (hfarmer1) 26 Mar 2015 15:21:05

Generated On: 20 Jul 2016 12:37:46

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	13 FEB 2014
---------------------	-------------

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

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day 0)

Form: Oxysterols

Data signed: (hfarmer1) 26 Mar 2015 15:21:06

Generated On: 20 Jul 2016 12:37:46

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

If Not Done, please specify the reason: _____

Was the subject fasting for at least 10 hours at time of sample collection?	Yes <input checked="" type="radio"/>
--	--------------------------------------

Date DD/MMM/YYYY	13 FEB 2014
---------------------	-------------

Time hour:min 24-hour clock	05:15
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day 0)

Form: CO Breath Test (1)

Data signed: (hfarmer1) 26 Mar 2015 15:21:05

Generated On: 20 Jul 2016 12:37:46

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	06:45
---	-------

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day 0)

Form: CO Breath Test (2)

Data signed: (hfarmer1) 26 Mar 2015 15:21:05

Generated On: 20 Jul 2016 12:37:46

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	12:12
---	-------

Result(ppm)	23
-------------	----

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day 0)

Form: CO Breath Test (3)

Data signed: (hfarmer1) 26 Mar 2015 15:21:05

Generated On: 20 Jul 2016 12:37:46

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	16:01
---	-------

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day 0)

Form: CO Breath Test (4)

Data signed: (hfarmer1) 26 Mar 2015 15:21:05

Generated On: 20 Jul 2016 12:37:46

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	20:00
---	-------

Result(ppm)	32
-------------	----

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1077

Folder: Baseline (Day 0)

Form: CYP2A6 activity Sample

Data signed: (hfarmer1) 26 Mar 2015 15:21:05

Generated On: 20 Jul 2016 12:37:46

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

If Not Done, please specify the reason: _____

Date of sample collection
DD/MMM/YYYY

Time of sample collection
hour:min 24-hour clock

Parameter

13 FEB 2014

05:15

trans-3'-hydroxyc
otinine

13 FEB 2014

05:15

cotinine

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1077

Folder: Baseline (Day 0)

Form: CYP1A2 activity Sample

Data signed: (hfarmer1) 26 Mar 2015 15:21:05

Generated On: 20 Jul 2016 12:37:46

Time of caffeine tablet intake	10:14
	hour:min 24-hour clock

Sample collection Not Done	False
----------------------------	-------

If Not Done, please specify the reason: _____

Date of sample collection DD/MMM/YYYY	Time of sample collection hour:min 24-hour clock	Parameter
13 FEB 2014	16:45	Caffeine
13 FEB 2014	16:45	Paraxanthine

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day 0)

**Form: Risk Marker: hs-CRP, fibrinogen, homocysteine, LDL, HDL,
sICAM-1, HbA1c, Apo A1, Apo B**

Data signed: (hfarmer1) 26 Mar 2015 15:21:06

Generated On: 20 Jul 2016 12:37:46

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	13 FEB 2014
---------------------	-------------

Time hour:min 24-hour clock	05:15
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day 0)

Form: 24 hour urine collections

Data signed: (hfarmer1) 26 Mar 2015 15:21:06

Generated On: 20 Jul 2016 12:37:46

Start Date	13 FEB 2014 DD/MMM/YYYY
------------	----------------------------

Start Time	06:21 hour:min 24-hour clock
------------	---------------------------------

End Date	14 FEB 2014 DD/MMM/YYYY
----------	----------------------------

End Time	06:50 hour:min 24-hour clock
----------	---------------------------------

Volume	3519 mL
--------	------------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day 0)

Form: Sample Urine Collection

Data signed: (hfarmer1) 26 Mar 2015 15:21:06

Generated On: 20 Jul 2016 12:37:46

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: 1077

Folder: Baseline (Day 0)

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Data signed: (hfarmer1) 26 Mar 2015 15:21:06

Generated On: 20 Jul 2016 12:37:46

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

Date of assessment DD/MMM/YYYY	2014 FEB 13 DD/MMM/YYYY
-----------------------------------	----------------------------

Time of assessment	06:16 hour:min 24-hour clock
--------------------	---------------------------------

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

Please indicate for each of the items below, how you have been feeling over the past 24 hours

How have you been feeling over the past 24 hours?	None <input type="radio"/>
---	----------------------------

1. Angry, irritable, frustrated

How have you been feeling over the past 24 hours?	None <input type="radio"/>
---	----------------------------

2. Anxious, nervous

How have you been feeling over the past 24 hours?	None <input type="radio"/>
---	----------------------------

3. Depressed Mood, sad

How have you been feeling over the past 24 hours?	Moderate <input type="radio"/>
---	--------------------------------

4. Desire or craving to smoke

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1077

Folder: Baseline (Day 0)

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Data signed: (hfarmer1) 26 Mar 2015 15:21:06

Generated On: 20 Jul 2016 12:37:46

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? 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: 1077**

Folder: Baseline (Day 0)

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Data signed: (hfarmer1) 26 Mar 2015 15:21:06

Generated On: 20 Jul 2016 12:37:46

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: 1077

Folder: Baseline (Day 0)

Form: Cough Assessment

Data signed: (hfarmer1) 26 Mar 2015 15:21:07

Generated On: 20 Jul 2016 12:37:46

Date of Birth

(b) (6)

Date of assessment
DD/MMM/YYYY

2014 FEB 13
DD/MMM/YYYY

Time of assessment

06:14
hour:min 24-hour clock

Assessment Status

Completed ☒

Have you experienced a regular need to cough e.g.
coughing several times in the last 24 hrs?

No ☒

If YES, please answer the following questions:

First Question: Cough Impact Scale
How much is your cough bothering you?

-9

Second Question: Cough Intensity Scale:
How intense is your cough?

Not Applicable ☒

Third Question: Cough Frequency Scale:
How frequently do you normally have to cough each
day?

Not Applicable ☒

Fourth Question: Sputum Production
To what extent do you produce sputum when coughing?

Not Applicable ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day 0)

Form: Bio-banking (Transcriptomics)

Data signed: (hfarmer1) 26 Mar 2015 15:21:06

Generated On: 20 Jul 2016 12:37:46

Was a Bio-banking sample for transcriptomics taken?

Yes ☒

Time of Sample Collection

05:15
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: 1077**

Folder: Baseline (Day 0)

Form: Bio-banking (Biomarkers of exposure and risk markers)

Data signed: (hfarmer1) 26 Mar 2015 15:21:06

Generated On: 20 Jul 2016 12:37:46

Was a Bio-banking sample for biomarkers of exposure
and risk markers taken?

Yes ☒

Time of Sample Collection

05:15
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: 1077**

Folder: Baseline (Day 0)

Form: Bio-banking (nasal epithelial collection/buccal collection)

Data signed: (hfarmer1) 26 Mar 2015 15:21:06

Generated On: 20 Jul 2016 12:37:46

Was a Bio-banking sample for nasal epithelial
collection/buccal collection taken?

Yes ☒

Time of Buccal Collection

17:04
hour:min 24-hour clock

Time of Nasal Epithelial Collection

17:01
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: 1077

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (1)

Data signed: (hfarmer1) 26 Mar 2015 15:21:07

Generated On: 20 Jul 2016 12:37:46

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	W098761
--------------	---------

Actual Collection Date	2014 02 13
------------------------	------------

Actual Collection Time	05:15
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	RC1029
------------	--------

Battery Name	TRIGLYCERIDES
--------------	---------------

Lab Test ID	RCT19
-------------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1077

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (1)

Data signed: (hfarmer1) 26 Mar 2015 15:21:07

Generated On: 20 Jul 2016 12:37:46

Lab Test Name	TRIGLYCERIDES (GPO)
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	238
Reported Numeric Result	238
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: 1077**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (1)

Data signed: (hfarmer1) 26 Mar 2015 15:21:07

Generated On: 20 Jul 2016 12:37:46

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (2)

Data signed: (hfarmer1) 26 Mar 2015 15:21:07

Generated On: 20 Jul 2016 12:37:46

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6) 

Visit Name _____

Visit Type Scheduled ☒

Accession ID W098761

Actual Collection Date 2014 02 13

Actual Collection Time 05:15

Specimen Condition _____

Battery ID RC1092

Battery Name FASTING GLUCOSE

Lab Test ID RCT142

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (2)

Data signed: (hfarmer1) 26 Mar 2015 15:21:07

Generated On: 20 Jul 2016 12:37:46

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: 1077**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (2)

Data signed: (hfarmer1) 26 Mar 2015 15:21:07

Generated On: 20 Jul 2016 12:37:46

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (3)

Data signed: (hfarmer1) 26 Mar 2015 15:21:07

Generated On: 20 Jul 2016 12:37:46

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6)

Visit Name _____

Visit Type Scheduled ☒

Accession ID W098761

Actual Collection Date 2014 02 13

Actual Collection Time 05:15

Specimen Condition _____

Battery ID RC272

Battery Name TOTAL CHOLESTEROL

Lab Test ID RCT20

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (3)

Data signed: (hfarmer1) 26 Mar 2015 15:21:07

Generated On: 20 Jul 2016 12:37:46

Lab Test Name	CHOLESTEROL (HIGH PERFORMANCE)
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	239
Reported Numeric Result	239
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: 1077**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (3)

Data signed: (hfarmer1) 26 Mar 2015 15:21:07

Generated On: 20 Jul 2016 12:37:46

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: 1077**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (4)

Data signed: (hfarmer1) 26 Mar 2015 15:21:07

Generated On: 20 Jul 2016 12:37:46

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6) 

Visit Name _____

Visit Type Scheduled ☒

Accession ID W098761

Actual Collection Date 2014 02 13

Actual Collection Time 05:15

Specimen Condition _____

Battery ID RC9255

Battery Name CHEMISTRY PANEL

Lab Test ID RCT1

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1077

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (4)

Data signed: (hfarmer1) 26 Mar 2015 15:21:07

Generated On: 20 Jul 2016 12:37:46

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: 1077**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (4)

Data signed: (hfarmer1) 26 Mar 2015 15:21:07

Generated On: 20 Jul 2016 12:37:46

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (5)

Data signed: (hfarmer1) 26 Mar 2015 15:21:07

Generated On: 20 Jul 2016 12:37:46

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6) 

Visit Name _____

Visit Type Scheduled ☒

Accession ID W098761

Actual Collection Date 2014 02 13

Actual Collection Time 05:15

Specimen Condition _____

Battery ID RC9255

Battery Name CHEMISTRY PANEL

Lab Test ID RCT12

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (5)

Data signed: (hfarmer1) 26 Mar 2015 15:21:07

Generated On: 20 Jul 2016 12:37:46

Lab Test Name	TOTAL PROTEIN
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	7.5
Reported Numeric Result	7.5
Reference Range low	6.1
Reference Range high	8.4
Range Units	G/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (5)

Data signed: (hfarmer1) 26 Mar 2015 15:21:07

Generated On: 20 Jul 2016 12:37:46

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (6)

Data signed: (hfarmer1) 26 Mar 2015 15:21:07

Generated On: 20 Jul 2016 12:37:46

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6)

Visit Name _____

Visit Type Scheduled ☒

Accession ID W098761

Actual Collection Date 2014 02 13

Actual Collection Time 05:15

Specimen Condition _____

Battery ID RC9255

Battery Name CHEMISTRY PANEL

Lab Test ID RCT13

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (6)

Data signed: (hfarmer1) 26 Mar 2015 15:21:07

Generated On: 20 Jul 2016 12:37:46

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: 1077**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (6)

Data signed: (hfarmer1) 26 Mar 2015 15:21:07

Generated On: 20 Jul 2016 12:37:46

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (7)

Data signed: (hfarmer1) 26 Mar 2015 15:21:07

Generated On: 20 Jul 2016 12:37:46

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	W098761
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Actual Collection Date	2014 02 13
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Actual Collection Time	05:15
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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	RCT1407
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1077

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (7)

Data signed: (hfarmer1) 26 Mar 2015 15:21:07

Generated On: 20 Jul 2016 12:37:46

Lab Test Name	ALKALINE PHOSPHATASE
Test ID	
Test Status	Done <input type="checkbox"/>
Reported Text Result	91
Reported Numeric Result	91
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: 1077**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (7)

Data signed: (hfarmer1) 26 Mar 2015 15:21:07

Generated On: 20 Jul 2016 12:37:46

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (8)

Data signed: (hfarmer1) 26 Mar 2015 15:21:07

Generated On: 20 Jul 2016 12:37:46

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	W098761
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Actual Collection Date	2014 02 13
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Actual Collection Time	05:15
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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	RCT1408
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (8)

Data signed: (hfarmer1) 26 Mar 2015 15:21:07

Generated On: 20 Jul 2016 12:37:46

Lab Test Name	LDH
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	154
Reported Numeric Result	154
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: 1077**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (8)

Data signed: (hfarmer1) 26 Mar 2015 15:21:07

Generated On: 20 Jul 2016 12:37:46

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (9)

Data signed: (hfarmer1) 26 Mar 2015 15:21:07

Generated On: 20 Jul 2016 12:37:46

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	W098761
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Actual Collection Date	2014 02 13
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Actual Collection Time	05:15
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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: 1077

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (9)

Data signed: (hfarmer1) 26 Mar 2015 15:21:07

Generated On: 20 Jul 2016 12:37:46

Lab Test Name	SERUM SODIUM
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	142
Reported Numeric Result	142
Reference Range low	132
Reference Range high	147
Range Units	MEQ/L
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (9)

Data signed: (hfarmer1) 26 Mar 2015 15:21:07

Generated On: 20 Jul 2016 12:37:46

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (10)

Data signed: (hfarmer1) 26 Mar 2015 15:21:07

Generated On: 20 Jul 2016 12:37:46

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	W098761
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Actual Collection Date	2014 02 13
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Actual Collection Time	05:15
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Specimen Condition	<hr/>
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Battery ID	RC9255
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Battery Name	CHEMISTRY PANEL
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Lab Test ID	RCT16
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1077

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (10)

Data signed: (hfarmer1) 26 Mar 2015 15:21:07

Generated On: 20 Jul 2016 12:37:46

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: 1077**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (10)

Data signed: (hfarmer1) 26 Mar 2015 15:21:07

Generated On: 20 Jul 2016 12:37:46

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (11)

Data signed: (hfarmer1) 26 Mar 2015 15:21:07

Generated On: 20 Jul 2016 12:37:46

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	W098761
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Actual Collection Date	2014 02 13
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Actual Collection Time	05:15
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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: 1077

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (11)

Data signed: (hfarmer1) 26 Mar 2015 15:21:07

Generated On: 20 Jul 2016 12:37:46

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: 1077**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (11)

Data signed: (hfarmer1) 26 Mar 2015 15:21:07

Generated On: 20 Jul 2016 12:37:46

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (12)

Data signed: (hfarmer1) 26 Mar 2015 15:21:07

Generated On: 20 Jul 2016 12:37:46

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	W098761
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Actual Collection Date	2014 02 13
------------------------	------------

Actual Collection Time	05:15
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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	RCT3
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1077

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (12)

Data signed: (hfarmer1) 26 Mar 2015 15:21:07

Generated On: 20 Jul 2016 12:37:46

Lab Test Name	GGT
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	14
Reported Numeric Result	14
Reference Range low	10
Reference Range high	61
Range Units	U/L
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (12)

Data signed: (hfarmer1) 26 Mar 2015 15:21:07

Generated On: 20 Jul 2016 12:37:46

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (13)

Data signed: (hfarmer1) 26 Mar 2015 15:21:07

Generated On: 20 Jul 2016 12:37:46

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	W098761
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Actual Collection Date	2014 02 13
------------------------	------------

Actual Collection Time	05:15
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Specimen Condition	<hr/>
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Battery ID	RC9255
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Battery Name	CHEMISTRY PANEL
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Lab Test ID	RCT392
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1077

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (13)

Data signed: (hfarmer1) 26 Mar 2015 15:21:07

Generated On: 20 Jul 2016 12:37:46

Lab Test Name	CREATININE (RATE BLANKED)
Test ID	
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	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (13)

Data signed: (hfarmer1) 26 Mar 2015 15:21:07

Generated On: 20 Jul 2016 12:37:46

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (14)

Data signed: (hfarmer1) 26 Mar 2015 15:21:07

Generated On: 20 Jul 2016 12:37:46

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	W098761
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Actual Collection Date	2014 02 13
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Actual Collection Time	05:15
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Specimen Condition	<hr/>
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Battery ID	RC9255
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Battery Name	CHEMISTRY PANEL
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Lab Test ID	RCT4
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (14)

Data signed: (hfarmer1) 26 Mar 2015 15:21:07

Generated On: 20 Jul 2016 12:37:46

Lab Test Name	ALT (SGPT)
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	22
Reported Numeric Result	22
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: 1077**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (14)

Data signed: (hfarmer1) 26 Mar 2015 15:21:07

Generated On: 20 Jul 2016 12:37:46

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (15)

Data signed: (hfarmer1) 26 Mar 2015 15:21:07

Generated On: 20 Jul 2016 12:37:46

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	W098761
--------------	---------

Actual Collection Date	2014 02 13
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Actual Collection Time	05:15
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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	RCT5
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1077

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (15)

Data signed: (hfarmer1) 26 Mar 2015 15:21:07

Generated On: 20 Jul 2016 12:37:46

Lab Test Name	AST (SGOT)
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	29
Reported Numeric Result	29
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: 1077**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (15)

Data signed: (hfarmer1) 26 Mar 2015 15:21:07

Generated On: 20 Jul 2016 12:37:46

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (16)

Data signed: (hfarmer1) 26 Mar 2015 15:21:07

Generated On: 20 Jul 2016 12:37:46

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	W098761
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Actual Collection Date	2014 02 13
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Actual Collection Time	05:15
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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: 1077

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (16)

Data signed: (hfarmer1) 26 Mar 2015 15:21:07

Generated On: 20 Jul 2016 12:37:46

Lab Test Name	UREA NITROGEN
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	19
Reported Numeric Result	19
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: 1077**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (16)

Data signed: (hfarmer1) 26 Mar 2015 15:21:07

Generated On: 20 Jul 2016 12:37:46

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (17)

Data signed: (hfarmer1) 26 Mar 2015 15:21:07

Generated On: 20 Jul 2016 12:37:46

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	W098761
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Actual Collection Date	2014 02 13
------------------------	------------

Actual Collection Time	05:15
------------------------	-------

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: 1077**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (17)

Data signed: (hfarmer1) 26 Mar 2015 15:21:07

Generated On: 20 Jul 2016 12:37:46

Lab Test Name	MONOCYTES
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	0.38
Reported Numeric Result	0.38
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: 1077**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (17)

Data signed: (hfarmer1) 26 Mar 2015 15:21:07

Generated On: 20 Jul 2016 12:37:46

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (18)

Data signed: (hfarmer1) 26 Mar 2015 15:21:07

Generated On: 20 Jul 2016 12:37:46

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	W098761
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Actual Collection Date	2014 02 13
------------------------	------------

Actual Collection Time	05:15
------------------------	-------

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: 1077

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (18)

Data signed: (hfarmer1) 26 Mar 2015 15:21:07

Generated On: 20 Jul 2016 12:37:46

Lab Test Name	MCH
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	30
Reported Numeric Result	30
Reference Range low	26
Reference Range high	34
Range Units	PG
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (18)

Data signed: (hfarmer1) 26 Mar 2015 15:21:07

Generated On: 20 Jul 2016 12:37:46

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (19)

Data signed: (hfarmer1) 26 Mar 2015 15:21:07

Generated On: 20 Jul 2016 12:37:46

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	W098761
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Actual Collection Date	2014 02 13
------------------------	------------

Actual Collection Time	05:15
------------------------	-------

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: 1077

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (19)

Data signed: (hfarmer1) 26 Mar 2015 15:21:07

Generated On: 20 Jul 2016 12:37:46

Lab Test Name	MCHC
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	34
Reported Numeric Result	34
Reference Range low	31
Reference Range high	38
Range Units	G/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (19)

Data signed: (hfarmer1) 26 Mar 2015 15:21:07

Generated On: 20 Jul 2016 12:37:46

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (20)

Data signed: (hfarmer1) 26 Mar 2015 15:21:07

Generated On: 20 Jul 2016 12:37:46

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	W098761
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Actual Collection Date	2014 02 13
------------------------	------------

Actual Collection Time	05:15
------------------------	-------

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: 1077

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (20)

Data signed: (hfarmer1) 26 Mar 2015 15:21:07

Generated On: 20 Jul 2016 12:37:46

Lab Test Name	EOSINOPHILS
Test ID	
Test Status	Done <input checked="" type="checkbox"/>
Reported Text Result	0.38
Reported Numeric Result	0.38
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: 1077**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (20)

Data signed: (hfarmer1) 26 Mar 2015 15:21:07

Generated On: 20 Jul 2016 12:37:46

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (21)

Data signed: (hfarmer1) 26 Mar 2015 15:21:07

Generated On: 20 Jul 2016 12:37:46

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	W098761
--------------	---------

Actual Collection Date	2014 02 13
------------------------	------------

Actual Collection Time	05:15
------------------------	-------

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: 1077

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (21)

Data signed: (hfarmer1) 26 Mar 2015 15:21:07

Generated On: 20 Jul 2016 12:37:46

Lab Test Name	BASOPHILS
Test ID	
Test Status	Done <input checked="" type="checkbox"/>
Reported Text Result	0.03
Reported Numeric Result	0.03
Reference Range low	0.00
Reference Range high	0.20
Range Units	X10^3/UL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (21)

Data signed: (hfarmer1) 26 Mar 2015 15:21:07

Generated On: 20 Jul 2016 12:37:46

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (22)

Data signed: (hfarmer1) 26 Mar 2015 15:21:07

Generated On: 20 Jul 2016 12:37:46

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	W098761
--------------	---------

Actual Collection Date	2014 02 13
------------------------	------------

Actual Collection Time	05:15
------------------------	-------

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: 1077**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (22)

Data signed: (hfarmer1) 26 Mar 2015 15:21:07

Generated On: 20 Jul 2016 12:37:46

Lab Test Name	PLATELETS
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	343
Reported Numeric Result	343
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: 1077**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (22)

Data signed: (hfarmer1) 26 Mar 2015 15:21:07

Generated On: 20 Jul 2016 12:37:46

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1077

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (23)

Data signed: (hfarmer1) 26 Mar 2015 15:21:07

Generated On: 20 Jul 2016 12:37:46

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	W098761
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Actual Collection Date	2014 02 13
------------------------	------------

Actual Collection Time	05:15
------------------------	-------

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: 1077**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (23)

Data signed: (hfarmer1) 26 Mar 2015 15:21:07

Generated On: 20 Jul 2016 12:37:46

Lab Test Name	NEUTROPHILS (%)
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	58.7
Reported Numeric Result	58.7
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: 1077**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (23)

Data signed: (hfarmer1) 26 Mar 2015 15:21:07

Generated On: 20 Jul 2016 12:37:46

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (24)

Data signed: (hfarmer1) 26 Mar 2015 15:21:07

Generated On: 20 Jul 2016 12:37:46

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	W098761
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Actual Collection Date	2014 02 13
------------------------	------------

Actual Collection Time	05:15
------------------------	-------

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: 1077

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (24)

Data signed: (hfarmer1) 26 Mar 2015 15:21:07

Generated On: 20 Jul 2016 12:37:46

Lab Test Name	LYMPHOCYTES (%)
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	31.8
Reported Numeric Result	31.8
Reference Range low	15.4
Reference Range high	48.5
Range Units	%
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (24)

Data signed: (hfarmer1) 26 Mar 2015 15:21:07

Generated On: 20 Jul 2016 12:37:46

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (25)

Data signed: (hfarmer1) 26 Mar 2015 15:21:07

Generated On: 20 Jul 2016 12:37:46

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	W098761
--------------	---------

Actual Collection Date	2014 02 13
------------------------	------------

Actual Collection Time	05:15
------------------------	-------

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: 1077

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (25)

Data signed: (hfarmer1) 26 Mar 2015 15:21:07

Generated On: 20 Jul 2016 12:37:46

Lab Test Name	MONOCYTES (%)
Test ID	
Test Status	Done <input checked="" type="checkbox"/>
Reported Text Result	4.6
Reported Numeric Result	4.6
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: 1077**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (25)

Data signed: (hfarmer1) 26 Mar 2015 15:21:07

Generated On: 20 Jul 2016 12:37:46

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1077

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (26)

Data signed: (hfarmer1) 26 Mar 2015 15:21:07

Generated On: 20 Jul 2016 12:37:46

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	W098761
--------------	---------

Actual Collection Date	2014 02 13
------------------------	------------

Actual Collection Time	05:15
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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: 1077

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (26)

Data signed: (hfarmer1) 26 Mar 2015 15:21:07

Generated On: 20 Jul 2016 12:37:46

Lab Test Name	EOSINOPHILS (%)
Test ID	
Test Status	Done <input checked="" type="checkbox"/>
Reported Text Result	4.6
Reported Numeric Result	4.6
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: 1077**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (26)

Data signed: (hfarmer1) 26 Mar 2015 15:21:07

Generated On: 20 Jul 2016 12:37:46

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1077

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (27)

Data signed: (hfarmer1) 26 Mar 2015 15:21:07

Generated On: 20 Jul 2016 12:37:46

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	W098761
--------------	---------

Actual Collection Date	2014 02 13
------------------------	------------

Actual Collection Time	05:15
------------------------	-------

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: 1077

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (27)

Data signed: (hfarmer1) 26 Mar 2015 15:21:07

Generated On: 20 Jul 2016 12:37:46

Lab Test Name	BASOPHILS (%)
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	0.4
Reported Numeric Result	0.4
Reference Range low	0.0
Reference Range high	2.0
Range Units	%
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (27)

Data signed: (hfarmer1) 26 Mar 2015 15:21:07

Generated On: 20 Jul 2016 12:37:46

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (28)

Data signed: (hfarmer1) 26 Mar 2015 15:21:07

Generated On: 20 Jul 2016 12:37:46

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	W098761
--------------	---------

Actual Collection Date	2014 02 13
------------------------	------------

Actual Collection Time	05:15
------------------------	-------

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: 1077

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (28)

Data signed: (hfarmer1) 26 Mar 2015 15:21:07

Generated On: 20 Jul 2016 12:37:46

Lab Test Name	HEMATOCRIT
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	46
Reported Numeric Result	46
Reference Range low	39
Reference Range high	54
Range Units	%
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (28)

Data signed: (hfarmer1) 26 Mar 2015 15:21:07

Generated On: 20 Jul 2016 12:37:46

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (29)

Data signed: (hfarmer1) 26 Mar 2015 15:21:07

Generated On: 20 Jul 2016 12:37:46

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	W098761
--------------	---------

Actual Collection Date	2014 02 13
------------------------	------------

Actual Collection Time	05:15
------------------------	-------

Specimen Condition	<hr/>
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Battery ID	HM1604
------------	--------

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: 1077**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (29)

Data signed: (hfarmer1) 26 Mar 2015 15:21:07

Generated On: 20 Jul 2016 12:37:46

Lab Test Name	RBC
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	5.2
Reported Numeric Result	5.2
Reference Range low	4.5
Reference Range high	6.4
Range Units	X10^6/UL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (29)

Data signed: (hfarmer1) 26 Mar 2015 15:21:07

Generated On: 20 Jul 2016 12:37:46

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (30)

Data signed: (hfarmer1) 26 Mar 2015 15:21:07

Generated On: 20 Jul 2016 12:37:46

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	<hr/>
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Subject Sex	M
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Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	W098761
--------------	---------

Actual Collection Date	2014 02 13
------------------------	------------

Actual Collection Time	05:15
------------------------	-------

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: 1077

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (30)

Data signed: (hfarmer1) 26 Mar 2015 15:21:07

Generated On: 20 Jul 2016 12:37:46

Lab Test Name	MCV
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	89
Reported Numeric Result	89
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: 1077**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (30)

Data signed: (hfarmer1) 26 Mar 2015 15:21:07

Generated On: 20 Jul 2016 12:37:46

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (31)

Data signed: (hfarmer1) 26 Mar 2015 15:21:07

Generated On: 20 Jul 2016 12:37:46

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	W098761
--------------	---------

Actual Collection Date	2014 02 13
------------------------	------------

Actual Collection Time	05:15
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	HM1604
------------	--------

Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
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Lab Test ID	HMT40
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1077

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (31)

Data signed: (hfarmer1) 26 Mar 2015 15:21:07

Generated On: 20 Jul 2016 12:37:46

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: 1077**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (31)

Data signed: (hfarmer1) 26 Mar 2015 15:21:07

Generated On: 20 Jul 2016 12:37:46

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (32)

Data signed: (hfarmer1) 26 Mar 2015 15:21:07

Generated On: 20 Jul 2016 12:37:46

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	<hr/>
----------------------	-------

Subject Sex	M
-------------	---

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

Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	W098761
--------------	---------

Actual Collection Date	2014 02 13
------------------------	------------

Actual Collection Time	05:15
------------------------	-------

Specimen Condition	<hr/>
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Battery ID	HM1604
------------	--------

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: 1077**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (32)

Data signed: (hfarmer1) 26 Mar 2015 15:21:07

Generated On: 20 Jul 2016 12:37:46

Lab Test Name	WBC
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	8.25
Reported Numeric Result	8.25
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: 1077**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (32)

Data signed: (hfarmer1) 26 Mar 2015 15:21:07

Generated On: 20 Jul 2016 12:37:46

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (33)

Data signed: (hfarmer1) 26 Mar 2015 15:21:07

Generated On: 20 Jul 2016 12:37:46

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	<hr/>
----------------------	-------

Subject Sex	M
-------------	---

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

Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	W098761
--------------	---------

Actual Collection Date	2014 02 13
------------------------	------------

Actual Collection Time	05:15
------------------------	-------

Specimen Condition	<hr/>
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Battery ID	HM1604
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Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
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Lab Test ID	HMT71
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1077

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (33)

Data signed: (hfarmer1) 26 Mar 2015 15:21:07


Generated On: 20 Jul 2016 12:37:46

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: 1077**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (33)

Data signed: (hfarmer1) 26 Mar 2015 15:21:07

Generated On: 20 Jul 2016 12:37:46

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1077

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (34)

Data signed: (hfarmer1) 26 Mar 2015 15:21:07

Generated On: 20 Jul 2016 12:37:46

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	<hr/>
----------------------	-------

Subject Sex	M
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Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	W098761
--------------	---------

Actual Collection Date	2014 02 13
------------------------	------------

Actual Collection Time	05:15
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	HM1604
------------	--------

Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
--------------	-----------------------------------

Lab Test ID	HMT8
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (34)

Data signed: (hfarmer1) 26 Mar 2015 15:21:07

Generated On: 20 Jul 2016 12:37:46

Lab Test Name	NEUTROPHILS
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	4.84
Reported Numeric Result	4.84
Reference Range low	1.96
Reference Range high	7.23
Range Units	X10^3/UL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (34)

Data signed: (hfarmer1) 26 Mar 2015 15:21:07

Generated On: 20 Jul 2016 12:37:46

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1077

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (35)

Data signed: (hfarmer1) 26 Mar 2015 15:21:07

Generated On: 20 Jul 2016 12:37:46

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	W098761
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Actual Collection Date	2014 02 13
------------------------	------------

Actual Collection Time	05:15
------------------------	-------

Specimen Condition	<hr/>
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Battery ID	HM1604
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Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
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Lab Test ID	HMT9
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1077

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (35)

Data signed: (hfarmer1) 26 Mar 2015 15:21:07

Generated On: 20 Jul 2016 12:37:46

Lab Test Name	LYMPHOCYTES
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	2.62
Reported Numeric Result	2.62
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: 1077**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (35)

Data signed: (hfarmer1) 26 Mar 2015 15:21:07

Generated On: 20 Jul 2016 12:37:46

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (36)

Data signed: (hfarmer1) 26 Mar 2015 15:21:07

Generated On: 20 Jul 2016 12:37:46

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	<hr/>
----------------------	-------

Subject Sex	M
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Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	W098761
--------------	---------

Actual Collection Date	2014 02 13
------------------------	------------

Actual Collection Time	05:15
------------------------	-------

Specimen Condition	<hr/>
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Battery ID	UA1538
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Battery Name	URINE MACRO PANEL
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Lab Test ID	UAT10
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (36)

Data signed: (hfarmer1) 26 Mar 2015 15:21:07


Generated On: 20 Jul 2016 12:37:46

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: 1077**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (36)

Data signed: (hfarmer1) 26 Mar 2015 15:21:07

Generated On: 20 Jul 2016 12:37:46

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (37)

Data signed: (hfarmer1) 26 Mar 2015 15:21:07

Generated On: 20 Jul 2016 12:37:46

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	W098761
--------------	---------

Actual Collection Date	2014 02 13
------------------------	------------

Actual Collection Time	05:15
------------------------	-------

Specimen Condition	<hr/>
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Battery ID	UA1538
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Battery Name	URINE MACRO PANEL
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Lab Test ID	UAT2
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1077

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (37)

Data signed: (hfarmer1) 26 Mar 2015 15:21:07

Generated On: 20 Jul 2016 12:37:46

Lab Test Name	UR SPECIFIC GRAVITY
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	1.022
Reported Numeric Result	1.022
Reference Range low	1.003
Reference Range high	1.035
Range Units	
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (37)

Data signed: (hfarmer1) 26 Mar 2015 15:21:07

Generated On: 20 Jul 2016 12:37:46

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (38)

Data signed: (hfarmer1) 26 Mar 2015 15:21:07

Generated On: 20 Jul 2016 12:37:46

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	W098761
--------------	---------

Actual Collection Date	2014 02 13
------------------------	------------

Actual Collection Time	05:15
------------------------	-------

Specimen Condition	<hr/>
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Battery ID	UA1538
------------	--------

Battery Name	URINE MACRO PANEL
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Lab Test ID	UAT3
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1077

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (38)

Data signed: (hfarmer1) 26 Mar 2015 15:21:07

Generated On: 20 Jul 2016 12:37:46

Lab Test Name	UR PH
Test ID	
Test Status	Done <input type="checkbox"/>
Reported Text Result	5.0
Reported Numeric Result	5.0
Reference Range low	5.0
Reference Range high	8.0
Range Units	
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (38)

Data signed: (hfarmer1) 26 Mar 2015 15:21:07

Generated On: 20 Jul 2016 12:37:46

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (39)

Data signed: (hfarmer1) 26 Mar 2015 15:21:07

Generated On: 20 Jul 2016 12:37:46

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	<hr/>
----------------------	-------

Subject Sex	M
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Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	W098761
--------------	---------

Actual Collection Date	2014 02 13
------------------------	------------

Actual Collection Time	05:15
------------------------	-------

Specimen Condition	<hr/>
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Battery ID	UA1538
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Battery Name	URINE MACRO PANEL
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Lab Test ID	UAT43
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1077

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (39)

Data signed: (hfarmer1) 26 Mar 2015 15:21:07


Generated On: 20 Jul 2016 12:37:46

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: 1077**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (39)

Data signed: (hfarmer1) 26 Mar 2015 15:21:07

Generated On: 20 Jul 2016 12:37:46

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (40)

Data signed: (hfarmer1) 26 Mar 2015 15:21:07

Generated On: 20 Jul 2016 12:37:46

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	<hr/>
----------------------	-------

Subject Sex	M
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Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	W098761
--------------	---------

Actual Collection Date	2014 02 13
------------------------	------------

Actual Collection Time	05:15
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	UA1538
------------	--------

Battery Name	URINE MACRO PANEL
--------------	-------------------

Lab Test ID	UAT49
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (40)

Data signed: (hfarmer1) 26 Mar 2015 15:21:07


Generated On: 20 Jul 2016 12:37:46

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: 1077**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (40)

Data signed: (hfarmer1) 26 Mar 2015 15:21:07

Generated On: 20 Jul 2016 12:37:46

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (41)

Data signed: (hfarmer1) 26 Mar 2015 15:21:07

Generated On: 20 Jul 2016 12:37:46

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	M
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Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	W098761
--------------	---------

Actual Collection Date	2014 02 13
------------------------	------------

Actual Collection Time	05:15
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	UA1538
------------	--------

Battery Name	URINE MACRO PANEL
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Lab Test ID	UAT5
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (41)

Data signed: (hfarmer1) 26 Mar 2015 15:21:07


Generated On: 20 Jul 2016 12:37:46

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: 1077**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (41)

Data signed: (hfarmer1) 26 Mar 2015 15:21:07

Generated On: 20 Jul 2016 12:37:46

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (42)

Data signed: (hfarmer1) 26 Mar 2015 15:21:07

Generated On: 20 Jul 2016 12:37:46

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	M
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Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	W098761
--------------	---------

Actual Collection Date	2014 02 13
------------------------	------------

Actual Collection Time	05:15
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	UA1538
------------	--------

Battery Name	URINE MACRO PANEL
--------------	-------------------

Lab Test ID	UAT7
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1077

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (42)

Data signed: (hfarmer1) 26 Mar 2015 15:21:07


Generated On: 20 Jul 2016 12:37:46

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: 1077**

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (42)

Data signed: (hfarmer1) 26 Mar 2015 15:21:07

Generated On: 20 Jul 2016 12:37:46

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day 0)

Form: Oxysterol results (1)

Generated On: 20 Jul 2016 12:37:46

Sample Accession number	3209876139
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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: 1077**

Folder: Baseline (Day 0)

Form: Oxysterol results (2)

Generated On: 20 Jul 2016 12:37:46

Sample Accession number	3209876139
-------------------------	------------

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: 1077**

Folder: Baseline (Day 0)

Form: Oxysterol results (3)

Generated On: 20 Jul 2016 12:37:46

Sample Accession number	3209876139
-------------------------	------------

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: 1077**

Folder: Baseline (Day 0)

Form: Oxysterol results (4)

Generated On: 20 Jul 2016 12:37:46

Sample Accession number	3209876139
-------------------------	------------

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: 1077**

Folder: Baseline (Day 0)

Form: Oxysterol results (5)

Generated On: 20 Jul 2016 12:37:46

Sample Accession number	3209876139
-------------------------	------------

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: 1077**

Folder: Baseline (Day 0)

Form: Oxysterol results (6)

Generated On: 20 Jul 2016 12:37:46

Sample Accession number	3209876139
-------------------------	------------

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: 1077**

Folder: Baseline (Day 0)

Form: Oxysterol results (7)

Generated On: 20 Jul 2016 12:37:46

Sample Accession number	3209876139
-------------------------	------------

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: 1077**

Folder: Baseline (Day 0)

Form: Oxysterol results (8)

Generated On: 20 Jul 2016 12:37:46

Sample Accession number	3209876139
-------------------------	------------

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: 1077**

Folder: Baseline (Day 0)

Form: Oxysterol results (9)

Generated On: 20 Jul 2016 12:37:46

Sample Accession number	3209876139
-------------------------	------------

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: 1077**

Folder: Baseline (Day 0)

Form: Oxysterol results (10)

Generated On: 20 Jul 2016 12:37:46

Sample Accession number	3209876139
-------------------------	------------

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: 1077**

Folder: Baseline (Day 0)

Form: Oxysterol results (11)

Generated On: 20 Jul 2016 12:37:46

Sample Accession number	3209876139
-------------------------	------------

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: 1077**

Folder: Baseline (Day 0)

Form: Oxysterol results (12)

Generated On: 20 Jul 2016 12:37:46

Sample Accession number	3209876139
-------------------------	------------

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: 1077**

Folder: Baseline (Day 0)

Form: Lab_BU_COHB (1)

Data signed: (hfarmer1) 26 Mar 2015 15:21:30

Generated On: 20 Jul 2016 12:37:46

Sample Barcode	05115150000466
----------------	----------------

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

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

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

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

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

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

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

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

Planned time point (Hour)	6
---------------------------	---

Day of Visit	0
--------------	---

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

Date of Collection	2014-FEB-13
--------------------	-------------

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day 0)

Form: Lab_BU_COHB (1)

Data signed: (hfarmer1) 26 Mar 2015 15:21:30

Generated On: 20 Jul 2016 12:37:46

Start Day (24 hour urine only) _____

End Day (24 hour Urine Only) _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day 0)

Form: Lab_BU_COHB (2)

Data signed: (hfarmer1) 26 Mar 2015 15:21:30

Generated On: 20 Jul 2016 12:37:46

Sample Barcode	05115150000467
Analyte	CARBOXYHEMOGLOBIN
Sample type	BLOOD
Result	.
Result Unit	%
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	SPECTROPHOTOMETRIC
Lower limit of quantification	0.500
Planned time point (Hour)	20
Day of Visit	0
Celerion Study Number	AA99128-16
Date of Collection	2014-FEB-13
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day 0)

Form: Lab_BU_COHB (2)

Data signed: (hfarmer1) 26 Mar 2015 15:21:30

Generated On: 20 Jul 2016 12:37:46

Start Day (24 hour urine only) _____

End Day (24 hour Urine Only) _____

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1077

Folder: Baseline (Day 0)

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)

Data signed: (hfarmer1) 26 Mar 2015 15:21:06

Generated On: 20 Jul 2016 12:37:46

Date of Birth

(b) (6)

Date of assessment

2014 FEB 13

DD/MMM/YYYY

DD/MMM/YYYY

Time of assessment

20:03

hour:min 24-hour clock

Assessment Status

Completed ☒

1. Was smoking satisfying?

Quite a lot ☒

2. Did cigarettes taste good?

Quite a lot ☒

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

Little ☒

4. Did smoking calm you down?

Moderately ☒

5. Did smoking make you feel more awake?

Little ☒

6. Did smoking make you feel less irritable?

Moderately ☒

7. Did smoking help you concentrate?

Little ☒

8. Did smoking reduce your hunger for food?

Little ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day 0)

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)

Data signed: (hfarmer1) 26 Mar 2015 15:21:06

Generated On: 20 Jul 2016 12:37:46

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

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

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

12. Did you enjoy smoking? Extremely ☐

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1077

Folder: Baseline (Day 0)

Form: Human Smoking Topography Questionnaire

Data signed: (hfarmer1) 26 Mar 2015 15:21:06

Generated On: 20 Jul 2016 12:37:46

Type	HUMAN SMOKING TOPOGRAPHY QUESTIONNAIRE
------	--

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

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

Date of assessment	13 FEB 2014 DD/MMM/YYYY
--------------------	----------------------------

Time of assessment	20:37 hour:min 24-hour clock
--------------------	---------------------------------

How do you agree with the following sentences/affirmations :

1. The smoking of the conventional cigarettes/products is different with the device.	Agree <input type="radio"/>
--	-----------------------------

If you agree or strongly agree, please describe :	LESS AMOUNT OF SMOKE.
---	-----------------------

2. You enjoy smoking with the device as much as without it.	Neither agree nor disagree <input type="radio"/>
---	--

If you disagree or strongly disagree, please describe :	<hr/>
---	-------

3. The taste of the conventional cigarettes/products is different with the device.	Agree <input type="radio"/>
--	-----------------------------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day 0)

Form: Human Smoking Topography Questionnaire

Data signed: (hfarmer1) 26 Mar 2015 15:21:06

Generated On: 20 Jul 2016 12:37:46

If you agree or strongly agree, please describe : MORE METHOLY

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. Neither agree nor disagree ☒

If you agree or strongly agree, please describe : _____

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1077

Folder: Baseline (Day 0)

Form: Questionnaire on smoking urges (QSU)

Data signed: (hfarmer1) 26 Mar 2015 15:21:07

Generated On: 20 Jul 2016 12:37:46

Type	QSU
Date of Birth	(b) (6)
Date of assessment	2014 FEB 13
DD/MMM/YYYY	
Time of assessment	20:01
hour:min 24-hour clock	
Assessment Status	Completed <input checked="" type="radio"/>
1. I have a desire for a cigarette right now	Do not agree or disagree <input type="radio"/>
2. Nothing would be better than smoking a cigarette right now	Somewhat disagree <input type="radio"/>
3. If it were possible I would probably smoke now	Somewhat agree <input type="radio"/>
4. I could control things better right now if I could smoke	Somewhat disagree <input type="radio"/>
5. All I want right now is a cigarette	Somewhat disagree <input type="radio"/>
6. I have an urge for a cigarette	Somewhat disagree <input type="radio"/>

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day 0)

Form: Questionnaire on smoking urges (QSU)

Data signed: (hfarmer1) 26 Mar 2015 15:21:07

Generated On: 20 Jul 2016 12:37:46

7. A cigarette would taste good now	Somewhat disagree <input type="radio"/>
-------------------------------------	---

8. I would do almost anything for a cigarette now	Somewhat disagree <input type="radio"/>
---	---

9. Smoking would make me less depressed	Somewhat disagree <input type="radio"/>
---	---

10. I am going to smoke as soon as possible	Somewhat disagree <input type="radio"/>
---	---

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1077

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (1)

Data signed: (hfarmer1) 26 Mar 2015 15:21:27

Generated On: 20 Jul 2016 12:37:46

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	1077
----------------------	------

Subject Sex	M
-------------	---

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

Visit Name	DAY0
------------	------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	W098761
--------------	---------

Actual Collection Date	2014 02 13
------------------------	------------

Actual Collection Time	05:15
------------------------	-------

Specimen Condition	
--------------------	--

Battery ID	HM1054
------------	--------

Battery Name	HEMOGLOBIN A1C
--------------	----------------

Lab Test ID	HMT370
-------------	--------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (1)

Data signed: (hfarmer1) 26 Mar 2015 15:21:27

Generated On: 20 Jul 2016 12:37:46

Lab Test Name

HEMOGLOBIN
A1C,VARIANT(-70)

Test ID

Test Status

Done ☒

Reported Text Result

5.5

Reported Numeric Result

5.5

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: 1077**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (1)

Data signed: (hfarmer1) 26 Mar 2015 15:21:27

Generated On: 20 Jul 2016 12:37:46

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: 1077

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (2)

Data signed: (hfarmer1) 26 Mar 2015 15:21:27

Generated On: 20 Jul 2016 12:37:46

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	1077
----------------------	------

Subject Sex	M
-------------	---

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

Visit Name	DAY0
------------	------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	W098761
--------------	---------

Actual Collection Date	2014 02 13
------------------------	------------

Actual Collection Time	05:15
------------------------	-------

Specimen Condition	
--------------------	--

Battery ID	RC6871
------------	--------

Battery Name	HDL
--------------	-----

Lab Test ID	RCT1684
-------------	---------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (2)

Data signed: (hfarmer1) 26 Mar 2015 15:21:27

Generated On: 20 Jul 2016 12:37:46

Lab Test Name

DIRECT HDL-C 3RD
GENERATION

Test ID

Test Status

Done ☒

Reported Text Result

37

Reported Numeric Result

37

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: 1077**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (2)

Data signed: (hfarmer1) 26 Mar 2015 15:21:27

Generated On: 20 Jul 2016 12:37:46

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: 1077

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (3)

Data signed: (hfarmer1) 26 Mar 2015 15:21:27

Generated On: 20 Jul 2016 12:37:46

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	1077
----------------------	------

Subject Sex	M
-------------	---

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

Visit Name	DAY0
------------	------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	W098761
--------------	---------

Actual Collection Date	2014 02 13
------------------------	------------

Actual Collection Time	05:15
------------------------	-------

Specimen Condition	
--------------------	--

Battery ID	SC3249
------------	--------

Battery Name	HS-CRP
--------------	--------

Lab Test ID	SCT1528
-------------	---------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (3)

Data signed: (hfarmer1) 26 Mar 2015 15:21:27

Generated On: 20 Jul 2016 12:37:46

Lab Test Name	C-REACTIVE PROTEIN (N HS)-QT
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	0.045
Reported Numeric Result	0.045
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: 1077**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (3)

Data signed: (hfarmer1) 26 Mar 2015 15:21:27

Generated On: 20 Jul 2016 12:37:46

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: 1077**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (4)

Data signed: (hfarmer1) 26 Mar 2015 15:21:27

Generated On: 20 Jul 2016 12:37:46

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	1077
----------------------	------

Subject Sex	M
-------------	---

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

Visit Name	DAY0
------------	------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	W098761
--------------	---------

Actual Collection Date	2014 02 13
------------------------	------------

Actual Collection Time	05:15
------------------------	-------

Specimen Condition	
--------------------	--

Battery ID	SC3582
------------	--------

Battery Name	APOLIPOPROTEIN
--------------	----------------

Lab Test ID	SCT3639
-------------	---------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1077

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (4)

Data signed: (hfarmer1) 26 Mar 2015 15:21:27

Generated On: 20 Jul 2016 12:37:46

Lab Test Name	APOLIPOPROTEIN A1, RAND
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	124
Reported Numeric Result	124
Reference Range low	110
Reference Range high	205
Range Units	MG/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (4)

Data signed: (hfarmer1) 26 Mar 2015 15:21:27

Generated On: 20 Jul 2016 12:37:46

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: 1077

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (5)

Data signed: (hfarmer1) 26 Mar 2015 15:21:27

Generated On: 20 Jul 2016 12:37:46

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	1077
----------------------	------

Subject Sex	M
-------------	---

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

Visit Name	DAY0
------------	------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	W098761
--------------	---------

Actual Collection Date	2014 02 13
------------------------	------------

Actual Collection Time	05:15
------------------------	-------

Specimen Condition	
--------------------	--

Battery ID	SC3582
------------	--------

Battery Name	APOLIPOPROTEIN
--------------	----------------

Lab Test ID	SCT3643
-------------	---------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1077

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (5)

Data signed: (hfarmer1) 26 Mar 2015 15:21:27

Generated On: 20 Jul 2016 12:37:46

Lab Test Name	APOLIPOPROTEIN B, RAND
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	142
Reported Numeric Result	142
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: 1077**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (5)

Data signed: (hfarmer1) 26 Mar 2015 15:21:27

Generated On: 20 Jul 2016 12:37:46

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: 1077**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (6)

Data signed: (hfarmer1) 26 Mar 2015 15:21:27

Generated On: 20 Jul 2016 12:37:46

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	1077
----------------------	------

Subject Sex	M
-------------	---

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

Visit Name	DAY0
------------	------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	W098761
--------------	---------

Actual Collection Date	2014 02 13
------------------------	------------

Actual Collection Time	05:15
------------------------	-------

Specimen Condition	
--------------------	--

Battery ID	CG267
------------	-------

Battery Name	FIBRINOGEN
--------------	------------

Lab Test ID	CGT285
-------------	--------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1077

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (6)

Data signed: (hfarmer1) 26 Mar 2015 15:21:27

Generated On: 20 Jul 2016 12:37:46

Lab Test Name	FIBRINOGEN
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	370
Reported Numeric Result	370
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: 1077**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (6)

Data signed: (hfarmer1) 26 Mar 2015 15:21:27

Generated On: 20 Jul 2016 12:37:46

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: 1077**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (7)

Data signed: (hfarmer1) 26 Mar 2015 15:21:27

Generated On: 20 Jul 2016 12:37:46

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	1077
----------------------	------

Subject Sex	M
-------------	---

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

Visit Name	DAY0
------------	------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	W098761
--------------	---------

Actual Collection Date	2014 02 13
------------------------	------------

Actual Collection Time	05:15
------------------------	-------

Specimen Condition	
--------------------	--

Battery ID	CN236
------------	-------

Battery Name	HOMOCYSTEINE
--------------	--------------

Lab Test ID	CNT145
-------------	--------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1077

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (7)

Data signed: (hfarmer1) 26 Mar 2015 15:21:27

Generated On: 20 Jul 2016 12:37:46

Lab Test Name	HOMOCYSTEINE, EDTAPL
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	11.98
Reported Numeric Result	11.98
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: 1077**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (7)

Data signed: (hfarmer1) 26 Mar 2015 15:21:27

Generated On: 20 Jul 2016 12:37:46

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: 1077**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (8)

Data signed: (hfarmer1) 26 Mar 2015 15:21:27

Generated On: 20 Jul 2016 12:37:46

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	1077
----------------------	------

Subject Sex	M
-------------	---

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

Visit Name	DAY0
------------	------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	W098761
--------------	---------

Actual Collection Date	2014 02 13
------------------------	------------

Actual Collection Time	05:15
------------------------	-------

Specimen Condition	
--------------------	--

Battery ID	IM2293
------------	--------

Battery Name	SICAM-1
--------------	---------

Lab Test ID	IMT1768
-------------	---------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1077

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (8)

Data signed: (hfarmer1) 26 Mar 2015 15:21:27

Generated On: 20 Jul 2016 12:37:46

Lab Test Name	SICAM-1-RUO
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	283.0
Reported Numeric Result	283.0
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: 1077**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (8)

Data signed: (hfarmer1) 26 Mar 2015 15:21:27

Generated On: 20 Jul 2016 12:37:46

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: 1077**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (9)

Data signed: (hfarmer1) 26 Mar 2015 15:21:27

Generated On: 20 Jul 2016 12:37:46

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	1077
----------------------	------

Subject Sex	M
-------------	---

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

Visit Name	DAY0
------------	------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	W098761
--------------	---------

Actual Collection Date	2014 02 13
------------------------	------------

Actual Collection Time	05:15
------------------------	-------

Specimen Condition	
--------------------	--

Battery ID	RC9267
------------	--------

Battery Name	LDL
--------------	-----

Lab Test ID	RCT2394
-------------	---------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (9)

Data signed: (hfarmer1) 26 Mar 2015 15:21:27

Generated On: 20 Jul 2016 12:37:46

Lab Test Name	DIRECT LDL-C 2ND GEN (-70)
---------------	----------------------------

Test ID	<hr/>
---------	-------

Test Status	Done 
-------------	--

Reported Text Result	172
----------------------	-----

Reported Numeric Result	172
-------------------------	-----

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/>
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day 0)

Form: Risk Markers(CCLS) (9)

Data signed: (hfarmer1) 26 Mar 2015 15:21:27

Generated On: 20 Jul 2016 12:37:46

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: 1077**

Folder: Baseline (Day 0)

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

Data signed: (hfarmer1) 26 Mar 2015 15:21:30

Generated On: 20 Jul 2016 12:37:46

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day 0)

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

Data signed: (hfarmer1) 26 Mar 2015 15:21:30

Generated On: 20 Jul 2016 12:37:46

Sample Barcode	05112450000377
Analyte	HPMA
Sample type	URINE
Result	.
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	0
Celerion Study Number	AA99128-03
Date of Collection	2014-FEB-13
Timepoint-minutes	
Urine Start Day	0

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day 0)

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

Data signed: (hfarmer1) 26 Mar 2015 15:21:30

Generated On: 20 Jul 2016 12:37:46

Urine End Day	1
---------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day 0)

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

Data signed: (hfarmer1) 26 Mar 2015 15:21:30

Generated On: 20 Jul 2016 12:37:46

Sample Barcode	05112450000377
Analyte	CEMA
Sample type	URINE
Result	.
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	0
Celerion Study Number	AA99128-03
Date of Collection	2014-FEB-13
Timepoint-minutes	
Urine Start Day	0

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day 0)

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

Data signed: (hfarmer1) 26 Mar 2015 15:21:30

Generated On: 20 Jul 2016 12:37:46

Urine End Day	1
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day 0)

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

Data signed: (hfarmer1) 26 Mar 2015 15:21:30

Generated On: 20 Jul 2016 12:37:46

Sample Barcode	05112450000377
Analyte	HBMA
Sample type	URINE
Result	.
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	0
Celerion Study Number	AA99128-03
Date of Collection	2014-FEB-13
Timepoint-minutes	
Urine Start Day	0

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day 0)

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

Data signed: (hfarmer1) 26 Mar 2015 15:21:30

Generated On: 20 Jul 2016 12:37:46

Urine End Day	1
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (NNN, NNAL)

Data signed: (hfarmer1) 26 Mar 2015 15:21:30

Generated On: 20 Jul 2016 12:37:46

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day 0)

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

Data signed: (hfarmer1) 26 Mar 2015 15:21:30

Generated On: 20 Jul 2016 12:37:46

Sample Barcode	05112460001488
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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	OTHER
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Sample comment	ANALYSIS NOT REQUIRED
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Detection method	LC-MS/MS
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Planned time point (Hour)	0
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Day of Visit	0
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Celerion Study Number	AA99128-04
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Date of Collection	2014-FEB-13
--------------------	-------------

Timepoint-minutes	
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Urine Start Day	0
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day 0)

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

Data signed: (hfarmer1) 26 Mar 2015 15:21:30

Generated On: 20 Jul 2016 12:37:46

Urine End Day	1
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1077

Folder: Baseline (Day 0)

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

Data signed: (hfarmer1) 26 Mar 2015 15:21:30

Generated On: 20 Jul 2016 12:37:46

Sample Barcode	05112460001488
Analyte	NNN
Sample type	URINE
Result	.
Result Unit	PG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	0
Celerion Study Number	AA99128-04
Date of Collection	2014-FEB-13
Timepoint-minutes	
Urine Start Day	0

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day 0)

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

Data signed: (hfarmer1) 26 Mar 2015 15:21:30

Generated On: 20 Jul 2016 12:37:46

Urine End Day

1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (HEMA)

Data signed: (hfarmer1) 26 Mar 2015 15:21:30

Generated On: 20 Jul 2016 12:37:46

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (HEMA) (1)

Data signed: (hfarmer1) 26 Mar 2015 15:21:30

Generated On: 20 Jul 2016 12:37:46

Sample Barcode	05112470000366
Analyte	HEMA
Sample type	URINE
Result	.
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	0
Celerion Study Number	AA99128-05
Date of Collection	2014-FEB-13
Timepoint-minutes	
Urine Start Day	0

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (HEMA) (1)

Data signed: (hfarmer1) 26 Mar 2015 15:21:30

Generated On: 20 Jul 2016 12:37:46

Urine End Day	1
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day 0)

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

Data signed: (hfarmer1) 26 Mar 2015 15:21:31

Generated On: 20 Jul 2016 12:37:46

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day 0)

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

Data signed: (hfarmer1) 26 Mar 2015 15:21:31

Generated On: 20 Jul 2016 12:37:46

Sample Barcode	05112550000036
Analyte	COT
Sample type	URINE
Result	.
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	0
Celerion Study Number	AA99128-13
Date of Collection	2014-FEB-13
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day 0)

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

Data signed: (hfarmer1) 26 Mar 2015 15:21:31

Generated On: 20 Jul 2016 12:37:46

Urine Start Day	0
<hr/>	
Urine End Day	1
<hr/>	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day 0)

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

Data signed: (hfarmer1) 26 Mar 2015 15:21:31

Generated On: 20 Jul 2016 12:37:46

Sample Barcode	05112550000036
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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
-------------	-------

Lab Status	OTHER
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Sample comment	ANALYSIS NOT REQUIRED
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Detection method	LC-MS/MS
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Planned time point (Hour)	0
---------------------------	---

Day of Visit	0
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Celerion Study Number	AA99128-13
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Date of Collection	2014-FEB-13
--------------------	-------------

Timepoint-minutes	
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day 0)

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

Data signed: (hfarmer1) 26 Mar 2015 15:21:31

Generated On: 20 Jul 2016 12:37:46

Urine Start Day	0
<hr/>	
Urine End Day	1
<hr/>	

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1077

Folder: Baseline (Day 0)

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

Data signed: (hfarmer1) 26 Mar 2015 15:21:31

Generated On: 20 Jul 2016 12:37:46

Sample Barcode	05112550000036
Analyte	NIC
Sample type	URINE
Result	.
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	0
Celerion Study Number	AA99128-13
Date of Collection	2014-FEB-13
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day 0)

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

Data signed: (hfarmer1) 26 Mar 2015 15:21:31

Generated On: 20 Jul 2016 12:37:46

Urine Start Day	0
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Urine End Day	1
---------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day 0)

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

Data signed: (hfarmer1) 26 Mar 2015 15:21:31

Generated On: 20 Jul 2016 12:37:46

Sample Barcode	05112550000036
Analyte	NIC-GLUC
Sample type	URINE
Result	.
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	0
Celerion Study Number	AA99128-13
Date of Collection	2014-FEB-13
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day 0)

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

Data signed: (hfarmer1) 26 Mar 2015 15:21:31

Generated On: 20 Jul 2016 12:37:46

Urine Start Day	0
-----------------	---

Urine End Day	1
---------------	---

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1077

Folder: Baseline (Day 0)

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

Data signed: (hfarmer1) 26 Mar 2015 15:21:31

Generated On: 20 Jul 2016 12:37:46

Sample Barcode	05112550000036
Analyte	THCOT
Sample type	URINE
Result	.
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	0
Celerion Study Number	AA99128-13
Date of Collection	2014-FEB-13
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day 0)

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

Data signed: (hfarmer1) 26 Mar 2015 15:21:31

Generated On: 20 Jul 2016 12:37:46

Urine Start Day	0
<hr/>	
Urine End Day	1
<hr/>	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day 0)

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(6)**

Data signed: (hfarmer1) 26 Mar 2015 15:21:31

Generated On: 20 Jul 2016 12:37:46

Sample Barcode	05112550000036
----------------	----------------

Analyte	THCOT-GLUC
---------	------------

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

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

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

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

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

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

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

Day of Visit	0
--------------	---

Celerion Study Number	AA99128-13
-----------------------	------------

Date of Collection	2014-FEB-13
--------------------	-------------

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day 0)

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(6)**

Data signed: (hfarmer1) 26 Mar 2015 15:21:31

Generated On: 20 Jul 2016 12:37:46

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: 1077**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (3-OH BaP)

Data signed: (hfarmer1) 26 Mar 2015 15:21:31

Generated On: 20 Jul 2016 12:37:46

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (3-OH BaP) (1)

Data signed: (hfarmer1) 26 Mar 2015 15:21:31

Generated On: 20 Jul 2016 12:37:46

Sample Barcode	05112490000366
Analyte	3-OH BAP
Sample type	URINE
Result	.
Result Unit	FG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	0
Celerion Study Number	AA99128-07
Date of Collection	2014-FEB-13
Timepoint-minutes	
Urine Start Day	0

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (3-OH BaP) (1)

Data signed: (hfarmer1) 26 Mar 2015 15:21:31

Generated On: 20 Jul 2016 12:37:46

Urine End Day

1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day 0)

Form: Biomarker-Plasma (Caffeine, Paraxanthine)

Generated On: 20 Jul 2016 12:37:46

Sample type

PLASMA

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day 0)

Form: Biomarker-Plasma (Caffeine, Paraxanthine) (1)

Generated On: 20 Jul 2016 12:37:46

Sample Barcode	05112500000202
----------------	----------------

Analyte	CAFFEINE
---------	----------

Sample type	PLASMA
-------------	--------

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

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

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

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

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

Planned time point (Hour)	6
---------------------------	---

Day of Visit	0
--------------	---

Celerion Study Number	AA99128-08
-----------------------	------------

Date of Collection	2014-FEB-13
--------------------	-------------

Timepoint-minutes	0
-------------------	---

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day 0)

Form: Biomarker-Plasma (Caffeine, Paraxanthine) (1)

Generated On: 20 Jul 2016 12:37:46

Urine End Day	0
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day 0)

Form: Biomarker-Plasma (Caffeine, Paraxanthine) (2)

Generated On: 20 Jul 2016 12:37:46

Sample Barcode	05112500000202
----------------	----------------

Analyte	PARAXANTHINE
---------	--------------

Sample type	PLASMA
-------------	--------

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

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

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

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

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

Planned time point (Hour)	6
---------------------------	---

Day of Visit	0
--------------	---

Celerion Study Number	AA99128-08
-----------------------	------------

Date of Collection	2014-FEB-13
--------------------	-------------

Timepoint-minutes	0
-------------------	---

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day 0)

Form: Biomarker-Plasma (Caffeine, Paraxanthine) (2)

Generated On: 20 Jul 2016 12:37:46

Urine End Day	0
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP)

Data signed: (hfarmer1) 26 Mar 2015 15:21:31

Generated On: 20 Jul 2016 12:37:46

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (1)

Data signed: (hfarmer1) 26 Mar 2015 15:21:31

Generated On: 20 Jul 2016 12:37:46

Sample Barcode	05112510000366
Analyte	1-NA
Sample type	URINE
Result	.
Result Unit	PG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	0
Celerion Study Number	AA99128-09
Date of Collection	2014-FEB-13
Timepoint-minutes	
Urine Start Day	0

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (1)

Data signed: (hfarmer1) 26 Mar 2015 15:21:31

Generated On: 20 Jul 2016 12:37:46

Urine End Day	1
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (2)

Data signed: (hfarmer1) 26 Mar 2015 15:21:31

Generated On: 20 Jul 2016 12:37:46

Sample Barcode	05112510000366
Analyte	2-NA
Sample type	URINE
Result	.
Result Unit	PG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	0
Celerion Study Number	AA99128-09
Date of Collection	2014-FEB-13
Timepoint-minutes	
Urine Start Day	0

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (2)

Data signed: (hfarmer1) 26 Mar 2015 15:21:31

Generated On: 20 Jul 2016 12:37:46

Urine End Day	1
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (3)

Data signed: (hfarmer1) 26 Mar 2015 15:21:31

Generated On: 20 Jul 2016 12:37:46

Sample Barcode	05112510000366
Analyte	4-ABP
Sample type	URINE
Result	.
Result Unit	PG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	0
Celerion Study Number	AA99128-09
Date of Collection	2014-FEB-13
Timepoint-minutes	
Urine Start Day	0

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (3)

Data signed: (hfarmer1) 26 Mar 2015 15:21:31

Generated On: 20 Jul 2016 12:37:46

Urine End Day	1
---------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (4)

Data signed: (hfarmer1) 26 Mar 2015 15:21:31

Generated On: 20 Jul 2016 12:37:46

Sample Barcode	05112510000366
Analyte	O-TOL
Sample type	URINE
Result	.
Result Unit	PG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	0
Celerion Study Number	AA99128-09
Date of Collection	2014-FEB-13
Timepoint-minutes	
Urine Start Day	0

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (4)

Data signed: (hfarmer1) 26 Mar 2015 15:21:31

Generated On: 20 Jul 2016 12:37:46

Urine End Day	1
---------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (11-dTXb2)

Data signed: (hfarmer1) 26 Mar 2015 15:21:30

Generated On: 20 Jul 2016 12:37:46

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (11-dTXb2) (1)

Data signed: (hfarmer1) 26 Mar 2015 15:21:30

Generated On: 20 Jul 2016 12:37:46

Sample Barcode	05112530000234
Analyte	11-DTXB2
Sample type	URINE
Result	.
Result Unit	PG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	0
Celerion Study Number	AA99128-11
Date of Collection	2014-FEB-13
Timepoint-minutes	
Urine Start Day	0

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (11-dTXb2) (1)

Data signed: (hfarmer1) 26 Mar 2015 15:21:30

Generated On: 20 Jul 2016 12:37:46

Urine End Day	1
---------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (iPF2a-III)

Data signed: (hfarmer1) 26 Mar 2015 15:21:30

Generated On: 20 Jul 2016 12:37:46

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (iPF2a-III) (1)

Data signed: (hfarmer1) 26 Mar 2015 15:21:30

Generated On: 20 Jul 2016 12:37:46

Sample Barcode	05112540000234
Analyte	IPF2A-III
Sample type	URINE
Result	.
Result Unit	PG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	0
Celerion Study Number	AA99128-12
Date of Collection	2014-FEB-13
Timepoint-minutes	
Urine Start Day	0

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (iPF2a-III) (1)

Data signed: (hfarmer1) 26 Mar 2015 15:21:30

Generated On: 20 Jul 2016 12:37:46

Urine End Day	1
---------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (Ames)

Data signed: (hfarmer1) 26 Mar 2015 15:21:31

Generated On: 20 Jul 2016 12:37:46

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (Ames) (1)

Data signed: (hfarmer1) 26 Mar 2015 15:21:31

Generated On: 20 Jul 2016 12:37:46

Sample Barcode	05113320000088
Analyte	AMES
Sample type	URINE
Result	.
Result Unit	REV/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	COUNT
Planned time point (Hour)	0
Day of Visit	0
Celerion Study Number	AA99128-15
Date of Collection	2014-FEB-13
Timepoint-minutes	
Urine Start Day	0

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (Ames) (1)

Data signed: (hfarmer1) 26 Mar 2015 15:21:31

Generated On: 20 Jul 2016 12:37:46

Urine End Day	1
---------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (1-OHP)

Data signed: (hfarmer1) 26 Mar 2015 15:21:31

Generated On: 20 Jul 2016 12:37:46

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (1-OHP) (1)

Data signed: (hfarmer1) 26 Mar 2015 15:21:31

Generated On: 20 Jul 2016 12:37:46

Sample Barcode	05115190001323
Analyte	1-OHP
Sample type	URINE
Result	.
Result Unit	PG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	0
Celerion Study Number	AA99598-03
Date of Collection	2014-FEB-13
Timepoint-minutes	
Urine Start Day	0

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (1-OHP) (1)

Data signed: (hfarmer1) 26 Mar 2015 15:21:31

Generated On: 20 Jul 2016 12:37:46

Urine End Day	1
---------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (SPMA, SBMA)

Data signed: (hfarmer1) 26 Mar 2015 15:21:30

Generated On: 20 Jul 2016 12:37:46

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (SPMA, SBMA) (1)

Data signed: (hfarmer1) 26 Mar 2015 15:21:30

Generated On: 20 Jul 2016 12:37:46

Sample Barcode	05115170001279
Analyte	SBMA
Sample type	URINE
Result	.
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	0
Celerion Study Number	AA99598-01
Date of Collection	2014-FEB-13
Timepoint-minutes	
Urine Start Day	0

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (SPMA, SBMA) (1)

Data signed: (hfarmer1) 26 Mar 2015 15:21:30

Generated On: 20 Jul 2016 12:37:46

Urine End Day	1
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (SPMA, SBMA) (2)

Data signed: (hfarmer1) 26 Mar 2015 15:21:30

Generated On: 20 Jul 2016 12:37:46

Sample Barcode	05115170001279
Analyte	SPMA
Sample type	URINE
Result	.
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	0
Celerion Study Number	AA99598-01
Date of Collection	2014-FEB-13
Timepoint-minutes	
Urine Start Day	0

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (SPMA, SBMA) (2)

Data signed: (hfarmer1) 26 Mar 2015 15:21:30

Generated On: 20 Jul 2016 12:37:46

Urine End Day

1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (MHBMA)

Data signed: (hfarmer1) 26 Mar 2015 15:21:30

Generated On: 20 Jul 2016 12:37:46

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (MHBMA) (1)

Data signed: (hfarmer1) 26 Mar 2015 15:21:30

Generated On: 20 Jul 2016 12:37:46

Sample Barcode	05115180001323
Analyte	MHBMA
Sample type	URINE
Result	.
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	0
Celerion Study Number	AA99598-02
Date of Collection	2014-FEB-13
Timepoint-minutes	
Urine Start Day	0

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (MHBMA) (1)

Data signed: (hfarmer1) 26 Mar 2015 15:21:30

Generated On: 20 Jul 2016 12:37:46

Urine End Day

1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (Creatinine)

Data signed: (hfarmer1) 26 Mar 2015 15:21:31

Generated On: 20 Jul 2016 12:37:46

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (Creatinine) (1)

Data signed: (hfarmer1) 26 Mar 2015 15:21:31

Generated On: 20 Jul 2016 12:37:46

Sample Barcode	05115160000672
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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	OTHER
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Sample comment	ANALYSIS NOT REQUIRED
----------------	-----------------------

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

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

Day of Visit	0
--------------	---

Celerion Study Number	AA99128-14
-----------------------	------------

Date of Collection	2014-FEB-13
--------------------	-------------

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

Urine Start Day	0
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day 0)

Form: Biomarker-Urine (Creatinine) (1)

Data signed: (hfarmer1) 26 Mar 2015 15:21:31

Generated On: 20 Jul 2016 12:37:46

Urine End Day

1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day 0)

Form: Biomarker-Plasma (Nic, Cot, tHCot)

Generated On: 20 Jul 2016 12:37:46

Sample type

PLASMA

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day 0)

Form: Biomarker-Plasma (Nic, Cot, tHCot) (1)

Generated On: 20 Jul 2016 12:37:46

Sample Barcode	05112440000031
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Analyte	COT
---------	-----

Sample type	PLASMA
-------------	--------

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

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

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

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

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

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

Day of Visit	0
--------------	---

Celerion Study Number	AA99128-02
-----------------------	------------

Date of Collection	2014-FEB-13
--------------------	-------------

Timepoint-minutes	0
-------------------	---

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day 0)

Form: Biomarker-Plasma (Nic, Cot, tHCot) (1)

Generated On: 20 Jul 2016 12:37:46

Urine End Day	0
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day 0)

Form: Biomarker-Plasma (Nic, Cot, tHCot) (2)

Generated On: 20 Jul 2016 12:37:46

Sample Barcode	05112440000031
----------------	----------------

Analyte	NIC
---------	-----

Sample type	PLASMA
-------------	--------

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

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

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

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

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

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

Day of Visit	0
--------------	---

Celerion Study Number	AA99128-02
-----------------------	------------

Date of Collection	2014-FEB-13
--------------------	-------------

Timepoint-minutes	0
-------------------	---

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day 0)

Form: Biomarker-Plasma (Nic, Cot, tHCot) (2)

Generated On: 20 Jul 2016 12:37:46

Urine End Day	0
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day 0)

Form: Biomarker-Plasma (Nic, Cot, tHCot) (3)

Generated On: 20 Jul 2016 12:37:46

Sample Barcode	05112520000100
----------------	----------------

Analyte	COT
---------	-----

Sample type	PLASMA
-------------	--------

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

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

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

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

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

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

Day of Visit	0
--------------	---

Celerion Study Number	AA99128-10
-----------------------	------------

Date of Collection	2014-FEB-13
--------------------	-------------

Timepoint-minutes	0
-------------------	---

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day 0)

Form: Biomarker-Plasma (Nic, Cot, tHCot) (3)

Generated On: 20 Jul 2016 12:37:46

Urine End Day	0
---------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day 0)

Form: Biomarker-Plasma (Nic, Cot, tHCot) (4)

Generated On: 20 Jul 2016 12:37:46

Sample Barcode	05112520000100
----------------	----------------

Analyte	THCOT
---------	-------

Sample type	PLASMA
-------------	--------

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

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

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

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

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

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

Day of Visit	0
--------------	---

Celerion Study Number	AA99128-10
-----------------------	------------

Date of Collection	2014-FEB-13
--------------------	-------------

Timepoint-minutes	0
-------------------	---

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Baseline (Day 0)

Form: Biomarker-Plasma (Nic, Cot, tHCot) (4)

Generated On: 20 Jul 2016 12:37:46

Urine End Day	0
---------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 1

Form: Date of Visit

Data signed: (hfarmer1) 26 Mar 2015 15:21:31

Generated On: 20 Jul 2016 12:37:46

Date of Visit

14 FEB 2014
DD/MMM/YYYY

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 1

Form: Vital Signs

Data signed: (hcoleman1) 18 Jun 2015 20:00:09

Generated On: 20 Jul 2016 12:37:46

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 10:44
hour:min 24-hour clock

Pulse rate 63
beats per minute

Respiratory rate 16
breaths per minute

Blood Pressure (systolic) 110
mmHg

Blood Pressure (diastolic) 71
mmHg

Vital Signs Position of Subject Supine ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 1

Form: Plasma Nicotine Sample

Data signed: (hfarmer1) 26 Mar 2015 15:21:31

Generated On: 20 Jul 2016 12:37:46

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	14 FEB 2014
---------------------	-------------

Time hour:min 24-hour clock	21:12
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 1

Form: Plasma Cotinine Sample

Data signed: (hfarmer1) 26 Mar 2015 15:21:31

Generated On: 20 Jul 2016 12:37:46

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	14 FEB 2014
---------------------	-------------

Time hour:min 24-hour clock	21:12
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 1

Form: CoHb Blood Sample

Data signed: (hfarmer1) 26 Mar 2015 15:21:31

Generated On: 20 Jul 2016 12:37:46

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	14 FEB 2014
---------------------	-------------

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

Time hour:min 24-hour clock	21:12
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 1

Form: CO Breath Test <SA arm/> (1)

Data signed: (hfarmer1) 26 Mar 2015 15:21:31

Generated On: 20 Jul 2016 12:37:46

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

If Not Done, please specify the reason: _____

Scheduled Time	08:00 - 09:30 
----------------	---

Actual Time of Assessment hour:min 24-hour clock	08:06
---	-------

Result(ppm)	12
-------------	----

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 1

Form: CO Breath Test <SA arm/> (2)

Data signed: (hfarmer1) 26 Mar 2015 15:21:31

Generated On: 20 Jul 2016 12:37:46

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	13:21
---	-------

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 1

Form: CO Breath Test <SA arm/> (3)

Data signed: (hfarmer1) 26 Mar 2015 15:21:31

Generated On: 20 Jul 2016 12:37:46

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)	4
-------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 1

Form: CO Breath Test <SA arm/> (4)

Data signed: (hfarmer1) 26 Mar 2015 15:21:31

Generated On: 20 Jul 2016 12:37:46

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	20:47
---	-------

Result(ppm)	3
-------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 1

Form: 24 hour urine collections

Data signed: (hfarmer1) 26 Mar 2015 15:21:31

Generated On: 20 Jul 2016 12:37:46

Start Time	06:50
	hour:min 24-hour clock

End Date	15 FEB 2014
	DD/MMM/YYYY

End Time	06:04
	hour:min 24-hour clock

Volume	1511
	mL

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 1

Form: Sample Urine Collection

Data signed: (hfarmer1) 26 Mar 2015 15:21:31

Generated On: 20 Jul 2016 12:37:46

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: 1077**

Folder: Day 1

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Data signed: (hfarmer1) 26 Mar 2015 15:21:32

Generated On: 20 Jul 2016 12:37:46

Date of Birth

(b) (6)

Date of assessment
DD/MMM/YYYY

2014 FEB 14
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?

None ☐

2. Anxious, nervous

How have you been feeling over the past 24 hours?

None ☐

3. Depressed Mood, sad

How have you been feeling over the past 24 hours?

Slight ☐

4. Desire or craving to smoke

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 1

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Data signed: (hfarmer1) 26 Mar 2015 15:21:32

Generated On: 20 Jul 2016 12:37:46

How have you been feeling over the past 24 hours? None ☐

5. Difficulty concentrating

How have you been feeling over the past 24 hours? None ☐

6. Increased appetite, hungry, weight gain

How have you been feeling over the past 24 hours? None ☐

7. Insomnia, sleep problems, awakening at night

How have you been feeling over the past 24 hours? None ☐

8. Restless

How have you been feeling over the past 24 hours? None ☐

9. Impatient

How have you been feeling over the past 24 hours? None ☐

10. Constipation

How have you been feeling over the past 24 hours? None ☐

11. Dizziness

How have you been feeling over the past 24 hours? None ☐

12. Coughing

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 1

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Data signed: (hfarmer1) 26 Mar 2015 15:21:32

Generated On: 20 Jul 2016 12:37:46

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: 1077**

Folder: Day 1

Form: Cough Assessment

Data signed: (hfarmer1) 26 Mar 2015 15:21:32

Generated On: 20 Jul 2016 12:37:46

Date of Birth

(b) (6)

Date of assessment
DD/MMM/YYYY

2014 FEB 14
DD/MMM/YYYY

Time of assessment

06:14
hour:min 24-hour clock

Assessment Status

Completed ☒

Have you experienced a regular need to cough e.g.
coughing several times in the last 24 hrs?

No ☒

If YES, please answer the following questions:

First Question: Cough Impact Scale
How much is your cough bothering you?

-9

Second Question: Cough Intensity Scale:
How intense is your cough?

Not Applicable ☒

Third Question: Cough Frequency Scale:
How frequently do you normally have to cough each
day?

Not Applicable ☒

Fourth Question: Sputum Production
To what extent do you produce sputum when coughing?

Not Applicable ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 1

Form: Lab_BU_COHB (1)

Data signed: (hfarmer1) 26 Mar 2015 15:21:32

Generated On: 20 Jul 2016 12:37:46

Sample Barcode	05115150000468
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Analyte	CARBOXYHEMOGLOBIN
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Sample type	BLOOD
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Result	.
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Result Unit	%
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Lab Status	OTHER
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Sample comment	ANALYSIS NOT REQUIRED
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Detection method	SPECTROPHOTOMETRIC
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Lower limit of quantification	0.500
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Planned time point (Hour)	20
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Day of Visit	1
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Celerion Study Number	AA99128-16
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Date of Collection	2014-FEB-14
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Timepoint-minutes	
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 1

Form: Lab_BU_COHB (1)

Data signed: (hfarmer1) 26 Mar 2015 15:21:32

Generated On: 20 Jul 2016 12:37:46

Start Day (24 hour urine only) _____

End Day (24 hour Urine Only) _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 1

Form: Questionnaire on smoking urges (QSU)

Data signed: (hfarmer1) 26 Mar 2015 15:21:32

Generated On: 20 Jul 2016 12:37:46

Type	QSU
Date of Birth	(b) (6)
Date of assessment	2014 FEB 14
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	Agree <input checked="" type="radio"/>
2. Nothing would be better than smoking a cigarette right now	Agree <input checked="" type="radio"/>
3. If it were possible I would probably smoke now	Agree <input checked="" type="radio"/>
4. I could control things better right now if I could smoke	Somewhat disagree <input checked="" type="radio"/>
5. All I want right now is a cigarette	Do not agree or disagree <input checked="" type="radio"/>
6. I have an urge for a cigarette	Agree <input checked="" type="radio"/>

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 1

Form: Questionnaire on smoking urges (QSU)

Data signed: (hfarmer1) 26 Mar 2015 15:21:32

Generated On: 20 Jul 2016 12:37:46

7. A cigarette would taste good now Agree ☐

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

9. Smoking would make me less depressed Disagree ☐

10. I am going to smoke as soon as possible Disagree ☐

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 1

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

Data signed: (hfarmer1) 26 Mar 2015 15:21:32

Generated On: 20 Jul 2016 12:37:46

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 1

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

Data signed: (hfarmer1) 26 Mar 2015 15:21:32

Generated On: 20 Jul 2016 12:37:46

Sample Barcode	05112450000378
Analyte	HPMA
Sample type	URINE
Result	.
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	1
Celerion Study Number	AA99128-03
Date of Collection	2014-FEB-14
Timepoint-minutes	
Urine Start Day	1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 1

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

Data signed: (hfarmer1) 26 Mar 2015 15:21:32

Generated On: 20 Jul 2016 12:37:46

Urine End Day

2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 1

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

Data signed: (hfarmer1) 26 Mar 2015 15:21:32

Generated On: 20 Jul 2016 12:37:46

Sample Barcode	05112450000378
Analyte	CEMA
Sample type	URINE
Result	.
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	1
Celerion Study Number	AA99128-03
Date of Collection	2014-FEB-14
Timepoint-minutes	
Urine Start Day	1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 1

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

Data signed: (hfarmer1) 26 Mar 2015 15:21:32

Generated On: 20 Jul 2016 12:37:46

Urine End Day

2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 1

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

Data signed: (hfarmer1) 26 Mar 2015 15:21:32

Generated On: 20 Jul 2016 12:37:46

Sample Barcode	05112450000378
Analyte	HBMA
Sample type	URINE
Result	.
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	1
Celerion Study Number	AA99128-03
Date of Collection	2014-FEB-14
Timepoint-minutes	
Urine Start Day	1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 1

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

Data signed: (hfarmer1) 26 Mar 2015 15:21:32

Generated On: 20 Jul 2016 12:37:46

Urine End Day

2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 1

Form: Biomarker-Urine (NNN, NNAL)

Data signed: (hfarmer1) 26 Mar 2015 15:21:32

Generated On: 20 Jul 2016 12:37:46

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 1

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

Data signed: (hfarmer1) 26 Mar 2015 15:21:32

Generated On: 20 Jul 2016 12:37:46

Sample Barcode	05112460001489
Analyte	NNAL
Sample type	URINE
Result	.
Result Unit	PG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	1
Celerion Study Number	AA99128-04
Date of Collection	2014-FEB-14
Timepoint-minutes	
Urine Start Day	1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 1

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

Data signed: (hfarmer1) 26 Mar 2015 15:21:32

Generated On: 20 Jul 2016 12:37:46

Urine End Day

2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 1

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

Data signed: (hfarmer1) 26 Mar 2015 15:21:32

Generated On: 20 Jul 2016 12:37:46

Sample Barcode	05112460001489
Analyte	NNN
Sample type	URINE
Result	.
Result Unit	PG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	1
Celerion Study Number	AA99128-04
Date of Collection	2014-FEB-14
Timepoint-minutes	
Urine Start Day	1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 1

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

Data signed: (hfarmer1) 26 Mar 2015 15:21:32

Generated On: 20 Jul 2016 12:37:46

Urine End Day

2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 1

Form: Biomarker-Urine (HEMA)

Data signed: (hfarmer1) 26 Mar 2015 15:21:32

Generated On: 20 Jul 2016 12:37:46

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 1

Form: Biomarker-Urine (HEMA) (1)

Data signed: (hfarmer1) 26 Mar 2015 15:21:32

Generated On: 20 Jul 2016 12:37:46

Sample Barcode	05112470000367
Analyte	HEMA
Sample type	URINE
Result	.
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	1
Celerion Study Number	AA99128-05
Date of Collection	2014-FEB-14
Timepoint-minutes	
Urine Start Day	1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 1

Form: Biomarker-Urine (HEMA) (1)

Data signed: (hfarmer1) 26 Mar 2015 15:21:32

Generated On: 20 Jul 2016 12:37:46

Urine End Day

2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 1

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

Data signed: (hfarmer1) 26 Mar 2015 15:21:33

Generated On: 20 Jul 2016 12:37:46

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 1

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

Data signed: (hfarmer1) 26 Mar 2015 15:21:33

Generated On: 20 Jul 2016 12:37:46

Sample Barcode	05112550000037
Analyte	COT
Sample type	URINE
Result	.
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	1
Celerion Study Number	AA99128-13
Date of Collection	2014-FEB-14
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 1

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

Data signed: (hfarmer1) 26 Mar 2015 15:21:33

Generated On: 20 Jul 2016 12:37:46

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: 1077**

Folder: Day 1

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

Data signed: (hfarmer1) 26 Mar 2015 15:21:33

Generated On: 20 Jul 2016 12:37:46

Sample Barcode	05112550000037
Analyte	COT-GLUC
Sample type	URINE
Result	.
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	1
Celerion Study Number	AA99128-13
Date of Collection	2014-FEB-14
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 1

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

Data signed: (hfarmer1) 26 Mar 2015 15:21:33

Generated On: 20 Jul 2016 12:37:46

Urine Start Day	1
-----------------	---

Urine End Day	2
---------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 1

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

Data signed: (hfarmer1) 26 Mar 2015 15:21:33

Generated On: 20 Jul 2016 12:37:46

Sample Barcode	05112550000037
Analyte	NIC
Sample type	URINE
Result	.
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	1
Celerion Study Number	AA99128-13
Date of Collection	2014-FEB-14
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 1

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

Data signed: (hfarmer1) 26 Mar 2015 15:21:33

Generated On: 20 Jul 2016 12:37:46

Urine Start Day	1
-----------------	---

Urine End Day	2
---------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 1

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

Data signed: (hfarmer1) 26 Mar 2015 15:21:33

Generated On: 20 Jul 2016 12:37:46

Sample Barcode	05112550000037
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Analyte	NIC-GLUC
---------	----------

Sample type	URINE
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Result	.
--------	---

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

Lab Status	OTHER
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Sample comment	ANALYSIS NOT REQUIRED
----------------	-----------------------

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

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

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

Celerion Study Number	AA99128-13
-----------------------	------------

Date of Collection	2014-FEB-14
--------------------	-------------

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 1

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

Data signed: (hfarmer1) 26 Mar 2015 15:21:33

Generated On: 20 Jul 2016 12:37:46

Urine Start Day	1
-----------------	---

Urine End Day	2
---------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 1

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

Data signed: (hfarmer1) 26 Mar 2015 15:21:33

Generated On: 20 Jul 2016 12:37:46

Sample Barcode	05112550000037
Analyte	THCOT
Sample type	URINE
Result	.
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	1
Celerion Study Number	AA99128-13
Date of Collection	2014-FEB-14
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 1

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

Data signed: (hfarmer1) 26 Mar 2015 15:21:33

Generated On: 20 Jul 2016 12:37:46

Urine Start Day	1
-----------------	---

Urine End Day	2
---------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 1

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(6)**

Data signed: (hfarmer1) 26 Mar 2015 15:21:33

Generated On: 20 Jul 2016 12:37:46

Sample Barcode	05112550000037
Analyte	THCOT-GLUC
Sample type	URINE
Result	.
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	1
Celerion Study Number	AA99128-13
Date of Collection	2014-FEB-14
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 1

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(6)**

Data signed: (hfarmer1) 26 Mar 2015 15:21:33

Generated On: 20 Jul 2016 12:37:46

Urine Start Day	1
-----------------	---

Urine End Day	2
---------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 1

Form: Biomarker-Urine (3-OH BaP)

Data signed: (hfarmer1) 26 Mar 2015 15:21:33

Generated On: 20 Jul 2016 12:37:46

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 1

Form: Biomarker-Urine (3-OH BaP) (1)

Data signed: (hfarmer1) 26 Mar 2015 15:21:33

Generated On: 20 Jul 2016 12:37:46

Sample Barcode	05112490000367
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Analyte	3-OH BAP
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Sample type	URINE
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Result	.
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Result Unit	FG/ML
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Lab Status	OTHER
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Sample comment	ANALYSIS NOT REQUIRED
----------------	-----------------------

Detection method	LC-MS/MS
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Planned time point (Hour)	0
---------------------------	---

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

Celerion Study Number	AA99128-07
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Date of Collection	2014-FEB-14
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Timepoint-minutes	
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Urine Start Day	1
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 1

Form: Biomarker-Urine (3-OH BaP) (1)

Data signed: (hfarmer1) 26 Mar 2015 15:21:33

Generated On: 20 Jul 2016 12:37:46

Urine End Day

2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 1

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP)

Data signed: (hfarmer1) 26 Mar 2015 15:21:33

Generated On: 20 Jul 2016 12:37:46

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 1

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (1)

Data signed: (hfarmer1) 26 Mar 2015 15:21:33

Generated On: 20 Jul 2016 12:37:46

Sample Barcode	05112510000367
Analyte	1-NA
Sample type	URINE
Result	.
Result Unit	PG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	1
Celerion Study Number	AA99128-09
Date of Collection	2014-FEB-14
Timepoint-minutes	
Urine Start Day	1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 1

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (1)

Data signed: (hfarmer1) 26 Mar 2015 15:21:33

Generated On: 20 Jul 2016 12:37:46

Urine End Day

2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 1

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (2)

Data signed: (hfarmer1) 26 Mar 2015 15:21:33

Generated On: 20 Jul 2016 12:37:46

Sample Barcode	05112510000367
Analyte	2-NA
Sample type	URINE
Result	.
Result Unit	PG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	1
Celerion Study Number	AA99128-09
Date of Collection	2014-FEB-14
Timepoint-minutes	
Urine Start Day	1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 1

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (2)

Data signed: (hfarmer1) 26 Mar 2015 15:21:33

Generated On: 20 Jul 2016 12:37:46

Urine End Day

2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 1

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (3)

Data signed: (hfarmer1) 26 Mar 2015 15:21:33

Generated On: 20 Jul 2016 12:37:46

Sample Barcode	05112510000367
Analyte	4-ABP
Sample type	URINE
Result	.
Result Unit	PG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	1
Celerion Study Number	AA99128-09
Date of Collection	2014-FEB-14
Timepoint-minutes	
Urine Start Day	1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 1

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (3)

Data signed: (hfarmer1) 26 Mar 2015 15:21:33

Generated On: 20 Jul 2016 12:37:46

Urine End Day

2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 1

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (4)

Data signed: (hfarmer1) 26 Mar 2015 15:21:33

Generated On: 20 Jul 2016 12:37:46

Sample Barcode	05112510000367
Analyte	O-TOL
Sample type	URINE
Result	.
Result Unit	PG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	1
Celerion Study Number	AA99128-09
Date of Collection	2014-FEB-14
Timepoint-minutes	
Urine Start Day	1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 1

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (4)

Data signed: (hfarmer1) 26 Mar 2015 15:21:33

Generated On: 20 Jul 2016 12:37:46

Urine End Day

2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 1

Form: Biomarker-Urine (1-OHP)

Data signed: (hfarmer1) 26 Mar 2015 15:21:33

Generated On: 20 Jul 2016 12:37:46

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 1

Form: Biomarker-Urine (1-OHP) (1)

Data signed: (hfarmer1) 26 Mar 2015 15:21:33

Generated On: 20 Jul 2016 12:37:46

Sample Barcode	05115190001324
Analyte	1-OHP
Sample type	URINE
Result	.
Result Unit	PG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	1
Celerion Study Number	AA99598-03
Date of Collection	2014-FEB-14
Timepoint-minutes	
Urine Start Day	1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 1

Form: Biomarker-Urine (1-OHP) (1)

Data signed: (hfarmer1) 26 Mar 2015 15:21:33

Generated On: 20 Jul 2016 12:37:46

Urine End Day

2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 1

Form: Biomarker-Urine (SPMA, SBMA)

Data signed: (hfarmer1) 26 Mar 2015 15:21:32

Generated On: 20 Jul 2016 12:37:46

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 1

Form: Biomarker-Urine (SPMA, SBMA) (1)

Data signed: (hfarmer1) 26 Mar 2015 15:21:32

Generated On: 20 Jul 2016 12:37:46

Sample Barcode	05115170001280
Analyte	SBMA
Sample type	URINE
Result	.
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	1
Celerion Study Number	AA99598-01
Date of Collection	2014-FEB-14
Timepoint-minutes	
Urine Start Day	1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 1

Form: Biomarker-Urine (SPMA, SBMA) (1)

Data signed: (hfarmer1) 26 Mar 2015 15:21:32

Generated On: 20 Jul 2016 12:37:46

Urine End Day

2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 1

Form: Biomarker-Urine (SPMA, SBMA) (2)

Data signed: (hfarmer1) 26 Mar 2015 15:21:32

Generated On: 20 Jul 2016 12:37:46

Sample Barcode	05115170001280
Analyte	SPMA
Sample type	URINE
Result	.
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	1
Celerion Study Number	AA99598-01
Date of Collection	2014-FEB-14
Timepoint-minutes	
Urine Start Day	1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 1

Form: Biomarker-Urine (SPMA, SBMA) (2)

Data signed: (hfarmer1) 26 Mar 2015 15:21:32

Generated On: 20 Jul 2016 12:37:46

Urine End Day

2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 1

Form: Biomarker-Urine (MHBMA)

Data signed: (hfarmer1) 26 Mar 2015 15:21:32

Generated On: 20 Jul 2016 12:37:46

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 1

Form: Biomarker-Urine (MHBMA) (1)

Data signed: (hfarmer1) 26 Mar 2015 15:21:32

Generated On: 20 Jul 2016 12:37:46

Sample Barcode	05115180001324
Analyte	MHBMA
Sample type	URINE
Result	.
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	1
Celerion Study Number	AA99598-02
Date of Collection	2014-FEB-14
Timepoint-minutes	
Urine Start Day	1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 1

Form: Biomarker-Urine (MHBMA) (1)

Data signed: (hfarmer1) 26 Mar 2015 15:21:32

Generated On: 20 Jul 2016 12:37:46

Urine End Day

2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 1

Form: Biomarker-Urine (Creatinine)

Data signed: (hfarmer1) 26 Mar 2015 15:21:33

Generated On: 20 Jul 2016 12:37:46

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 1

Form: Biomarker-Urine (Creatinine) (1)

Data signed: (hfarmer1) 26 Mar 2015 15:21:33

Generated On: 20 Jul 2016 12:37:46

Sample Barcode	05115160000673
Analyte	CREATININE
Sample type	URINE
Result	.
Result Unit	MG/DL
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	SPECTROPHOTOMETRIC
Planned time point (Hour)	0
Day of Visit	1
Celerion Study Number	AA99128-14
Date of Collection	2014-FEB-14
Timepoint-minutes	
Urine Start Day	1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 1

Form: Biomarker-Urine (Creatinine) (1)

Data signed: (hfarmer1) 26 Mar 2015 15:21:33

Generated On: 20 Jul 2016 12:37:46

Urine End Day

2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 1

Form: Biomarker-Plasma (Nic, Cot, tHCot)

Data signed: (hfarmer1) 26 Mar 2015 15:21:32

Generated On: 20 Jul 2016 12:37:46

Sample type

PLASMA

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 1

Form: Biomarker-Plasma (Nic, Cot, tHCot) (1)

Data signed: (hfarmer1) 26 Mar 2015 15:21:32

Generated On: 20 Jul 2016 12:37:46

Sample Barcode	05112440000032
Analyte	COT
Sample type	PLASMA
Result	.
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	1
Celerion Study Number	AA99128-02
Date of Collection	2014-FEB-14
Timepoint-minutes	0
Urine Start Day	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 1

Form: Biomarker-Plasma (Nic, Cot, tHCot) (1)

Data signed: (hfarmer1) 26 Mar 2015 15:21:32

Generated On: 20 Jul 2016 12:37:46

Urine End Day

1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 1

Form: Biomarker-Plasma (Nic, Cot, tHCot) (2)

Data signed: (hfarmer1) 26 Mar 2015 15:21:32

Generated On: 20 Jul 2016 12:37:46

Sample Barcode	05112440000032
----------------	----------------

Analyte	NIC
---------	-----

Sample type	PLASMA
-------------	--------

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

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

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

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

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

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

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

Celerion Study Number	AA99128-02
-----------------------	------------

Date of Collection	2014-FEB-14
--------------------	-------------

Timepoint-minutes	0
-------------------	---

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 1

Form: Biomarker-Plasma (Nic, Cot, tHCot) (2)

Data signed: (hfarmer1) 26 Mar 2015 15:21:32

Generated On: 20 Jul 2016 12:37:46

Urine End Day

1

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 2

Form: Date of Visit

Data signed: (hfarmer1) 26 Mar 2015 15:21:33

Generated On: 20 Jul 2016 12:37:46

Date of Visit

15 FEB 2014
DD/MMM/YYYY

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 2

Form: Vital Signs

Data signed: (hcoleman1) 18 Jun 2015 20:00:10

Generated On: 20 Jul 2016 12:37:46

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 10:22
hour:min 24-hour clock

Pulse rate 54
beats per minute

Respiratory rate 16
breaths per minute

Blood Pressure (systolic) 107
mmHg

Blood Pressure (diastolic) 71
mmHg

Vital Signs Position of Subject Supine ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 2

Form: Plasma Nicotine Sample

Data signed: (hfarmer1) 26 Mar 2015 15:21:33

Generated On: 20 Jul 2016 12:37:46

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

If Not Done, please specify the reason: _____

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

Time hour:min 24-hour clock	20:11
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 2

Form: Plasma Cotinine Sample

Data signed: (hfarmer1) 26 Mar 2015 15:21:33

Generated On: 20 Jul 2016 12:37:46

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

If Not Done, please specify the reason: _____

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

Time hour:min 24-hour clock	20:11
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 2

Form: CoHb Blood Sample

Data signed: (hfarmer1) 26 Mar 2015 15:21:33

Generated On: 20 Jul 2016 12:37:46

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

If Not Done, please specify the reason: _____

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

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

Time hour:min 24-hour clock	20:11
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 2

Form: CO Breath Test <SA arm/> (1)

Data signed: (hfarmer1) 26 Mar 2015 15:21:33

Generated On: 20 Jul 2016 12:37:46

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

If Not Done, please specify the reason: _____

Scheduled Time	08:00 - 09:30 
----------------	---

Actual Time of Assessment hour:min 24-hour clock	08:22
---	-------

Result(ppm)	3
-------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 2

Form: CO Breath Test <SA arm/> (2)

Data signed: (hfarmer1) 26 Mar 2015 15:21:33

Generated On: 20 Jul 2016 12:37:46

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	12:19
---	-------

Result(ppm)	2
-------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 2

Form: CO Breath Test <SA arm/> (3)

Data signed: (hfarmer1) 26 Mar 2015 15:21:33

Generated On: 20 Jul 2016 12:37:46

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)	2
-------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 2

Form: CO Breath Test <SA arm/> (4)

Data signed: (hfarmer1) 26 Mar 2015 15:21:33

Generated On: 20 Jul 2016 12:37:46

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

If Not Done, please specify the reason: _____

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

Actual Time of Assessment hour:min 24-hour clock	20:11
---	-------

Result(ppm)	1
-------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 2

Form: 24 hour urine collections

Data signed: (hfarmer1) 26 Mar 2015 15:21:33

Generated On: 20 Jul 2016 12:37:46

Start Time	06:04
	hour:min 24-hour clock

End Date	16 FEB 2014
	DD/MMM/YYYY

End Time	06:04
	hour:min 24-hour clock

Volume	2109
	mL

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 2

Form: Sample Urine Collection

Data signed: (hfarmer1) 26 Mar 2015 15:21:33

Generated On: 20 Jul 2016 12:37:46

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: 1077**

Folder: Day 2

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Data signed: (hfarmer1) 26 Mar 2015 15:21:33

Generated On: 20 Jul 2016 12:37:46

Date of Birth

(b) (6)

Date of assessment
DD/MMM/YYYY

2014 FEB 15
DD/MMM/YYYY

Time of assessment

06:02
hour:min 24-hour clock

Assessment Status

Completed ☒

Please indicate for each of the items below, how you have been feeling over the past 24 hours

How have you been feeling over the past 24 hours?

Slight ☒

1. Angry, irritable, frustrated

How have you been feeling over the past 24 hours?

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?

Moderate ☒

4. Desire or craving to smoke

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 2

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Data signed: (hfarmer1) 26 Mar 2015 15:21:33

Generated On: 20 Jul 2016 12:37:46

How have you been feeling over the past 24 hours? Slight ☒

5. Difficulty concentrating

How have you been feeling over the past 24 hours? Slight ☒

6. Increased appetite, hungry, weight gain

How have you been feeling over the past 24 hours? None ☒

7. Insomnia, sleep problems, awakening at night

How have you been feeling over the past 24 hours? Slight ☒

8. Restless

How have you been feeling over the past 24 hours? Slight ☒

9. Impatient

How have you been feeling over the past 24 hours? None ☒

10. Constipation

How have you been feeling over the past 24 hours? None ☒

11. Dizziness

How have you been feeling over the past 24 hours? None ☒

12. Coughing

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 2

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Data signed: (hfarmer1) 26 Mar 2015 15:21:33

Generated On: 20 Jul 2016 12:37:46

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: 1077**

Folder: Day 2

Form: Cough Assessment

Data signed: (hfarmer1) 26 Mar 2015 15:21:34

Generated On: 20 Jul 2016 12:37:46

Date of Birth

(b) (6)

Date of assessment
DD/MMM/YYYY

2014 FEB 15
DD/MMM/YYYY

Time of assessment

06:00
hour:min 24-hour clock

Assessment Status

Completed ☒

Have you experienced a regular need to cough e.g.
coughing several times in the last 24 hrs?

No ☒

If YES, please answer the following questions:

First Question: Cough Impact Scale
How much is your cough bothering you?

-9

Second Question: Cough Intensity Scale:
How intense is your cough?

Not Applicable ☒

Third Question: Cough Frequency Scale:
How frequently do you normally have to cough each
day?

Not Applicable ☒

Fourth Question: Sputum Production
To what extent do you produce sputum when coughing?

Not Applicable ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 2

Form: Lab_BU_COHB (1)

Data signed: (hfarmer1) 26 Mar 2015 15:21:34

Generated On: 20 Jul 2016 12:37:46

Sample Barcode	05115150000469
----------------	----------------

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

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

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

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

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

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

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

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

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

Day of Visit	2
--------------	---

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

Date of Collection	2014-FEB-15
--------------------	-------------

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 2

Form: Lab_BU_COHB (1)

Data signed: (hfarmer1) 26 Mar 2015 15:21:34

Generated On: 20 Jul 2016 12:37:46

Start Day (24 hour urine only)

End Day (24 hour Urine Only)

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 2

Form: Questionnaire on smoking urges (QSU)

Data signed: (hfarmer1) 26 Mar 2015 15:21:33

Generated On: 20 Jul 2016 12:37:46

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

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

Date of assessment	2014 FEB 15
--------------------	-------------

DD/MMM/YYYY

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

hour:min 24-hour clock

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

1. I have a desire for a cigarette right now	Strongly agree <input checked="" type="radio"/>
--	---

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

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

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

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

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 2

Form: Questionnaire on smoking urges (QSU)

Data signed: (hfarmer1) 26 Mar 2015 15:21:33

Generated On: 20 Jul 2016 12:37:46

7. A cigarette would taste good now Strongly agree ☐

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

9. Smoking would make me less depressed Strongly disagree ☐

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 2

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

Data signed: (hfarmer1) 26 Mar 2015 15:21:34

Generated On: 20 Jul 2016 12:37:46

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 2

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

Data signed: (hfarmer1) 26 Mar 2015 15:21:34

Generated On: 20 Jul 2016 12:37:46

Sample Barcode	05112450000379
Analyte	HPMA
Sample type	URINE
Result	.
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	2
Celerion Study Number	AA99128-03
Date of Collection	2014-FEB-15
Timepoint-minutes	
Urine Start Day	2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 2

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

Data signed: (hfarmer1) 26 Mar 2015 15:21:34

Generated On: 20 Jul 2016 12:37:46

Urine End Day

3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 2

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

Data signed: (hfarmer1) 26 Mar 2015 15:21:34

Generated On: 20 Jul 2016 12:37:46

Sample Barcode	05112450000379
Analyte	CEMA
Sample type	URINE
Result	.
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	2
Celerion Study Number	AA99128-03
Date of Collection	2014-FEB-15
Timepoint-minutes	
Urine Start Day	2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 2

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

Data signed: (hfarmer1) 26 Mar 2015 15:21:34

Generated On: 20 Jul 2016 12:37:46

Urine End Day

3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 2

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

Data signed: (hfarmer1) 26 Mar 2015 15:21:34

Generated On: 20 Jul 2016 12:37:46

Sample Barcode	05112450000379
Analyte	HBMA
Sample type	URINE
Result	.
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	2
Celerion Study Number	AA99128-03
Date of Collection	2014-FEB-15
Timepoint-minutes	
Urine Start Day	2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 2

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

Data signed: (hfarmer1) 26 Mar 2015 15:21:34

Generated On: 20 Jul 2016 12:37:46

Urine End Day

3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 2

Form: Biomarker-Urine (NNN, NNAL)

Data signed: (hfarmer1) 26 Mar 2015 15:21:34

Generated On: 20 Jul 2016 12:37:46

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 2

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

Data signed: (hfarmer1) 26 Mar 2015 15:21:34

Generated On: 20 Jul 2016 12:37:46

Sample Barcode	05112460001490
Analyte	NNAL
Sample type	URINE
Result	.
Result Unit	PG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	2
Celerion Study Number	AA99128-04
Date of Collection	2014-FEB-15
Timepoint-minutes	
Urine Start Day	2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 2

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

Data signed: (hfarmer1) 26 Mar 2015 15:21:34

Generated On: 20 Jul 2016 12:37:46

Urine End Day

3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 2

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

Data signed: (hfarmer1) 26 Mar 2015 15:21:34

Generated On: 20 Jul 2016 12:37:46

Sample Barcode	05112460001490
Analyte	NNN
Sample type	URINE
Result	.
Result Unit	PG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	2
Celerion Study Number	AA99128-04
Date of Collection	2014-FEB-15
Timepoint-minutes	
Urine Start Day	2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 2

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

Data signed: (hfarmer1) 26 Mar 2015 15:21:34

Generated On: 20 Jul 2016 12:37:46

Urine End Day

3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 2

Form: Biomarker-Urine (HEMA)

Data signed: (hfarmer1) 26 Mar 2015 15:21:34

Generated On: 20 Jul 2016 12:37:46

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 2

Form: Biomarker-Urine (HEMA) (1)

Data signed: (hfarmer1) 26 Mar 2015 15:21:34

Generated On: 20 Jul 2016 12:37:46

Sample Barcode	05112470000368
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Analyte	HEMA
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Sample type	URINE
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Result	.
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Result Unit	NG/ML
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Lab Status	OTHER
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Sample comment	ANALYSIS NOT REQUIRED
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Detection method	LC-MS/MS
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Planned time point (Hour)	0
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Day of Visit	2
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Celerion Study Number	AA99128-05
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Date of Collection	2014-FEB-15
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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: 1077**

Folder: Day 2

Form: Biomarker-Urine (HEMA) (1)

Data signed: (hfarmer1) 26 Mar 2015 15:21:34

Generated On: 20 Jul 2016 12:37:46

Urine End Day

3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 2

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

Data signed: (hfarmer1) 26 Mar 2015 15:21:35

Generated On: 20 Jul 2016 12:37:46

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 2

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

Data signed: (hfarmer1) 26 Mar 2015 15:21:35

Generated On: 20 Jul 2016 12:37:46

Sample Barcode	05112550000038
Analyte	COT
Sample type	URINE
Result	.
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	2
Celerion Study Number	AA99128-13
Date of Collection	2014-FEB-15
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 2

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

Data signed: (hfarmer1) 26 Mar 2015 15:21:35

Generated On: 20 Jul 2016 12:37:46

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: 1077**

Folder: Day 2

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

Data signed: (hfarmer1) 26 Mar 2015 15:21:35

Generated On: 20 Jul 2016 12:37:46

Sample Barcode	05112550000038
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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
-------------	-------

Lab Status	OTHER
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Sample comment	ANALYSIS NOT REQUIRED
----------------	-----------------------

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	AA99128-13
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Date of Collection	2014-FEB-15
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Timepoint-minutes	
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 2

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

Data signed: (hfarmer1) 26 Mar 2015 15:21:35

Generated On: 20 Jul 2016 12:37:46

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: 1077**

Folder: Day 2

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

Data signed: (hfarmer1) 26 Mar 2015 15:21:35

Generated On: 20 Jul 2016 12:37:46

Sample Barcode	05112550000038
Analyte	NIC
Sample type	URINE
Result	.
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	2
Celerion Study Number	AA99128-13
Date of Collection	2014-FEB-15
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 2

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

Data signed: (hfarmer1) 26 Mar 2015 15:21:35

Generated On: 20 Jul 2016 12:37:46

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: 1077**

Folder: Day 2

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

Data signed: (hfarmer1) 26 Mar 2015 15:21:35

Generated On: 20 Jul 2016 12:37:46

Sample Barcode	05112550000038
Analyte	NIC-GLUC
Sample type	URINE
Result	.
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	2
Celerion Study Number	AA99128-13
Date of Collection	2014-FEB-15
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 2

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

Data signed: (hfarmer1) 26 Mar 2015 15:21:35

Generated On: 20 Jul 2016 12:37:46

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: 1077**

Folder: Day 2

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

Data signed: (hfarmer1) 26 Mar 2015 15:21:35

Generated On: 20 Jul 2016 12:37:46

Sample Barcode	05112550000038
Analyte	THCOT
Sample type	URINE
Result	.
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	2
Celerion Study Number	AA99128-13
Date of Collection	2014-FEB-15
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 2

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

Data signed: (hfarmer1) 26 Mar 2015 15:21:35

Generated On: 20 Jul 2016 12:37:46

Urine Start Day	2
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Urine End Day	3
---------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 2

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(6)**

Data signed: (hfarmer1) 26 Mar 2015 15:21:35

Generated On: 20 Jul 2016 12:37:46

Sample Barcode	05112550000038
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Analyte	THCOT-GLUC
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Sample type	URINE
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Result	.
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Result Unit	NG/ML
-------------	-------

Lab Status	OTHER
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Sample comment	ANALYSIS NOT REQUIRED
----------------	-----------------------

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

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

Day of Visit	2
--------------	---

Celerion Study Number	AA99128-13
-----------------------	------------

Date of Collection	2014-FEB-15
--------------------	-------------

Timepoint-minutes	
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 2

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(6)**

Data signed: (hfarmer1) 26 Mar 2015 15:21:35

Generated On: 20 Jul 2016 12:37:46

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: 1077**

Folder: Day 2

Form: Biomarker-Urine (3-OH BaP)

Data signed: (hfarmer1) 26 Mar 2015 15:21:35

Generated On: 20 Jul 2016 12:37:46

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 2

Form: Biomarker-Urine (3-OH BaP) (1)

Data signed: (hfarmer1) 26 Mar 2015 15:21:35

Generated On: 20 Jul 2016 12:37:46

Sample Barcode	05112490000368
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Analyte	3-OH BAP
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Sample type	URINE
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Result	.
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Result Unit	FG/ML
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Lab Status	OTHER
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Sample comment	ANALYSIS NOT REQUIRED
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Detection method	LC-MS/MS
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Planned time point (Hour)	0
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Day of Visit	2
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Celerion Study Number	AA99128-07
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Date of Collection	2014-FEB-15
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Timepoint-minutes	
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Urine Start Day	2
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 2

Form: Biomarker-Urine (3-OH BaP) (1)

Data signed: (hfarmer1) 26 Mar 2015 15:21:35

Generated On: 20 Jul 2016 12:37:46

Urine End Day

3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 2

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP)

Data signed: (hfarmer1) 26 Mar 2015 15:21:35

Generated On: 20 Jul 2016 12:37:46

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 2

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (1)

Data signed: (hfarmer1) 26 Mar 2015 15:21:35

Generated On: 20 Jul 2016 12:37:46

Sample Barcode	05112510000368
Analyte	1-NA
Sample type	URINE
Result	.
Result Unit	PG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	2
Celerion Study Number	AA99128-09
Date of Collection	2014-FEB-15
Timepoint-minutes	
Urine Start Day	2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 2

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (1)

Data signed: (hfarmer1) 26 Mar 2015 15:21:35

Generated On: 20 Jul 2016 12:37:46

Urine End Day

3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 2

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (2)

Data signed: (hfarmer1) 26 Mar 2015 15:21:35

Generated On: 20 Jul 2016 12:37:46

Sample Barcode	05112510000368
Analyte	2-NA
Sample type	URINE
Result	.
Result Unit	PG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	2
Celerion Study Number	AA99128-09
Date of Collection	2014-FEB-15
Timepoint-minutes	
Urine Start Day	2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 2

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (2)

Data signed: (hfarmer1) 26 Mar 2015 15:21:35

Generated On: 20 Jul 2016 12:37:46

Urine End Day

3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 2

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (3)

Data signed: (hfarmer1) 26 Mar 2015 15:21:35

Generated On: 20 Jul 2016 12:37:46

Sample Barcode	05112510000368
Analyte	4-ABP
Sample type	URINE
Result	.
Result Unit	PG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	2
Celerion Study Number	AA99128-09
Date of Collection	2014-FEB-15
Timepoint-minutes	
Urine Start Day	2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 2

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (3)

Data signed: (hfarmer1) 26 Mar 2015 15:21:35

Generated On: 20 Jul 2016 12:37:46

Urine End Day

3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 2

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (4)

Data signed: (hfarmer1) 26 Mar 2015 15:21:35

Generated On: 20 Jul 2016 12:37:46

Sample Barcode	05112510000368
Analyte	O-TOL
Sample type	URINE
Result	.
Result Unit	PG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	2
Celerion Study Number	AA99128-09
Date of Collection	2014-FEB-15
Timepoint-minutes	
Urine Start Day	2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 2

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (4)

Data signed: (hfarmer1) 26 Mar 2015 15:21:35

Generated On: 20 Jul 2016 12:37:46

Urine End Day

3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 2

Form: Biomarker-Urine (1-OHP)

Data signed: (hfarmer1) 26 Mar 2015 15:21:35

Generated On: 20 Jul 2016 12:37:46

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 2

Form: Biomarker-Urine (1-OHP) (1)

Data signed: (hfarmer1) 26 Mar 2015 15:21:35

Generated On: 20 Jul 2016 12:37:46

Sample Barcode	05115190001325
Analyte	1-OHP
Sample type	URINE
Result	.
Result Unit	PG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	2
Celerion Study Number	AA99598-03
Date of Collection	2014-FEB-15
Timepoint-minutes	
Urine Start Day	2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 2

Form: Biomarker-Urine (1-OHP) (1)

Data signed: (hfarmer1) 26 Mar 2015 15:21:35

Generated On: 20 Jul 2016 12:37:46

Urine End Day

3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 2

Form: Biomarker-Urine (SPMA, SBMA)

Data signed: (hfarmer1) 26 Mar 2015 15:21:34

Generated On: 20 Jul 2016 12:37:46

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 2

Form: Biomarker-Urine (SPMA, SBMA) (1)

Data signed: (hfarmer1) 26 Mar 2015 15:21:34

Generated On: 20 Jul 2016 12:37:46

Sample Barcode	05115170001281
Analyte	SBMA
Sample type	URINE
Result	.
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	2
Celerion Study Number	AA99598-01
Date of Collection	2014-FEB-15
Timepoint-minutes	
Urine Start Day	2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 2

Form: Biomarker-Urine (SPMA, SBMA) (1)

Data signed: (hfarmer1) 26 Mar 2015 15:21:34

Generated On: 20 Jul 2016 12:37:46

Urine End Day

3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 2

Form: Biomarker-Urine (SPMA, SBMA) (2)

Data signed: (hfarmer1) 26 Mar 2015 15:21:34

Generated On: 20 Jul 2016 12:37:46

Sample Barcode	05115170001281
Analyte	SPMA
Sample type	URINE
Result	.
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	2
Celerion Study Number	AA99598-01
Date of Collection	2014-FEB-15
Timepoint-minutes	
Urine Start Day	2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 2

Form: Biomarker-Urine (SPMA, SBMA) (2)

Data signed: (hfarmer1) 26 Mar 2015 15:21:34

Generated On: 20 Jul 2016 12:37:46

Urine End Day

3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 2

Form: Biomarker-Urine (MHBMA)

Data signed: (hfarmer1) 26 Mar 2015 15:21:34

Generated On: 20 Jul 2016 12:37:46

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 2

Form: Biomarker-Urine (MHBMA) (1)

Data signed: (hfarmer1) 26 Mar 2015 15:21:34

Generated On: 20 Jul 2016 12:37:46

Sample Barcode	05115180001325
Analyte	MHBMA
Sample type	URINE
Result	.
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	2
Celerion Study Number	AA99598-02
Date of Collection	2014-FEB-15
Timepoint-minutes	
Urine Start Day	2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 2

Form: Biomarker-Urine (MHBMA) (1)

Data signed: (hfarmer1) 26 Mar 2015 15:21:34

Generated On: 20 Jul 2016 12:37:46

Urine End Day

3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 2

Form: Biomarker-Urine (Creatinine)

Data signed: (hfarmer1) 26 Mar 2015 15:21:35

Generated On: 20 Jul 2016 12:37:46

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 2

Form: Biomarker-Urine (Creatinine) (1)

Data signed: (hfarmer1) 26 Mar 2015 15:21:35

Generated On: 20 Jul 2016 12:37:46

Sample Barcode	05115160000674
Analyte	CREATININE
Sample type	URINE
Result	.
Result Unit	MG/DL
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	SPECTROPHOTOMETRIC
Planned time point (Hour)	0
Day of Visit	2
Celerion Study Number	AA99128-14
Date of Collection	2014-FEB-15
Timepoint-minutes	
Urine Start Day	2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 2

Form: Biomarker-Urine (Creatinine) (1)

Data signed: (hfarmer1) 26 Mar 2015 15:21:35

Generated On: 20 Jul 2016 12:37:46

Urine End Day

3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 2

Form: Biomarker-Plasma (Nic, Cot, tHCot)

Data signed: (hfarmer1) 26 Mar 2015 15:21:34

Generated On: 20 Jul 2016 12:37:46

Sample type

PLASMA

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 2

Form: Biomarker-Plasma (Nic, Cot, tHCot) (1)

Data signed: (hfarmer1) 26 Mar 2015 15:21:34

Generated On: 20 Jul 2016 12:37:46

Sample Barcode	05112440000033
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Analyte	COT
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Sample type	PLASMA
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Result	.
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Result Unit	NG/ML
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Lab Status	OTHER
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Sample comment	ANALYSIS NOT REQUIRED
----------------	-----------------------

Detection method	LC-MS/MS
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Planned time point (Hour)	0
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Day of Visit	2
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Celerion Study Number	AA99128-02
-----------------------	------------

Date of Collection	2014-FEB-15
--------------------	-------------

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: 1077**

Folder: Day 2

Form: Biomarker-Plasma (Nic, Cot, tHCot) (1)

Data signed: (hfarmer1) 26 Mar 2015 15:21:34

Generated On: 20 Jul 2016 12:37:46

Urine End Day

2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 2

Form: Biomarker-Plasma (Nic, Cot, tHCot) (2)

Data signed: (hfarmer1) 26 Mar 2015 15:21:34

Generated On: 20 Jul 2016 12:37:46

Sample Barcode	05112440000033
----------------	----------------

Analyte	NIC
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Sample type	PLASMA
-------------	--------

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

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

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

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

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

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

Day of Visit	2
--------------	---

Celerion Study Number	AA99128-02
-----------------------	------------

Date of Collection	2014-FEB-15
--------------------	-------------

Timepoint-minutes	0
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Urine Start Day	
-----------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 2

Form: Biomarker-Plasma (Nic, Cot, tHCot) (2)

Data signed: (hfarmer1) 26 Mar 2015 15:21:34

Generated On: 20 Jul 2016 12:37:46

Urine End Day

2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 3

Form: Date of Visit

Data signed: (hfarmer1) 26 Mar 2015 15:21:35

Generated On: 20 Jul 2016 12:37:46

Date of Visit

16 FEB 2014
DD/MMM/YYYY

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 3

Form: Vital Signs

Data signed: (hcoleman1) 18 Jun 2015 20:00:10

Generated On: 20 Jul 2016 12:37:46

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

10:45
hour:min 24-hour clock

Pulse rate

55
beats per minute

Respiratory rate

18
breaths per minute

Blood Pressure (systolic)

104
mmHg

Blood Pressure (diastolic)

74
mmHg

Vital Signs Position of Subject

Supine ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 3

Form: Plasma Nicotine Sample

Data signed: (hfarmer1) 26 Mar 2015 15:21:35

Generated On: 20 Jul 2016 12:37:46

Not Done	False
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If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	16 FEB 2014
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Time hour:min 24-hour clock	20:17
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 3

Form: Plasma Cotinine Sample

Data signed: (hfarmer1) 26 Mar 2015 15:21:35

Generated On: 20 Jul 2016 12:37:46

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	16 FEB 2014
---------------------	-------------

Time hour:min 24-hour clock	20:17
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 3

Form: CoHb Blood Sample

Data signed: (hfarmer1) 26 Mar 2015 15:21:35

Generated On: 20 Jul 2016 12:37:46

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	16 FEB 2014
---------------------	-------------

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

Time hour:min 24-hour clock	20:17
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 3

Form: CO Breath Test <SA arm/> (1)

Data signed: (hfarmer1) 26 Mar 2015 15:21:36

Generated On: 20 Jul 2016 12:37:46

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

If Not Done, please specify the reason: _____

Scheduled Time	08:00 - 09:30 <input checked="" type="radio"/>
----------------	--

Actual Time of Assessment hour:min 24-hour clock	08:51
---	-------

Result(ppm)	0
-------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 3

Form: CO Breath Test <SA arm/> (2)

Data signed: (hfarmer1) 26 Mar 2015 15:21:36

Generated On: 20 Jul 2016 12:37:46

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	12:56
---	-------

Result(ppm)	2
-------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 3

Form: CO Breath Test <SA arm/> (3)

Data signed: (hfarmer1) 26 Mar 2015 15:21:36

Generated On: 20 Jul 2016 12:37:46

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	16:22
---	-------

Result(ppm)	2
-------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 3

Form: CO Breath Test <SA arm/> (4)

Data signed: (hfarmer1) 26 Mar 2015 15:21:36

Generated On: 20 Jul 2016 12:37:46

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)	1
-------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 3

Form: 24 hour urine collections

Data signed: (hfarmer1) 26 Mar 2015 15:21:35

Generated On: 20 Jul 2016 12:37:46

Start Time	06:04
	hour:min 24-hour clock

End Date	17 FEB 2014
	DD/MMM/YYYY

End Time	06:02
	hour:min 24-hour clock

Volume	1443
	mL

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 3

Form: Sample Urine Collection

Data signed: (hfarmer1) 26 Mar 2015 15:21:35

Generated On: 20 Jul 2016 12:37:46

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: 1077

Folder: Day 3

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Data signed: (hfarmer1) 26 Mar 2015 15:21:36

Generated On: 20 Jul 2016 12:37:46

Date of Birth

(b) (6)

Date of assessment
DD/MMM/YYYY

2014 FEB 16
DD/MMM/YYYY

Time of assessment

06:02
hour:min 24-hour clock

Assessment Status

Completed ☒

Please indicate for each of the items below, how you have been feeling over the past 24 hours

How have you been feeling over the past 24 hours?

None ☐

1. Angry, irritable, frustrated

How have you been feeling over the past 24 hours?

None ☐

2. Anxious, nervous

How have you been feeling over the past 24 hours?

None ☐

3. Depressed Mood, sad

How have you been feeling over the past 24 hours?

Moderate ☐

4. Desire or craving to smoke

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 3

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Data signed: (hfarmer1) 26 Mar 2015 15:21:36

Generated On: 20 Jul 2016 12:37:46

How have you been feeling over the past 24 hours? None ☐

5. Difficulty concentrating

How have you been feeling over the past 24 hours? Mild ☐

6. Increased appetite, hungry, weight gain

How have you been feeling over the past 24 hours? None ☐

7. Insomnia, sleep problems, awakening at night

How have you been feeling over the past 24 hours? None ☐

8. Restless

How have you been feeling over the past 24 hours? None ☐

9. Impatient

How have you been feeling over the past 24 hours? None ☐

10. Constipation

How have you been feeling over the past 24 hours? None ☐

11. Dizziness

How have you been feeling over the past 24 hours? None ☐

12. Coughing

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 3

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Data signed: (hfarmer1) 26 Mar 2015 15:21:36

Generated On: 20 Jul 2016 12:37:46

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: 1077

Folder: Day 3

Form: Cough Assessment

Data signed: (hfarmer1) 26 Mar 2015 15:21:36

Generated On: 20 Jul 2016 12:37:46

Date of Birth

(b) (6)

Date of assessment
DD/MMM/YYYY

2014 FEB 16
DD/MMM/YYYY

Time of assessment

06:00
hour:min 24-hour clock

Assessment Status

Completed ☒

Have you experienced a regular need to cough e.g.
coughing several times in the last 24 hrs?

No ☒

If YES, please answer the following questions:

First Question: Cough Impact Scale
How much is your cough bothering you?

-9

Second Question: Cough Intensity Scale:
How intense is your cough?

Not Applicable ☒

Third Question: Cough Frequency Scale:
How frequently do you normally have to cough each
day?

Not Applicable ☒

Fourth Question: Sputum Production
To what extent do you produce sputum when coughing?

Not Applicable ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 3

Form: Lab_BU_COHB (1)

Data signed: (hfarmer1) 26 Mar 2015 15:21:37

Generated On: 20 Jul 2016 12:37:46

Sample Barcode	05115150000470
Analyte	CARBOXYHEMOGLOBIN
Sample type	BLOOD
Result	.
Result Unit	%
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	SPECTROPHOTOMETRIC
Lower limit of quantification	0.500
Planned time point (Hour)	20
Day of Visit	3
Celerion Study Number	AA99128-16
Date of Collection	2014-FEB-16
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 3

Form: Lab_BU_COHB (1)

Data signed: (hfarmer1) 26 Mar 2015 15:21:37

Generated On: 20 Jul 2016 12:37:46

Start Day (24 hour urine only) _____

End Day (24 hour Urine Only) _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 3

Form: Questionnaire on smoking urges (QSU)

Data signed: (hfarmer1) 26 Mar 2015 15:21:36

Generated On: 20 Jul 2016 12:37:46

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

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

Date of assessment	2014 FEB 16
--------------------	-------------

DD/MMM/YYYY

Time of assessment	20:16
--------------------	-------

hour:min 24-hour clock

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

1. I have a desire for a cigarette right now	Agree <input checked="" type="radio"/>
--	--

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

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

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

5. All I want right now is a cigarette	Do not agree or 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: 1077**

Folder: Day 3

Form: Questionnaire on smoking urges (QSU)

Data signed: (hfarmer1) 26 Mar 2015 15:21:36

Generated On: 20 Jul 2016 12:37:46

7. A cigarette would taste good now Somewhat agree ☐

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

9. Smoking would make me less depressed Disagree ☐

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 3

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

Data signed: (hfarmer1) 26 Mar 2015 15:21:37

Generated On: 20 Jul 2016 12:37:46

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 3

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

Data signed: (hfarmer1) 26 Mar 2015 15:21:37

Generated On: 20 Jul 2016 12:37:46

Sample Barcode	05112450000380
----------------	----------------

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

Sample type	URINE
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Result	.
--------	---

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

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

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

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

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

Day of Visit	3
--------------	---

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

Date of Collection	2014-FEB-16
--------------------	-------------

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

Urine Start Day	3
-----------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 3

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

Data signed: (hfarmer1) 26 Mar 2015 15:21:37

Generated On: 20 Jul 2016 12:37:46

Urine End Day

4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 3

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

Data signed: (hfarmer1) 26 Mar 2015 15:21:37

Generated On: 20 Jul 2016 12:37:46

Sample Barcode	05112450000380
Analyte	CEMA
Sample type	URINE
Result	.
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	3
Celerion Study Number	AA99128-03
Date of Collection	2014-FEB-16
Timepoint-minutes	
Urine Start Day	3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 3

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

Data signed: (hfarmer1) 26 Mar 2015 15:21:37

Generated On: 20 Jul 2016 12:37:46

Urine End Day

4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 3

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

Data signed: (hfarmer1) 26 Mar 2015 15:21:37

Generated On: 20 Jul 2016 12:37:46

Sample Barcode	05112450000380
Analyte	HBMA
Sample type	URINE
Result	.
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	3
Celerion Study Number	AA99128-03
Date of Collection	2014-FEB-16
Timepoint-minutes	
Urine Start Day	3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 3

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

Data signed: (hfarmer1) 26 Mar 2015 15:21:37

Generated On: 20 Jul 2016 12:37:46

Urine End Day

4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 3

Form: Biomarker-Urine (NNN, NNAL)

Data signed: (hfarmer1) 26 Mar 2015 15:21:36

Generated On: 20 Jul 2016 12:37:46

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 3

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

Data signed: (hfarmer1) 26 Mar 2015 15:21:36

Generated On: 20 Jul 2016 12:37:46

Sample Barcode	05112460001491
Analyte	NNAL
Sample type	URINE
Result	.
Result Unit	PG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	3
Celerion Study Number	AA99128-04
Date of Collection	2014-FEB-16
Timepoint-minutes	
Urine Start Day	3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 3

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

Data signed: (hfarmer1) 26 Mar 2015 15:21:36

Generated On: 20 Jul 2016 12:37:46

Urine End Day

4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 3

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

Data signed: (hfarmer1) 26 Mar 2015 15:21:36

Generated On: 20 Jul 2016 12:37:46

Sample Barcode	05112460001491
Analyte	NNN
Sample type	URINE
Result	.
Result Unit	PG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	3
Celerion Study Number	AA99128-04
Date of Collection	2014-FEB-16
Timepoint-minutes	
Urine Start Day	3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 3

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

Data signed: (hfarmer1) 26 Mar 2015 15:21:36

Generated On: 20 Jul 2016 12:37:46

Urine End Day

4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 3

Form: Biomarker-Urine (HEMA)

Data signed: (hfarmer1) 26 Mar 2015 15:21:36

Generated On: 20 Jul 2016 12:37:46

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 3

Form: Biomarker-Urine (HEMA) (1)

Data signed: (hfarmer1) 26 Mar 2015 15:21:36

Generated On: 20 Jul 2016 12:37:46

Sample Barcode	05112470000369
Analyte	HEMA
Sample type	URINE
Result	.
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	3
Celerion Study Number	AA99128-05
Date of Collection	2014-FEB-16
Timepoint-minutes	
Urine Start Day	3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 3

Form: Biomarker-Urine (HEMA) (1)

Data signed: (hfarmer1) 26 Mar 2015 15:21:36

Generated On: 20 Jul 2016 12:37:46

Urine End Day

4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 3

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

Data signed: (hfarmer1) 26 Mar 2015 15:21:38

Generated On: 20 Jul 2016 12:37:46

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 3

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

Data signed: (hfarmer1) 26 Mar 2015 15:21:38

Generated On: 20 Jul 2016 12:37:46

Sample Barcode	05112550000039
Analyte	COT
Sample type	URINE
Result	.
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	3
Celerion Study Number	AA99128-13
Date of Collection	2014-FEB-16
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 3

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

Data signed: (hfarmer1) 26 Mar 2015 15:21:38

Generated On: 20 Jul 2016 12:37:46

Urine Start Day	3
-----------------	---

Urine End Day	4
---------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 3

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

Data signed: (hfarmer1) 26 Mar 2015 15:21:38

Generated On: 20 Jul 2016 12:37:46

Sample Barcode	05112550000039
Analyte	COT-GLUC
Sample type	URINE
Result	.
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	3
Celerion Study Number	AA99128-13
Date of Collection	2014-FEB-16
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 3

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

Data signed: (hfarmer1) 26 Mar 2015 15:21:38

Generated On: 20 Jul 2016 12:37:46

Urine Start Day	3
-----------------	---

Urine End Day	4
---------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 3

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

Data signed: (hfarmer1) 26 Mar 2015 15:21:38

Generated On: 20 Jul 2016 12:37:46

Sample Barcode	05112550000039
Analyte	NIC
Sample type	URINE
Result	.
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	3
Celerion Study Number	AA99128-13
Date of Collection	2014-FEB-16
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 3

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

Data signed: (hfarmer1) 26 Mar 2015 15:21:38

Generated On: 20 Jul 2016 12:37:46

Urine Start Day	3
-----------------	---

Urine End Day	4
---------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 3

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

Data signed: (hfarmer1) 26 Mar 2015 15:21:38

Generated On: 20 Jul 2016 12:37:46

Sample Barcode	05112550000039
Analyte	NIC-GLUC
Sample type	URINE
Result	.
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	3
Celerion Study Number	AA99128-13
Date of Collection	2014-FEB-16
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 3

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

Data signed: (hfarmer1) 26 Mar 2015 15:21:38

Generated On: 20 Jul 2016 12:37:46

Urine Start Day	3
-----------------	---

Urine End Day	4
---------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 3

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

Data signed: (hfarmer1) 26 Mar 2015 15:21:38

Generated On: 20 Jul 2016 12:37:46

Sample Barcode	05112550000039
Analyte	THCOT
Sample type	URINE
Result	.
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	3
Celerion Study Number	AA99128-13
Date of Collection	2014-FEB-16
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 3

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

Data signed: (hfarmer1) 26 Mar 2015 15:21:38

Generated On: 20 Jul 2016 12:37:46

Urine Start Day	3
-----------------	---

Urine End Day	4
---------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 3

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(6)**

Data signed: (hfarmer1) 26 Mar 2015 15:21:38

Generated On: 20 Jul 2016 12:37:46

Sample Barcode	05112550000039
Analyte	THCOT-GLUC
Sample type	URINE
Result	.
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	3
Celerion Study Number	AA99128-13
Date of Collection	2014-FEB-16
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 3

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(6)**

Data signed: (hfarmer1) 26 Mar 2015 15:21:38

Generated On: 20 Jul 2016 12:37:46

Urine Start Day	3
-----------------	---

Urine End Day	4
---------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 3

Form: Biomarker-Urine (3-OH BaP)

Data signed: (hfarmer1) 26 Mar 2015 15:21:38

Generated On: 20 Jul 2016 12:37:46

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 3

Form: Biomarker-Urine (3-OH BaP) (1)

Data signed: (hfarmer1) 26 Mar 2015 15:21:38

Generated On: 20 Jul 2016 12:37:46

Sample Barcode	05112490000369
Analyte	3-OH BAP
Sample type	URINE
Result	.
Result Unit	FG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	3
Celerion Study Number	AA99128-07
Date of Collection	2014-FEB-16
Timepoint-minutes	
Urine Start Day	3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 3

Form: Biomarker-Urine (3-OH BaP) (1)

Data signed: (hfarmer1) 26 Mar 2015 15:21:38

Generated On: 20 Jul 2016 12:37:46

Urine End Day

4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 3

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP)

Data signed: (hfarmer1) 26 Mar 2015 15:21:38

Generated On: 20 Jul 2016 12:37:46

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 3

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (1)

Data signed: (hfarmer1) 26 Mar 2015 15:21:38

Generated On: 20 Jul 2016 12:37:46

Sample Barcode	05112510000369
Analyte	1-NA
Sample type	URINE
Result	.
Result Unit	PG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	3
Celerion Study Number	AA99128-09
Date of Collection	2014-FEB-16
Timepoint-minutes	
Urine Start Day	3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 3

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (1)

Data signed: (hfarmer1) 26 Mar 2015 15:21:38

Generated On: 20 Jul 2016 12:37:46

Urine End Day

4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 3

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (2)

Data signed: (hfarmer1) 26 Mar 2015 15:21:38

Generated On: 20 Jul 2016 12:37:46

Sample Barcode	05112510000369
Analyte	2-NA
Sample type	URINE
Result	.
Result Unit	PG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	3
Celerion Study Number	AA99128-09
Date of Collection	2014-FEB-16
Timepoint-minutes	
Urine Start Day	3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 3

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (2)

Data signed: (hfarmer1) 26 Mar 2015 15:21:38

Generated On: 20 Jul 2016 12:37:46

Urine End Day

4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 3

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (3)

Data signed: (hfarmer1) 26 Mar 2015 15:21:38

Generated On: 20 Jul 2016 12:37:46

Sample Barcode	05112510000369
Analyte	4-ABP
Sample type	URINE
Result	.
Result Unit	PG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	3
Celerion Study Number	AA99128-09
Date of Collection	2014-FEB-16
Timepoint-minutes	
Urine Start Day	3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 3

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (3)

Data signed: (hfarmer1) 26 Mar 2015 15:21:38

Generated On: 20 Jul 2016 12:37:46

Urine End Day

4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 3

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (4)

Data signed: (hfarmer1) 26 Mar 2015 15:21:38

Generated On: 20 Jul 2016 12:37:46

Sample Barcode	05112510000369
Analyte	O-TOL
Sample type	URINE
Result	.
Result Unit	PG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	3
Celerion Study Number	AA99128-09
Date of Collection	2014-FEB-16
Timepoint-minutes	
Urine Start Day	3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 3

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (4)

Data signed: (hfarmer1) 26 Mar 2015 15:21:38

Generated On: 20 Jul 2016 12:37:46

Urine End Day

4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 3

Form: Biomarker-Urine (1-OHP)

Data signed: (hfarmer1) 26 Mar 2015 15:21:39

Generated On: 20 Jul 2016 12:37:46

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 3

Form: Biomarker-Urine (1-OHP) (1)

Data signed: (hfarmer1) 26 Mar 2015 15:21:39

Generated On: 20 Jul 2016 12:37:46

Sample Barcode	05115190001326
Analyte	1-OHP
Sample type	URINE
Result	.
Result Unit	PG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	3
Celerion Study Number	AA99598-03
Date of Collection	2014-FEB-16
Timepoint-minutes	
Urine Start Day	3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 3

Form: Biomarker-Urine (1-OHP) (1)

Data signed: (hfarmer1) 26 Mar 2015 15:21:39

Generated On: 20 Jul 2016 12:37:46

Urine End Day

4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 3

Form: Biomarker-Urine (SPMA, SBMA)

Data signed: (hfarmer1) 26 Mar 2015 15:21:36

Generated On: 20 Jul 2016 12:37:46

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 3

Form: Biomarker-Urine (SPMA, SBMA) (1)

Data signed: (hfarmer1) 26 Mar 2015 15:21:36

Generated On: 20 Jul 2016 12:37:46

Sample Barcode	05115170001282
Analyte	SBMA
Sample type	URINE
Result	.
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	3
Celerion Study Number	AA99598-01
Date of Collection	2014-FEB-16
Timepoint-minutes	
Urine Start Day	3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 3

Form: Biomarker-Urine (SPMA, SBMA) (1)

Data signed: (hfarmer1) 26 Mar 2015 15:21:36

Generated On: 20 Jul 2016 12:37:46

Urine End Day

4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 3

Form: Biomarker-Urine (SPMA, SBMA) (2)

Data signed: (hfarmer1) 26 Mar 2015 15:21:36

Generated On: 20 Jul 2016 12:37:46

Sample Barcode	05115170001282
Analyte	SPMA
Sample type	URINE
Result	.
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	3
Celerion Study Number	AA99598-01
Date of Collection	2014-FEB-16
Timepoint-minutes	
Urine Start Day	3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 3

Form: Biomarker-Urine (SPMA, SBMA) (2)

Data signed: (hfarmer1) 26 Mar 2015 15:21:36

Generated On: 20 Jul 2016 12:37:46

Urine End Day

4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 3

Form: Biomarker-Urine (MHBMA)

Data signed: (hfarmer1) 26 Mar 2015 15:21:37

Generated On: 20 Jul 2016 12:37:46

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 3

Form: Biomarker-Urine (MHBMA) (1)

Data signed: (hfarmer1) 26 Mar 2015 15:21:37

Generated On: 20 Jul 2016 12:37:46

Sample Barcode	05115180001326
Analyte	MHBMA
Sample type	URINE
Result	.
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	3
Celerion Study Number	AA99598-02
Date of Collection	2014-FEB-16
Timepoint-minutes	
Urine Start Day	3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 3

Form: Biomarker-Urine (MHBMA) (1)

Data signed: (hfarmer1) 26 Mar 2015 15:21:37

Generated On: 20 Jul 2016 12:37:46

Urine End Day

4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 3

Form: Biomarker-Urine (Creatinine)

Data signed: (hfarmer1) 26 Mar 2015 15:21:39

Generated On: 20 Jul 2016 12:37:46

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 3

Form: Biomarker-Urine (Creatinine) (1)

Data signed: (hfarmer1) 26 Mar 2015 15:21:39

Generated On: 20 Jul 2016 12:37:46

Sample Barcode	05115160000675
Analyte	CREATININE
Sample type	URINE
Result	.
Result Unit	MG/DL
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	SPECTROPHOTOMETRIC
Planned time point (Hour)	0
Day of Visit	3
Celerion Study Number	AA99128-14
Date of Collection	2014-FEB-16
Timepoint-minutes	
Urine Start Day	3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 3

Form: Biomarker-Urine (Creatinine) (1)

Data signed: (hfarmer1) 26 Mar 2015 15:21:39

Generated On: 20 Jul 2016 12:37:46

Urine End Day

4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 3

Form: Biomarker-Plasma (Nic, Cot, tHCot)

Data signed: (hfarmer1) 26 Mar 2015 15:21:37

Generated On: 20 Jul 2016 12:37:46

Sample type

PLASMA

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 3

Form: Biomarker-Plasma (Nic, Cot, tHCot) (1)

Data signed: (hfarmer1) 26 Mar 2015 15:21:37

Generated On: 20 Jul 2016 12:37:46

Sample Barcode	05112440000034
----------------	----------------

Analyte	COT
---------	-----

Sample type	PLASMA
-------------	--------

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

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

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

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

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

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

Day of Visit	3
--------------	---

Celerion Study Number	AA99128-02
-----------------------	------------

Date of Collection	2014-FEB-16
--------------------	-------------

Timepoint-minutes	0
-------------------	---

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 3

Form: Biomarker-Plasma (Nic, Cot, tHCot) (1)

Data signed: (hfarmer1) 26 Mar 2015 15:21:37

Generated On: 20 Jul 2016 12:37:46

Urine End Day

3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 3

Form: Biomarker-Plasma (Nic, Cot, tHCot) (2)

Data signed: (hfarmer1) 26 Mar 2015 15:21:37

Generated On: 20 Jul 2016 12:37:46

Sample Barcode	05112440000034
----------------	----------------

Analyte	NIC
---------	-----

Sample type	PLASMA
-------------	--------

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

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

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

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

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

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

Day of Visit	3
--------------	---

Celerion Study Number	AA99128-02
-----------------------	------------

Date of Collection	2014-FEB-16
--------------------	-------------

Timepoint-minutes	0
-------------------	---

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 3

Form: Biomarker-Plasma (Nic, Cot, tHCot) (2)

Data signed: (hfarmer1) 26 Mar 2015 15:21:37

Generated On: 20 Jul 2016 12:37:46

Urine End Day

3

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 4

Form: Date of Visit

Data signed: (hfarmer1) 26 Mar 2015 15:21:40

Generated On: 20 Jul 2016 12:37:46

Date of Visit

17 FEB 2014
DD/MMM/YYYY

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 4

Form: Vital Signs

Data signed: (hcoleman1) 18 Jun 2015 20:00:10

Generated On: 20 Jul 2016 12:37:46

Were Vitals Signs assessed? Yes ☒

If No, please specify the reason: _____

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

Time of assessment 10:18
hour:min 24-hour clock

Pulse rate 53
beats per minute

Respiratory rate 16
breaths per minute

Blood Pressure (systolic) 111
mmHg

Blood Pressure (diastolic) 64
mmHg

Vital Signs Position of Subject Supine ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 4

Form: Socio-Economic Status

Data signed: (hfarmer1) 26 Mar 2015 15:21:39

Generated On: 20 Jul 2016 12:37:46

Was paper questionnaire used? Yes ☒

Reason not done _____

Date 17 FEB 2014
DD/MMM/YYYY

Time 10:21
hour:min 24-hour clock

Q1. What is the highest level of education you have completed? Some College ☒

Q2. What is your current occupational status? Working now ☒

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? 01

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 4

Form: Socio-Economic Status

Data signed: (hfarmer1) 26 Mar 2015 15:21:39

Generated On: 20 Jul 2016 12:37:46

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.

\$30,000 through \$44,999 ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 4

Form: Plasma Nicotine Sample

Data signed: (hfarmer1) 26 Mar 2015 15:21:39

Generated On: 20 Jul 2016 12:37:46

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	17 FEB 2014
---------------------	-------------

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 4

Form: Plasma Cotinine Sample

Data signed: (hfarmer1) 26 Mar 2015 15:21:39

Generated On: 20 Jul 2016 12:37:46

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	17 FEB 2014
---------------------	-------------

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 4

Form: CoHb Blood Sample

Data signed: (hfarmer1) 26 Mar 2015 15:21:39

Generated On: 20 Jul 2016 12:37:46

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	17 FEB 2014
---------------------	-------------

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

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 4

Form: CO Breath Test <SA arm/> (1)

Data signed: (hfarmer1) 26 Mar 2015 15:21:40

Generated On: 20 Jul 2016 12:37:46

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

If Not Done, please specify the reason: _____

Scheduled Time	08:00 - 09:30 
----------------	---

Actual Time of Assessment hour:min 24-hour clock	08:35
---	-------

Result(ppm)	1
-------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 4

Form: CO Breath Test <SA arm/> (2)

Data signed: (hfarmer1) 26 Mar 2015 15:21:40

Generated On: 20 Jul 2016 12:37:46

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)	2
-------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 4

Form: CO Breath Test <SA arm/> (3)

Data signed: (hfarmer1) 26 Mar 2015 15:21:40

Generated On: 20 Jul 2016 12:37:46

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

If Not Done, please specify the reason: _____

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

Actual Time of Assessment hour:min 24-hour clock	16:27
---	-------

Result(ppm)	2
-------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 4

Form: CO Breath Test <SA arm/> (4)

Data signed: (hfarmer1) 26 Mar 2015 15:21:40

Generated On: 20 Jul 2016 12:37:46

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	20:11
---	-------

Result(ppm)	1
-------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 4

Form: 24 hour urine collections

Data signed: (hfarmer1) 26 Mar 2015 15:21:40

Generated On: 20 Jul 2016 12:37:46

Start Time	06:02
	hour:min 24-hour clock

End Date	18 FEB 2014
	DD/MMM/YYYY

End Time	06:11
	hour:min 24-hour clock

Volume	1176
	mL

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 4

Form: Sample Urine Collection

Data signed: (hfarmer1) 26 Mar 2015 15:21:39

Generated On: 20 Jul 2016 12:37:46

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: 1077**

Folder: Day 4

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Data signed: (hfarmer1) 26 Mar 2015 15:21:40

Generated On: 20 Jul 2016 12:37:46

Date of Birth

(b) (6)

Date of assessment
DD/MMM/YYYY

2014 FEB 17
DD/MMM/YYYY

Time of assessment

06:03
hour:min 24-hour clock

Assessment Status

Completed ☒

Please indicate for each of the items below, how you have been feeling over the past 24 hours

How have you been feeling over the past 24 hours?

None ☐

1. Angry, irritable, frustrated

How have you been feeling over the past 24 hours?

None ☐

2. Anxious, nervous

How have you been feeling over the past 24 hours?

None ☐

3. Depressed Mood, sad

How have you been feeling over the past 24 hours?

Moderate ☐

4. Desire or craving to smoke

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 4

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Data signed: (hfarmer1) 26 Mar 2015 15:21:40

Generated On: 20 Jul 2016 12:37:46

How have you been feeling over the past 24 hours? None ☐

5. Difficulty concentrating

How have you been feeling over the past 24 hours? None ☐

6. Increased appetite, hungry, weight gain

How have you been feeling over the past 24 hours? None ☐

7. Insomnia, sleep problems, awakening at night

How have you been feeling over the past 24 hours? None ☐

8. Restless

How have you been feeling over the past 24 hours? None ☐

9. Impatient

How have you been feeling over the past 24 hours? None ☐

10. Constipation

How have you been feeling over the past 24 hours? None ☐

11. Dizziness

How have you been feeling over the past 24 hours? None ☐

12. Coughing

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 4

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Data signed: (hfarmer1) 26 Mar 2015 15:21:40

Generated On: 20 Jul 2016 12:37:46

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: 1077**

Folder: Day 4

Form: Cough Assessment

Data signed: (hfarmer1) 26 Mar 2015 15:21:40

Generated On: 20 Jul 2016 12:37:46

Date of Birth

(b) (6)

Date of assessment
DD/MMM/YYYY

2014 FEB 17
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?

No ☒

If YES, please answer the following questions:

First Question: Cough Impact Scale
How much is your cough bothering you?

-9

Second Question: Cough Intensity Scale:
How intense is your cough?

Not Applicable ☒

Third Question: Cough Frequency Scale:
How frequently do you normally have to cough each
day?

Not Applicable ☒

Fourth Question: Sputum Production
To what extent do you produce sputum when coughing?

Not Applicable ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 4

Form: Lab_BU_COHB (1)

Data signed: (hfarmer1) 26 Mar 2015 15:21:41

Generated On: 20 Jul 2016 12:37:46

Sample Barcode	05115150000471
----------------	----------------

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

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

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

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

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

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

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

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

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

Day of Visit	4
--------------	---

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

Date of Collection	2014-FEB-17
--------------------	-------------

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 4

Form: Lab_BU_COHB (1)

Data signed: (hfarmer1) 26 Mar 2015 15:21:41

Generated On: 20 Jul 2016 12:37:46

Start Day (24 hour urine only)

End Day (24 hour Urine Only)

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 4

Form: Questionnaire on smoking urges (QSU)

Data signed: (hfarmer1) 26 Mar 2015 15:21:40

Generated On: 20 Jul 2016 12:37:46

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

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

Date of assessment	2014 FEB 17
--------------------	-------------

DD/MMM/YYYY

Time of assessment	20:10
--------------------	-------

hour:min 24-hour clock

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

1. I have a desire for a cigarette right now	Somewhat agree <input checked="" type="radio"/>
--	---

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

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

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

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

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 4

Form: Questionnaire on smoking urges (QSU)

Data signed: (hfarmer1) 26 Mar 2015 15:21:40

Generated On: 20 Jul 2016 12:37:46

7. A cigarette would taste good now Somewhat agree ☐

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

9. Smoking would make me less depressed Strongly disagree ☐

10. I am going to smoke as soon as possible Disagree ☐

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 4

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

Data signed: (hfarmer1) 26 Mar 2015 15:21:41

Generated On: 20 Jul 2016 12:37:46

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 4

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

Data signed: (hfarmer1) 26 Mar 2015 15:21:41

Generated On: 20 Jul 2016 12:37:46

Sample Barcode	05112450000381
Analyte	HPMA
Sample type	URINE
Result	.
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	4
Celerion Study Number	AA99128-03
Date of Collection	2014-FEB-17
Timepoint-minutes	
Urine Start Day	4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 4

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

Data signed: (hfarmer1) 26 Mar 2015 15:21:41

Generated On: 20 Jul 2016 12:37:46

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 4

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

Data signed: (hfarmer1) 26 Mar 2015 15:21:41

Generated On: 20 Jul 2016 12:37:46

Sample Barcode	05112450000381
Analyte	CEMA
Sample type	URINE
Result	.
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	4
Celerion Study Number	AA99128-03
Date of Collection	2014-FEB-17
Timepoint-minutes	
Urine Start Day	4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 4

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

Data signed: (hfarmer1) 26 Mar 2015 15:21:41

Generated On: 20 Jul 2016 12:37:46

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 4

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

Data signed: (hfarmer1) 26 Mar 2015 15:21:41

Generated On: 20 Jul 2016 12:37:46

Sample Barcode	05112450000381
Analyte	HBMA
Sample type	URINE
Result	.
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	4
Celerion Study Number	AA99128-03
Date of Collection	2014-FEB-17
Timepoint-minutes	
Urine Start Day	4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 4

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

Data signed: (hfarmer1) 26 Mar 2015 15:21:41

Generated On: 20 Jul 2016 12:37:46

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 4

Form: Biomarker-Urine (NNN, NNAL)

Data signed: (hfarmer1) 26 Mar 2015 15:21:40

Generated On: 20 Jul 2016 12:37:46

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 4

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

Data signed: (hfarmer1) 26 Mar 2015 15:21:40

Generated On: 20 Jul 2016 12:37:46

Sample Barcode	05112460001492
Analyte	NNAL
Sample type	URINE
Result	.
Result Unit	PG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	4
Celerion Study Number	AA99128-04
Date of Collection	2014-FEB-17
Timepoint-minutes	
Urine Start Day	4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 4

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

Data signed: (hfarmer1) 26 Mar 2015 15:21:40

Generated On: 20 Jul 2016 12:37:46

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 4

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

Data signed: (hfarmer1) 26 Mar 2015 15:21:40

Generated On: 20 Jul 2016 12:37:46

Sample Barcode	05112460001492
Analyte	NNN
Sample type	URINE
Result	.
Result Unit	PG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	4
Celerion Study Number	AA99128-04
Date of Collection	2014-FEB-17
Timepoint-minutes	
Urine Start Day	4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 4

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

Data signed: (hfarmer1) 26 Mar 2015 15:21:40

Generated On: 20 Jul 2016 12:37:46

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 4

Form: Biomarker-Urine (HEMA)

Data signed: (hfarmer1) 26 Mar 2015 15:21:41

Generated On: 20 Jul 2016 12:37:46

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 4

Form: Biomarker-Urine (HEMA) (1)

Data signed: (hfarmer1) 26 Mar 2015 15:21:41

Generated On: 20 Jul 2016 12:37:46

Sample Barcode	05112470000370
Analyte	HEMA
Sample type	URINE
Result	.
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	4
Celerion Study Number	AA99128-05
Date of Collection	2014-FEB-17
Timepoint-minutes	
Urine Start Day	4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 4

Form: Biomarker-Urine (HEMA) (1)

Data signed: (hfarmer1) 26 Mar 2015 15:21:41

Generated On: 20 Jul 2016 12:37:46

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 4

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

Data signed: (hfarmer1) 26 Mar 2015 15:21:41

Generated On: 20 Jul 2016 12:37:46

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 4

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

Data signed: (hfarmer1) 26 Mar 2015 15:21:41

Generated On: 20 Jul 2016 12:37:46

Sample Barcode	05112550000040
Analyte	COT
Sample type	URINE
Result	.
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	4
Celerion Study Number	AA99128-13
Date of Collection	2014-FEB-17
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 4

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

Data signed: (hfarmer1) 26 Mar 2015 15:21:41

Generated On: 20 Jul 2016 12:37:46

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: 1077**

Folder: Day 4

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

Data signed: (hfarmer1) 26 Mar 2015 15:21:41

Generated On: 20 Jul 2016 12:37:46

Sample Barcode	05112550000040
Analyte	COT-GLUC
Sample type	URINE
Result	.
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	4
Celerion Study Number	AA99128-13
Date of Collection	2014-FEB-17
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 4

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

Data signed: (hfarmer1) 26 Mar 2015 15:21:41

Generated On: 20 Jul 2016 12:37:46

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: 1077**

Folder: Day 4

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

Data signed: (hfarmer1) 26 Mar 2015 15:21:41

Generated On: 20 Jul 2016 12:37:46

Sample Barcode	05112550000040
Analyte	NIC
Sample type	URINE
Result	.
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	4
Celerion Study Number	AA99128-13
Date of Collection	2014-FEB-17
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 4

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

Data signed: (hfarmer1) 26 Mar 2015 15:21:41

Generated On: 20 Jul 2016 12:37:46

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: 1077**

Folder: Day 4

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

Data signed: (hfarmer1) 26 Mar 2015 15:21:41

Generated On: 20 Jul 2016 12:37:46

Sample Barcode	05112550000040
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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	OTHER
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Sample comment	ANALYSIS NOT REQUIRED
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Detection method	LC-MS/MS
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Planned time point (Hour)	0
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Day of Visit	4
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Celerion Study Number	AA99128-13
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Date of Collection	2014-FEB-17
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Timepoint-minutes	
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 4

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

Data signed: (hfarmer1) 26 Mar 2015 15:21:41

Generated On: 20 Jul 2016 12:37:46

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: 1077**

Folder: Day 4

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

Data signed: (hfarmer1) 26 Mar 2015 15:21:41

Generated On: 20 Jul 2016 12:37:46

Sample Barcode	05112550000040
Analyte	THCOT
Sample type	URINE
Result	.
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	4
Celerion Study Number	AA99128-13
Date of Collection	2014-FEB-17
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 4

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

Data signed: (hfarmer1) 26 Mar 2015 15:21:41

Generated On: 20 Jul 2016 12:37:46

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: 1077**

Folder: Day 4

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(6)**

Data signed: (hfarmer1) 26 Mar 2015 15:21:41

Generated On: 20 Jul 2016 12:37:46

Sample Barcode	05112550000040
Analyte	THCOT-GLUC
Sample type	URINE
Result	.
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	4
Celerion Study Number	AA99128-13
Date of Collection	2014-FEB-17
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 4

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(6)**

Data signed: (hfarmer1) 26 Mar 2015 15:21:41

Generated On: 20 Jul 2016 12:37:46

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: 1077**

Folder: Day 4

Form: Biomarker-Urine (3-OH BaP)

Data signed: (hfarmer1) 26 Mar 2015 15:21:42

Generated On: 20 Jul 2016 12:37:46

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 4

Form: Biomarker-Urine (3-OH BaP) (1)

Data signed: (hfarmer1) 26 Mar 2015 15:21:42

Generated On: 20 Jul 2016 12:37:46

Sample Barcode	05112490000370
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Analyte	3-OH BAP
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Sample type	URINE
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Result	.
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Result Unit	FG/ML
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Lab Status	OTHER
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Sample comment	ANALYSIS NOT REQUIRED
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Detection method	LC-MS/MS
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Planned time point (Hour)	0
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Day of Visit	4
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Celerion Study Number	AA99128-07
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Date of Collection	2014-FEB-17
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Timepoint-minutes	
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Urine Start Day	4
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 4

Form: Biomarker-Urine (3-OH BaP) (1)

Data signed: (hfarmer1) 26 Mar 2015 15:21:42

Generated On: 20 Jul 2016 12:37:46

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 4

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP)

Data signed: (hfarmer1) 26 Mar 2015 15:21:42

Generated On: 20 Jul 2016 12:37:46

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 4

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (1)

Data signed: (hfarmer1) 26 Mar 2015 15:21:42

Generated On: 20 Jul 2016 12:37:46

Sample Barcode	05112510000370
Analyte	1-NA
Sample type	URINE
Result	.
Result Unit	PG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	4
Celerion Study Number	AA99128-09
Date of Collection	2014-FEB-17
Timepoint-minutes	
Urine Start Day	4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 4

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (1)

Data signed: (hfarmer1) 26 Mar 2015 15:21:42

Generated On: 20 Jul 2016 12:37:46

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 4

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (2)

Data signed: (hfarmer1) 26 Mar 2015 15:21:42

Generated On: 20 Jul 2016 12:37:46

Sample Barcode	05112510000370
Analyte	2-NA
Sample type	URINE
Result	.
Result Unit	PG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	4
Celerion Study Number	AA99128-09
Date of Collection	2014-FEB-17
Timepoint-minutes	
Urine Start Day	4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 4

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (2)

Data signed: (hfarmer1) 26 Mar 2015 15:21:42

Generated On: 20 Jul 2016 12:37:46

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 4

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (3)

Data signed: (hfarmer1) 26 Mar 2015 15:21:42

Generated On: 20 Jul 2016 12:37:46

Sample Barcode	05112510000370
Analyte	4-ABP
Sample type	URINE
Result	.
Result Unit	PG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	4
Celerion Study Number	AA99128-09
Date of Collection	2014-FEB-17
Timepoint-minutes	
Urine Start Day	4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 4

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (3)

Data signed: (hfarmer1) 26 Mar 2015 15:21:42

Generated On: 20 Jul 2016 12:37:46

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 4

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (4)

Data signed: (hfarmer1) 26 Mar 2015 15:21:42

Generated On: 20 Jul 2016 12:37:46

Sample Barcode	05112510000370
Analyte	O-TOL
Sample type	URINE
Result	.
Result Unit	PG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	4
Celerion Study Number	AA99128-09
Date of Collection	2014-FEB-17
Timepoint-minutes	
Urine Start Day	4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 4

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (4)

Data signed: (hfarmer1) 26 Mar 2015 15:21:42

Generated On: 20 Jul 2016 12:37:46

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 4

Form: Biomarker-Urine (1-OHP)

Data signed: (hfarmer1) 26 Mar 2015 15:21:42

Generated On: 20 Jul 2016 12:37:46

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 4

Form: Biomarker-Urine (1-OHP) (1)

Data signed: (hfarmer1) 26 Mar 2015 15:21:42

Generated On: 20 Jul 2016 12:37:46

Sample Barcode	05115190001327
Analyte	1-OHP
Sample type	URINE
Result	.
Result Unit	PG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	4
Celerion Study Number	AA99598-03
Date of Collection	2014-FEB-17
Timepoint-minutes	
Urine Start Day	4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 4

Form: Biomarker-Urine (1-OHP) (1)

Data signed: (hfarmer1) 26 Mar 2015 15:21:42

Generated On: 20 Jul 2016 12:37:46

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 4

Form: Biomarker-Urine (SPMA, SBMA)

Data signed: (hfarmer1) 26 Mar 2015 15:21:41

Generated On: 20 Jul 2016 12:37:46

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 4

Form: Biomarker-Urine (SPMA, SBMA) (1)

Data signed: (hfarmer1) 26 Mar 2015 15:21:41

Generated On: 20 Jul 2016 12:37:46

Sample Barcode	05115170001283
Analyte	SBMA
Sample type	URINE
Result	.
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	4
Celerion Study Number	AA99598-01
Date of Collection	2014-FEB-17
Timepoint-minutes	
Urine Start Day	4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 4

Form: Biomarker-Urine (SPMA, SBMA) (1)

Data signed: (hfarmer1) 26 Mar 2015 15:21:41

Generated On: 20 Jul 2016 12:37:46

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 4

Form: Biomarker-Urine (SPMA, SBMA) (2)

Data signed: (hfarmer1) 26 Mar 2015 15:21:41

Generated On: 20 Jul 2016 12:37:46

Sample Barcode	05115170001283
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Analyte	SPMA
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Sample type	URINE
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Result	.
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Result Unit	NG/ML
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Lab Status	OTHER
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Sample comment	ANALYSIS NOT REQUIRED
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Detection method	LC-MS/MS
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Planned time point (Hour)	0
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Day of Visit	4
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Celerion Study Number	AA99598-01
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Date of Collection	2014-FEB-17
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Timepoint-minutes	
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Urine Start Day	4
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 4

Form: Biomarker-Urine (SPMA, SBMA) (2)

Data signed: (hfarmer1) 26 Mar 2015 15:21:41

Generated On: 20 Jul 2016 12:37:46

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 4

Form: Biomarker-Urine (MHBMA)

Data signed: (hfarmer1) 26 Mar 2015 15:21:41

Generated On: 20 Jul 2016 12:37:46

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 4

Form: Biomarker-Urine (MHBMA) (1)

Data signed: (hfarmer1) 26 Mar 2015 15:21:41

Generated On: 20 Jul 2016 12:37:46

Sample Barcode	05115180001327
Analyte	MHBMA
Sample type	URINE
Result	.
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	4
Celerion Study Number	AA99598-02
Date of Collection	2014-FEB-17
Timepoint-minutes	
Urine Start Day	4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 4

Form: Biomarker-Urine (MHBMA) (1)

Data signed: (hfarmer1) 26 Mar 2015 15:21:41

Generated On: 20 Jul 2016 12:37:46

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 4

Form: Biomarker-Urine (Creatinine)

Data signed: (hfarmer1) 26 Mar 2015 15:21:42

Generated On: 20 Jul 2016 12:37:46

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 4

Form: Biomarker-Urine (Creatinine) (1)

Data signed: (hfarmer1) 26 Mar 2015 15:21:42

Generated On: 20 Jul 2016 12:37:46

Sample Barcode	05115160000676
Analyte	CREATININE
Sample type	URINE
Result	.
Result Unit	MG/DL
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	SPECTROPHOTOMETRIC
Planned time point (Hour)	0
Day of Visit	4
Celerion Study Number	AA99128-14
Date of Collection	2014-FEB-17
Timepoint-minutes	
Urine Start Day	4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 4

Form: Biomarker-Urine (Creatinine) (1)

Data signed: (hfarmer1) 26 Mar 2015 15:21:42

Generated On: 20 Jul 2016 12:37:46

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 4

Form: Biomarker-Plasma (Nic, Cot, tHCot)

Data signed: (hfarmer1) 26 Mar 2015 15:21:41

Generated On: 20 Jul 2016 12:37:46

Sample type

PLASMA

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 4

Form: Biomarker-Plasma (Nic, Cot, tHCot) (1)

Data signed: (hfarmer1) 26 Mar 2015 15:21:41

Generated On: 20 Jul 2016 12:37:46

Sample Barcode	05112440000035
----------------	----------------

Analyte	COT
---------	-----

Sample type	PLASMA
-------------	--------

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

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

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

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

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

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

Day of Visit	4
--------------	---

Celerion Study Number	AA99128-02
-----------------------	------------

Date of Collection	2014-FEB-17
--------------------	-------------

Timepoint-minutes	0
-------------------	---

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 4

Form: Biomarker-Plasma (Nic, Cot, tHCot) (1)

Data signed: (hfarmer1) 26 Mar 2015 15:21:41

Generated On: 20 Jul 2016 12:37:46

Urine End Day

4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 4

Form: Biomarker-Plasma (Nic, Cot, tHCot) (2)

Data signed: (hfarmer1) 26 Mar 2015 15:21:41

Generated On: 20 Jul 2016 12:37:46

Sample Barcode	05112440000035
----------------	----------------

Analyte	NIC
---------	-----

Sample type	PLASMA
-------------	--------

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

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

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

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

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

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

Day of Visit	4
--------------	---

Celerion Study Number	AA99128-02
-----------------------	------------

Date of Collection	2014-FEB-17
--------------------	-------------

Timepoint-minutes	0
-------------------	---

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 4

Form: Biomarker-Plasma (Nic, Cot, tHCot) (2)

Data signed: (hfarmer1) 26 Mar 2015 15:21:41

Generated On: 20 Jul 2016 12:37:46

Urine End Day

4

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 5

Form: Date of Visit

Data signed: (hfarmer1) 26 Mar 2015 15:21:46

Generated On: 20 Jul 2016 12:37:46

Date of Visit

18 FEB 2014
DD/MMM/YYYY

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 5

Form: Vital Signs

Data signed: (hfarmer1) 26 Mar 2015 15:21:46

Generated On: 20 Jul 2016 12:37:46

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

08:35
hour:min 24-hour clock

Pulse rate

46
beats per minute

Respiratory rate

14
breaths per minute

Blood Pressure (systolic)

113
mmHg

Blood Pressure (diastolic)

75
mmHg

Vital Signs Position of Subject

Supine ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 5

Form: Plasma Nicotine Sample

Data signed: (hfarmer1) 26 Mar 2015 15:21:47

Generated On: 20 Jul 2016 12:37:46

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

If Not Done, please specify the reason: _____

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

Time hour:min 24-hour clock	20:42
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 5

Form: Plasma Cotinine Sample

Data signed: (hfarmer1) 26 Mar 2015 15:21:47

Generated On: 20 Jul 2016 12:37:46

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

If Not Done, please specify the reason: _____

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

Time hour:min 24-hour clock	20:42
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 5

Form: CoHb Blood Sample(SA) (1)

Data signed: (hfarmer1) 26 Mar 2015 15:21:46

Generated On: 20 Jul 2016 12:37:46

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

If Not Done, please specify the reason: _____

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

Scheduled Time	08:00 - 09:30 <input checked="" type="checkbox"/>
----------------	---

Time hour:min 24-hour clock	08:42
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 5

Form: CoHb Blood Sample(SA) (2)

Data signed: (hfarmer1) 26 Mar 2015 15:21:46

Generated On: 20 Jul 2016 12:37:46

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

If Not Done, please specify the reason: _____

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

Scheduled Time	12:00 - 13:30 <input checked="" type="radio"/>
----------------	--

Time hour:min 24-hour clock	12:42
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 5

Form: CoHb Blood Sample(SA) (3)

Data signed: (hfarmer1) 26 Mar 2015 15:21:46

Generated On: 20 Jul 2016 12:37:46

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

If Not Done, please specify the reason: _____

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

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

Time hour:min 24-hour clock	16:15
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 5

Form: CoHb Blood Sample(SA) (4)

Data signed: (hfarmer1) 26 Mar 2015 15:21:46

Generated On: 20 Jul 2016 12:37:46

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

If Not Done, please specify the reason: _____

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

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

Time hour:min 24-hour clock	20:42
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 5

Form: CO Breath Test <SA arm/> (1)

Data signed: (hfarmer1) 26 Mar 2015 15:21:46

Generated On: 20 Jul 2016 12:37:46

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

If Not Done, please specify the reason: _____

Scheduled Time	08:00 - 09:30 
----------------	---

Actual Time of Assessment hour:min 24-hour clock	08:36
---	-------

Result(ppm)	2
-------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 5

Form: CO Breath Test <SA arm/> (2)

Data signed: (hfarmer1) 26 Mar 2015 15:21:46

Generated On: 20 Jul 2016 12:37:46

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	12:31
---	-------

Result(ppm)	0
-------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 5

Form: CO Breath Test <SA arm/> (3)

Data signed: (hfarmer1) 26 Mar 2015 15:21:46

Generated On: 20 Jul 2016 12:37:46

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	16:19
---	-------

Result(ppm)	0
-------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 5

Form: CO Breath Test <SA arm/> (4)

Data signed: (hfarmer1) 26 Mar 2015 15:21:46

Generated On: 20 Jul 2016 12:37:46

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	20:46
---	-------

Result(ppm)	1
-------------	---

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1077

Folder: Day 5

Form: CYP1A2 activity Sample

Data signed: (hfarmer1) 26 Mar 2015 15:21:42

Generated On: 20 Jul 2016 12:37:46

Time of caffeine tablet intake	10:12
	hour:min 24-hour clock

Sample collection Not Done	False
----------------------------	-------

If Not Done, please specify the reason: _____

Date of sample collection DD/MMM/YYYY	Time of sample collection hour:min 24-hour clock	Parameter
18 FEB 2014	16:15	Caffeine
18 FEB 2014	16:15	Paraxanthine

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 5

Form: 24 hour urine collections

Data signed: (hfarmer1) 26 Mar 2015 15:21:46

Generated On: 20 Jul 2016 12:37:46

Start Time	06:11
	hour:min 24-hour clock

End Date	19 FEB 2014
	DD/MMM/YYYY

End Time	06:11
	hour:min 24-hour clock

Volume	2677
	mL

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 5

Form: Sample Urine Collection

Data signed: (hfarmer1) 26 Mar 2015 15:21:46

Generated On: 20 Jul 2016 12:37:46

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: 1077

Folder: Day 5

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Data signed: (hfarmer1) 26 Mar 2015 15:21:47

Generated On: 20 Jul 2016 12:37:46

Date of Birth

(b) (6)

Date of assessment
DD/MMM/YYYY

2014 FEB 18
DD/MMM/YYYY

Time of assessment

06:40
hour:min 24-hour clock

Assessment Status

Completed ☒

Please indicate for each of the items below, how you have been feeling over the past 24 hours

How have you been feeling over the past 24 hours?

None ☐

1. Angry, irritable, frustrated

How have you been feeling over the past 24 hours?

None ☐

2. Anxious, nervous

How have you been feeling over the past 24 hours?

None ☐

3. Depressed Mood, sad

How have you been feeling over the past 24 hours?

Moderate ☐

4. Desire or craving to smoke

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 5

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Data signed: (hfarmer1) 26 Mar 2015 15:21:47

Generated On: 20 Jul 2016 12:37:46

How have you been feeling over the past 24 hours? None ☐

5. Difficulty concentrating

How have you been feeling over the past 24 hours? None ☐

6. Increased appetite, hungry, weight gain

How have you been feeling over the past 24 hours? None ☐

7. Insomnia, sleep problems, awakening at night

How have you been feeling over the past 24 hours? None ☐

8. Restless

How have you been feeling over the past 24 hours? None ☐

9. Impatient

How have you been feeling over the past 24 hours? None ☐

10. Constipation

How have you been feeling over the past 24 hours? None ☐

11. Dizziness

How have you been feeling over the past 24 hours? None ☐

12. Coughing

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 5

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Data signed: (hfarmer1) 26 Mar 2015 15:21:47

Generated On: 20 Jul 2016 12:37:46

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: 1077

Folder: Day 5

Form: Cough Assessment

Data signed: (hfarmer1) 26 Mar 2015 15:21:47

Generated On: 20 Jul 2016 12:37:46

Date of Birth

(b) (6)

Date of assessment
DD/MMM/YYYY

2014 FEB 18
DD/MMM/YYYY

Time of assessment

06:39
hour:min 24-hour clock

Assessment Status

Completed ☒

Have you experienced a regular need to cough e.g.
coughing several times in the last 24 hrs?

No ☒

If YES, please answer the following questions:

First Question: Cough Impact Scale
How much is your cough bothering you?

-9

Second Question: Cough Intensity Scale:
How intense is your cough?

Not Applicable ☒

Third Question: Cough Frequency Scale:
How frequently do you normally have to cough each
day?

Not Applicable ☒

Fourth Question: Sputum Production
To what extent do you produce sputum when coughing?

Not Applicable ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 5

Form: Lab_BU_COHB (1)

Data signed: (hfarmer1) 26 Mar 2015 15:21:49

Generated On: 20 Jul 2016 12:37:46

Sample Barcode	05115150000472
----------------	----------------

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

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

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

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

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

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

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

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

Planned time point (Hour)	8
---------------------------	---

Day of Visit	5
--------------	---

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

Date of Collection	2014-FEB-18
--------------------	-------------

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 5

Form: Lab_BU_COHB (1)

Data signed: (hfarmer1) 26 Mar 2015 15:21:49

Generated On: 20 Jul 2016 12:37:46

Start Day (24 hour urine only) _____

End Day (24 hour Urine Only) _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 5

Form: Lab_BU_COHB (2)

Data signed: (hfarmer1) 26 Mar 2015 15:21:49

Generated On: 20 Jul 2016 12:37:46

Sample Barcode	05115150000473
Analyte	CARBOXYHEMOGLOBIN
Sample type	BLOOD
Result	.
Result Unit	%
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	SPECTROPHOTOMETRIC
Lower limit of quantification	0.500
Planned time point (Hour)	12
Day of Visit	5
Celerion Study Number	AA99128-16
Date of Collection	2014-FEB-18
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 5

Form: Lab_BU_COHB (2)

Data signed: (hfarmer1) 26 Mar 2015 15:21:49

Generated On: 20 Jul 2016 12:37:46

Start Day (24 hour urine only) _____

End Day (24 hour Urine Only) _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 5

Form: Lab_BU_COHB (3)

Data signed: (hfarmer1) 26 Mar 2015 15:21:49

Generated On: 20 Jul 2016 12:37:46

Sample Barcode	05115150000474
----------------	----------------

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

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

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

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

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

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

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

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

Planned time point (Hour)	16
---------------------------	----

Day of Visit	5
--------------	---

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

Date of Collection	2014-FEB-18
--------------------	-------------

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 5

Form: Lab_BU_COHB (3)

Data signed: (hfarmer1) 26 Mar 2015 15:21:49

Generated On: 20 Jul 2016 12:37:46

Start Day (24 hour urine only) _____

End Day (24 hour Urine Only) _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 5

Form: Lab_BU_COHB (4)

Data signed: (hfarmer1) 26 Mar 2015 15:21:49

Generated On: 20 Jul 2016 12:37:46

Sample Barcode	05115150000475
Analyte	CARBOXYHEMOGLOBIN
Sample type	BLOOD
Result	.
Result Unit	%
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	SPECTROPHOTOMETRIC
Lower limit of quantification	0.500
Planned time point (Hour)	20
Day of Visit	5
Celerion Study Number	AA99128-16
Date of Collection	2014-FEB-18
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 5

Form: Lab_BU_COHB (4)

Data signed: (hfarmer1) 26 Mar 2015 15:21:49

Generated On: 20 Jul 2016 12:37:46

Start Day (24 hour urine only)

End Day (24 hour Urine Only)

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 5

Form: Behavioral Risk Factor Surveillance System Questionnaire

Data signed: (hfarmer1) 26 Mar 2015 15:21:43

Generated On: 20 Jul 2016 12:37:46

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

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

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

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

Time of assessment	20:38 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: 1077**

Folder: Day 5

Form: Behavioral Risk Factor Surveillance System Questionnaire

Data signed: (hfarmer1) 26 Mar 2015 15:21:43

Generated On: 20 Jul 2016 12:37:46

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: 1077

Folder: Day 5

Form: Smoking Questionnaire (SQ)

Data signed: (hfarmer1) 26 Mar 2015 15:21:43

Generated On: 20 Jul 2016 12:37:46

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

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

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

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

Time of assessment	20:40 hour:min 24-hour clock
--------------------	---------------------------------

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

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

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

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

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

Years	00 Years
-------	----------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 5

Form: Smoking Questionnaire (SQ)

Data signed: (hfarmer1) 26 Mar 2015 15:21:43

Generated On: 20 Jul 2016 12:37:46

Months	00 Months
--------	-----------

Days	05 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	05 Days
------	---------

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

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1077

Folder: Day 5

Form: Smoking Questionnaire (SQ) (1)

Data signed: (hfarmer1) 26 Mar 2015 15:21:43

Generated On: 20 Jul 2016 12:37:46

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

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

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

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

Time of assessment	20:40 hour:min 24-hour clock
--------------------	---------------------------------

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

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

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

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

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

Years	00 Years
-------	----------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 5

Form: Smoking Questionnaire (SQ) (1)

Data signed: (hfarmer1) 26 Mar 2015 15:21:43

Generated On: 20 Jul 2016 12:37:46

Months	00 Months
--------	-----------

Days	05 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	05 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) <input checked="" type="radio"/>
------	--

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?

Hand-rolled Cigarettes per day	0
-----------------------------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 5

Form: Smoking Questionnaire (SQ) (1)

Data signed: (hfarmer1) 26 Mar 2015 15:21:43

Generated On: 20 Jul 2016 12:37:46

8. On average, how many cigars do/did you smoke per
day? _____

Cigars per day	0
-------------------	---

8. On average, how many pipes do/did you smoke per
day? _____

Pipes per day	0
------------------	---

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1077

Folder: Day 5

Form: Smoking Questionnaire (SQ) (2)

Data signed: (hfarmer1) 26 Mar 2015 15:21:43

Generated On: 20 Jul 2016 12:37:46

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

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

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

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

Time of assessment	20:40 hour:min 24-hour clock
--------------------	---------------------------------

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

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

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

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

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

Years	00 Years
-------	----------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 5

Form: Smoking Questionnaire (SQ) (2)

Data signed: (hfarmer1) 26 Mar 2015 15:21:43

Generated On: 20 Jul 2016 12:37:46

Months	00 Months
--------	-----------

Days	05 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	05 Days
------	---------

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

Time	1 year ago <input checked="" type="radio"/>
------	---

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?

Hand-rolled Cigarettes per day	0
-----------------------------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 5

Form: Smoking Questionnaire (SQ) (2)

Data signed: (hfarmer1) 26 Mar 2015 15:21:43

Generated On: 20 Jul 2016 12:37:46

8. On average, how many cigars do/did you smoke per
day? _____

Cigars per day	0
-------------------	---

8. On average, how many pipes do/did you smoke per
day? _____

Pipes per day	0
------------------	---

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1077

Folder: Day 5

Form: Smoking Questionnaire (SQ) (3)

Data signed: (hfarmer1) 26 Mar 2015 15:21:43

Generated On: 20 Jul 2016 12:37:46

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

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

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

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

Time of assessment	20:40 hour:min 24-hour clock
--------------------	---------------------------------

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

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

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

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

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

Years	00 Years
-------	----------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 5

Form: Smoking Questionnaire (SQ) (3)

Data signed: (hfarmer1) 26 Mar 2015 15:21:43

Generated On: 20 Jul 2016 12:37:46

Months	00 Months
--------	-----------

Days	05 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	05 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?

Hand-rolled Cigarettes per day	0
-----------------------------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 5

Form: Smoking Questionnaire (SQ) (3)

Data signed: (hfarmer1) 26 Mar 2015 15:21:43

Generated On: 20 Jul 2016 12:37:46

8. On average, how many cigars do/did you smoke per
day? _____

Cigars per day	0
-------------------	---

8. On average, how many pipes do/did you smoke per
day? _____

Pipes per day	0
------------------	---

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1077

Folder: Day 5

Form: Smoking Questionnaire (SQ) (4)

Data signed: (hfarmer1) 26 Mar 2015 15:21:43

Generated On: 20 Jul 2016 12:37:46

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

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

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

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

Time of assessment	20:40 hour:min 24-hour clock
--------------------	---------------------------------

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

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

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

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

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

Years	00 Years
-------	----------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 5

Form: Smoking Questionnaire (SQ) (4)

Data signed: (hfarmer1) 26 Mar 2015 15:21:43

Generated On: 20 Jul 2016 12:37:46

Months	00 Months
--------	-----------

Days	05 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	05 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?

Hand-rolled Cigarettes per day	0
-----------------------------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 5

Form: Smoking Questionnaire (SQ) (4)

Data signed: (hfarmer1) 26 Mar 2015 15:21:43

Generated On: 20 Jul 2016 12:37:46

8. On average, how many cigars do/did you smoke per
day? _____

Cigars per day	0
-------------------	---

8. On average, how many pipes do/did you smoke per
day? _____

Pipes per day	0
------------------	---

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1077

Folder: Day 5

Form: Smoking Questionnaire (SQ) (5)

Data signed: (hfarmer1) 26 Mar 2015 15:21:43

Generated On: 20 Jul 2016 12:37:46

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

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

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

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

Time of assessment	20:40 hour:min 24-hour clock
--------------------	---------------------------------

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

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

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

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

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

Years	00 Years
-------	----------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 5

Form: Smoking Questionnaire (SQ) (5)

Data signed: (hfarmer1) 26 Mar 2015 15:21:43

Generated On: 20 Jul 2016 12:37:46

Months	00 Months
--------	-----------

Days	05 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	05 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?

Hand-rolled Cigarettes per day	0
-----------------------------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 5

Form: Smoking Questionnaire (SQ) (5)

Data signed: (hfarmer1) 26 Mar 2015 15:21:43

Generated On: 20 Jul 2016 12:37:46

8. On average, how many cigars do/did you smoke per
day? _____

Cigars per day	0
-------------------	---

8. On average, how many pipes do/did you smoke per
day? _____

Pipes per day	0
------------------	---

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1077

Folder: Day 5

Form: Smoking Questionnaire (SQ) (6)

Data signed: (hfarmer1) 26 Mar 2015 15:21:43

Generated On: 20 Jul 2016 12:37:46

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

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

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

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

Time of assessment	20:40 hour:min 24-hour clock
--------------------	---------------------------------

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

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

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

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

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

Years	00 Years
-------	----------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 5

Form: Smoking Questionnaire (SQ) (6)

Data signed: (hfarmer1) 26 Mar 2015 15:21:43

Generated On: 20 Jul 2016 12:37:46

Months	00 Months
--------	-----------

Days	05 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	05 Days
------	---------

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

Time	20 years ago <input checked="" type="radio"/>
------	---

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?

Hand-rolled Cigarettes per day	0
-----------------------------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 5

Form: Smoking Questionnaire (SQ) (6)

Data signed: (hfarmer1) 26 Mar 2015 15:21:43

Generated On: 20 Jul 2016 12:37:46

8. On average, how many cigars do/did you smoke per
day? _____

Cigars per day	0
-------------------	---

8. On average, how many pipes do/did you smoke per
day? _____

Pipes per day	0
------------------	---

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1077

Folder: Day 5

Form: Smoking Questionnaire (SQ) (7)

Data signed: (hfarmer1) 26 Mar 2015 15:21:43

Generated On: 20 Jul 2016 12:37:46

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

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

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

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

Time of assessment	20:40 hour:min 24-hour clock
--------------------	---------------------------------

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

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

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

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

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

Years	00 Years
-------	----------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 5

Form: Smoking Questionnaire (SQ) (7)

Data signed: (hfarmer1) 26 Mar 2015 15:21:43

Generated On: 20 Jul 2016 12:37:46

Months	00 Months
--------	-----------

Days	05 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	05 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 <input checked="" type="radio"/>
------	---

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?

Hand-rolled Cigarettes per day	0
-----------------------------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 5

Form: Smoking Questionnaire (SQ) (7)

Data signed: (hfarmer1) 26 Mar 2015 15:21:43

Generated On: 20 Jul 2016 12:37:46

8. On average, how many cigars do/did you smoke per
day? _____

Cigars 0
per day

8. On average, how many pipes do/did you smoke per
day? _____

Pipes 0
per day

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 5

Form: Supplemental Questions

Data signed: (hfarmer1) 26 Mar 2015 15:21:45

Generated On: 20 Jul 2016 12:37:46

Was paper questionnaire used?

Yes ☒

Reason not done

Date of Assessment

18 FEB 2014
DD/MMM/YYYY

Time of assessment

20:41

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

02 minutes

Comments (open-end)

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 5

Form: Supplemental Questions (1)

Data signed: (hfarmer1) 26 Mar 2015 15:21:45

Generated On: 20 Jul 2016 12:37:46

Was paper questionnaire used? Yes ☐

Reason not done _____

Date of Assessment 18 FEB 2014
DD/MMM/YYYY

Time of assessment 20:41

1. How long it takes for the subject to complete the SQ 02 minutes

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

Answer Yes ☐

Comments (open-end) _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 5

Form: Supplemental Questions (2)

Data signed: (hfarmer1) 26 Mar 2015 15:21:45

Generated On: 20 Jul 2016 12:37:46

Was paper questionnaire used? Yes ☐

Reason not done _____

Date of Assessment 18 FEB 2014
DD/MMM/YYYY

Time of assessment 20:41

1. How long it takes for the subject to complete the SQ 02 minutes

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

Answer Yes ☐

Comments (open-end) _____

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1077

Folder: Day 5

Form: Supplemental Questions (3)

Data signed: (hfarmer1) 26 Mar 2015 15:21:45

Generated On: 20 Jul 2016 12:37:46

Was paper questionnaire used? Yes ☐

Reason not done _____

Date of Assessment 18 FEB 2014
DD/MMM/YYYY

Time of assessment 20:41

1. How long it takes for the subject to complete the SQ 02 minutes

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

Answer Yes ☐

Comments (open-end) _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 5

Form: Supplemental Questions (4)

Data signed: (hfarmer1) 26 Mar 2015 15:21:45

Generated On: 20 Jul 2016 12:37:46

Was paper questionnaire used? Yes ☐

Reason not done _____

Date of Assessment 18 FEB 2014
DD/MMM/YYYY

Time of assessment 20:41

1. How long it takes for the subject to complete the SQ 02 minutes

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

Answer Yes ☐

Comments (open-end) _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 5

Form: Supplemental Questions (5)

Data signed: (hfarmer1) 26 Mar 2015 15:21:45

Generated On: 20 Jul 2016 12:37:46

Was paper questionnaire used? Yes ☐

Reason not done _____

Date of Assessment 18 FEB 2014
DD/MMM/YYYY

Time of assessment 20:41

1. How long it takes for the subject to complete the SQ 02 minutes

Question 6. Was the SQ self-explaining? ☐

Answer Yes ☐

Comments (open-end) _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 5

Form: Supplemental Questions (6)

Data signed: (hfarmer1) 26 Mar 2015 15:21:45

Generated On: 20 Jul 2016 12:37:46

Was paper questionnaire used? Yes ☐

Reason not done _____

Date of Assessment 18 FEB 2014
DD/MMM/YYYY

Time of assessment 20:41

1. How long it takes for the subject to complete the SQ 02 minutes

Question 7. Was the SQ easy to use? ☐

Answer Yes ☐

Comments (open-end) _____

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1077

Folder: Day 5

Form: Questionnaire on smoking urges (QSU)

Data signed: (hfarmer1) 26 Mar 2015 15:21:47

Generated On: 20 Jul 2016 12:37:46

Type	QSU
Date of Birth	(b) (6)
Date of assessment	2014 FEB 18
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	Somewhat agree <input checked="" type="radio"/>
3. If it were possible I would probably smoke now	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	Somewhat 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: 1077**

Folder: Day 5

Form: Questionnaire on smoking urges (QSU)

Data signed: (hfarmer1) 26 Mar 2015 15:21:47

Generated On: 20 Jul 2016 12:37:46

7. A cigarette would taste good now Somewhat agree ☐

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

9. Smoking would make me less depressed Strongly disagree ☐

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 5

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

Data signed: (hfarmer1) 26 Mar 2015 15:21:49

Generated On: 20 Jul 2016 12:37:46

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 5

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

Data signed: (hfarmer1) 26 Mar 2015 15:21:49

Generated On: 20 Jul 2016 12:37:46

Sample Barcode	05112450000382
----------------	----------------

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

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

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

Result Unit	NG/ML
-------------	-------

Lab Status	OTHER
------------	-------

Sample comment	ANALYSIS NOT REQUIRED
----------------	-----------------------

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	5
--------------	---

Celerion Study Number	AA99128-03
-----------------------	------------

Date of Collection	2014-FEB-18
--------------------	-------------

Timepoint-minutes	
-------------------	--

Urine Start Day	5
-----------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 5

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (1)

Data signed: (hfarmer1) 26 Mar 2015 15:21:49

Generated On: 20 Jul 2016 12:37:46

Urine End Day

6

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 5

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (2)

Data signed: (hfarmer1) 26 Mar 2015 15:21:49

Generated On: 20 Jul 2016 12:37:46

Sample Barcode	05112450000382
----------------	----------------

Analyte	CEMA
---------	------

Sample type	URINE
-------------	-------

Result	.
--------	---

Result Unit	NG/ML
-------------	-------

Lab Status	OTHER
------------	-------

Sample comment	ANALYSIS NOT REQUIRED
----------------	-----------------------

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	5
--------------	---

Celerion Study Number	AA99128-03
-----------------------	------------

Date of Collection	2014-FEB-18
--------------------	-------------

Timepoint-minutes	
-------------------	--

Urine Start Day	5
-----------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 5

Form: Biomarker-Urine (CEMA, HPMa, HBMA) (2)

Data signed: (hfarmer1) 26 Mar 2015 15:21:49

Generated On: 20 Jul 2016 12:37:46

Urine End Day

6

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 5

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (3)

Data signed: (hfarmer1) 26 Mar 2015 15:21:49

Generated On: 20 Jul 2016 12:37:46

Sample Barcode	05112450000382
Analyte	HBMA
Sample type	URINE
Result	.
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	5
Celerion Study Number	AA99128-03
Date of Collection	2014-FEB-18
Timepoint-minutes	
Urine Start Day	5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 5

Form: Biomarker-Urine (CEMA, HPMA, HBMA) (3)

Data signed: (hfarmer1) 26 Mar 2015 15:21:49

Generated On: 20 Jul 2016 12:37:46

Urine End Day

6

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 5

Form: Biomarker-Urine (NNN, NNAL)

Data signed: (hfarmer1) 26 Mar 2015 15:21:48

Generated On: 20 Jul 2016 12:37:46

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 5

Form: Biomarker-Urine (NNN, NNAL) (1)

Data signed: (hfarmer1) 26 Mar 2015 15:21:48

Generated On: 20 Jul 2016 12:37:46

Sample Barcode	05112460001493
Analyte	NNAL
Sample type	URINE
Result	.
Result Unit	PG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	5
Celerion Study Number	AA99128-04
Date of Collection	2014-FEB-18
Timepoint-minutes	
Urine Start Day	5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 5

Form: Biomarker-Urine (NNN, NNAL) (1)

Data signed: (hfarmer1) 26 Mar 2015 15:21:48

Generated On: 20 Jul 2016 12:37:46

Urine End Day

6

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 5

Form: Biomarker-Urine (NNN, NNAL) (2)

Data signed: (hfarmer1) 26 Mar 2015 15:21:48

Generated On: 20 Jul 2016 12:37:46

Sample Barcode	05112460001493
Analyte	NNN
Sample type	URINE
Result	.
Result Unit	PG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	5
Celerion Study Number	AA99128-04
Date of Collection	2014-FEB-18
Timepoint-minutes	
Urine Start Day	5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 5

Form: Biomarker-Urine (NNN, NNAL) (2)

Data signed: (hfarmer1) 26 Mar 2015 15:21:48

Generated On: 20 Jul 2016 12:37:46

Urine End Day

6

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 5

Form: Biomarker-Urine (HEMA)

Data signed: (hfarmer1) 26 Mar 2015 15:21:48

Generated On: 20 Jul 2016 12:37:46

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 5

Form: Biomarker-Urine (HEMA) (1)

Data signed: (hfarmer1) 26 Mar 2015 15:21:48

Generated On: 20 Jul 2016 12:37:46

Sample Barcode	05112470000371
Analyte	HEMA
Sample type	URINE
Result	.
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	5
Celerion Study Number	AA99128-05
Date of Collection	2014-FEB-18
Timepoint-minutes	
Urine Start Day	5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 5

Form: Biomarker-Urine (HEMA) (1)

Data signed: (hfarmer1) 26 Mar 2015 15:21:48

Generated On: 20 Jul 2016 12:37:46

Urine End Day

6

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 5

Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)

Data signed: (hfarmer1) 26 Mar 2015 15:21:49

Generated On: 20 Jul 2016 12:37:46

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 5

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(1)**

Data signed: (hfarmer1) 26 Mar 2015 15:21:49

Generated On: 20 Jul 2016 12:37:46

Sample Barcode	05112550000041
Analyte	COT
Sample type	URINE
Result	.
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	5
Celerion Study Number	AA99128-13
Date of Collection	2014-FEB-18
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 5

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(1)**

Data signed: (hfarmer1) 26 Mar 2015 15:21:49

Generated On: 20 Jul 2016 12:37:46

Urine Start Day	5
<hr/>	
Urine End Day	6
<hr/>	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 5

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(2)**

Data signed: (hfarmer1) 26 Mar 2015 15:21:49

Generated On: 20 Jul 2016 12:37:46

Sample Barcode	05112550000041
Analyte	COT-GLUC
Sample type	URINE
Result	.
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	5
Celerion Study Number	AA99128-13
Date of Collection	2014-FEB-18
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 5

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(2)**

Data signed: (hfarmer1) 26 Mar 2015 15:21:49

Generated On: 20 Jul 2016 12:37:46

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: 1077**

Folder: Day 5

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(3)**

Data signed: (hfarmer1) 26 Mar 2015 15:21:49

Generated On: 20 Jul 2016 12:37:46

Sample Barcode	05112550000041
Analyte	NIC
Sample type	URINE
Result	.
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	5
Celerion Study Number	AA99128-13
Date of Collection	2014-FEB-18
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 5

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(3)**

Data signed: (hfarmer1) 26 Mar 2015 15:21:49

Generated On: 20 Jul 2016 12:37:46

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: 1077**

Folder: Day 5

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(4)**

Data signed: (hfarmer1) 26 Mar 2015 15:21:49

Generated On: 20 Jul 2016 12:37:46

Sample Barcode	05112550000041
Analyte	NIC-GLUC
Sample type	URINE
Result	.
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	5
Celerion Study Number	AA99128-13
Date of Collection	2014-FEB-18
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 5

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(4)**

Data signed: (hfarmer1) 26 Mar 2015 15:21:49

Generated On: 20 Jul 2016 12:37:46

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: 1077**

Folder: Day 5

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(5)**

Data signed: (hfarmer1) 26 Mar 2015 15:21:49

Generated On: 20 Jul 2016 12:37:46

Sample Barcode	05112550000041
Analyte	THCOT
Sample type	URINE
Result	.
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	5
Celerion Study Number	AA99128-13
Date of Collection	2014-FEB-18
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 5

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(5)**

Data signed: (hfarmer1) 26 Mar 2015 15:21:49

Generated On: 20 Jul 2016 12:37:46

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: 1077**

Folder: Day 5

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(6)**

Data signed: (hfarmer1) 26 Mar 2015 15:21:49

Generated On: 20 Jul 2016 12:37:46

Sample Barcode	05112550000041
Analyte	THCOT-GLUC
Sample type	URINE
Result	.
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	5
Celerion Study Number	AA99128-13
Date of Collection	2014-FEB-18
Timepoint-minutes	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 5

**Form: Biomarker-Urine (Nic, Cot, tHCot, Nic-gluc, Cot-gluc, tHCot-gluc)
(6)**

Data signed: (hfarmer1) 26 Mar 2015 15:21:49

Generated On: 20 Jul 2016 12:37:46

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: 1077**

Folder: Day 5

Form: Biomarker-Urine (3-OH BaP)

Data signed: (hfarmer1) 26 Mar 2015 15:21:50

Generated On: 20 Jul 2016 12:37:46

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 5

Form: Biomarker-Urine (3-OH BaP) (1)

Data signed: (hfarmer1) 26 Mar 2015 15:21:50

Generated On: 20 Jul 2016 12:37:46

Sample Barcode	05112490000371
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Analyte	3-OH BAP
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Sample type	URINE
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Result	.
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Result Unit	FG/ML
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Lab Status	OTHER
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Sample comment	ANALYSIS NOT REQUIRED
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Detection method	LC-MS/MS
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Planned time point (Hour)	0
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Day of Visit	5
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Celerion Study Number	AA99128-07
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Date of Collection	2014-FEB-18
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Timepoint-minutes	
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Urine Start Day	5
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 5

Form: Biomarker-Urine (3-OH BaP) (1)

Data signed: (hfarmer1) 26 Mar 2015 15:21:50

Generated On: 20 Jul 2016 12:37:46

Urine End Day

6

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 5

Form: Biomarker-Plasma (Caffeine, Paraxanthine)

Generated On: 20 Jul 2016 12:37:46

Sample type

PLASMA

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 5

Form: Biomarker-Plasma (Caffeine, Paraxanthine) (1)

Generated On: 20 Jul 2016 12:37:46

Sample Barcode	05112500000203
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Analyte	CAFFEINE
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Sample type	PLASMA
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Result	.
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Result Unit	NG/ML
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Lab Status	OTHER
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Sample comment	ANALYSIS NOT REQUIRED
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Detection method	LC-MS/MS
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Planned time point (Hour)	6
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Day of Visit	5
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Celerion Study Number	AA99128-08
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Date of Collection	2014-FEB-18
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Timepoint-minutes	0
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Urine Start Day	
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 5

Form: Biomarker-Plasma (Caffeine, Paraxanthine) (1)

Generated On: 20 Jul 2016 12:37:46

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 5

Form: Biomarker-Plasma (Caffeine, Paraxanthine) (2)

Generated On: 20 Jul 2016 12:37:46

Sample Barcode	05112500000203
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Analyte	PARAXANTHINE
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Sample type	PLASMA
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Result	.
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Result Unit	NG/ML
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Lab Status	OTHER
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Sample comment	ANALYSIS NOT REQUIRED
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Detection method	LC-MS/MS
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Planned time point (Hour)	6
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Day of Visit	5
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Celerion Study Number	AA99128-08
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Date of Collection	2014-FEB-18
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Timepoint-minutes	0
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Urine Start Day	
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 5

Form: Biomarker-Plasma (Caffeine, Paraxanthine) (2)

Generated On: 20 Jul 2016 12:37:46

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 5

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP)

Data signed: (hfarmer1) 26 Mar 2015 15:21:50

Generated On: 20 Jul 2016 12:37:46

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 5

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (1)

Data signed: (hfarmer1) 26 Mar 2015 15:21:50

Generated On: 20 Jul 2016 12:37:46

Sample Barcode	05112510000371
Analyte	1-NA
Sample type	URINE
Result	.
Result Unit	PG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	5
Celerion Study Number	AA99128-09
Date of Collection	2014-FEB-18
Timepoint-minutes	
Urine Start Day	5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 5

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (1)

Data signed: (hfarmer1) 26 Mar 2015 15:21:50

Generated On: 20 Jul 2016 12:37:46

Urine End Day

6

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 5

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (2)

Data signed: (hfarmer1) 26 Mar 2015 15:21:50

Generated On: 20 Jul 2016 12:37:46

Sample Barcode	05112510000371
Analyte	2-NA
Sample type	URINE
Result	.
Result Unit	PG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	5
Celerion Study Number	AA99128-09
Date of Collection	2014-FEB-18
Timepoint-minutes	
Urine Start Day	5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 5

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (2)

Data signed: (hfarmer1) 26 Mar 2015 15:21:50

Generated On: 20 Jul 2016 12:37:46

Urine End Day

6

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 5

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (3)

Data signed: (hfarmer1) 26 Mar 2015 15:21:50

Generated On: 20 Jul 2016 12:37:46

Sample Barcode	05112510000371
Analyte	4-ABP
Sample type	URINE
Result	.
Result Unit	PG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	5
Celerion Study Number	AA99128-09
Date of Collection	2014-FEB-18
Timepoint-minutes	
Urine Start Day	5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 5

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (3)

Data signed: (hfarmer1) 26 Mar 2015 15:21:50

Generated On: 20 Jul 2016 12:37:46

Urine End Day

6

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 5

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (4)

Data signed: (hfarmer1) 26 Mar 2015 15:21:50

Generated On: 20 Jul 2016 12:37:46

Sample Barcode	05112510000371
Analyte	O-TOL
Sample type	URINE
Result	.
Result Unit	PG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	5
Celerion Study Number	AA99128-09
Date of Collection	2014-FEB-18
Timepoint-minutes	
Urine Start Day	5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 5

Form: Biomarker-Urine (o-tol, 1-NA, 2-NA, 4-ABP) (4)

Data signed: (hfarmer1) 26 Mar 2015 15:21:50

Generated On: 20 Jul 2016 12:37:46

Urine End Day

6

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 5

Form: Biomarker-Urine (11-dTXb2)

Data signed: (hfarmer1) 26 Mar 2015 15:21:48

Generated On: 20 Jul 2016 12:37:46

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 5

Form: Biomarker-Urine (11-dTXb2) (1)

Data signed: (hfarmer1) 26 Mar 2015 15:21:48

Generated On: 20 Jul 2016 12:37:46

Sample Barcode	05112530000235
Analyte	11-DTXB2
Sample type	URINE
Result	.
Result Unit	PG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	5
Celerion Study Number	AA99128-11
Date of Collection	2014-FEB-18
Timepoint-minutes	
Urine Start Day	5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 5

Form: Biomarker-Urine (11-dTXb2) (1)

Data signed: (hfarmer1) 26 Mar 2015 15:21:48

Generated On: 20 Jul 2016 12:37:46

Urine End Day

6

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 5

Form: Biomarker-Urine (iPF2a-III)

Data signed: (hfarmer1) 26 Mar 2015 15:21:48

Generated On: 20 Jul 2016 12:37:46

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 5

Form: Biomarker-Urine (iPF2a-III) (1)

Data signed: (hfarmer1) 26 Mar 2015 15:21:48

Generated On: 20 Jul 2016 12:37:46

Sample Barcode	05112540000235
Analyte	IPF2A-III
Sample type	URINE
Result	.
Result Unit	PG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	5
Celerion Study Number	AA99128-12
Date of Collection	2014-FEB-18
Timepoint-minutes	
Urine Start Day	5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 5

Form: Biomarker-Urine (iPF2a-III) (1)

Data signed: (hfarmer1) 26 Mar 2015 15:21:48

Generated On: 20 Jul 2016 12:37:46

Urine End Day

6

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 5

Form: Biomarker-Urine (Ames)

Data signed: (hfarmer1) 26 Mar 2015 15:21:50

Generated On: 20 Jul 2016 12:37:46

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 5

Form: Biomarker-Urine (Ames) (1)

Data signed: (hfarmer1) 26 Mar 2015 15:21:50

Generated On: 20 Jul 2016 12:37:46

Sample Barcode	05113320000089
Analyte	AMES
Sample type	URINE
Result	.
Result Unit	REV/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	COUNT
Planned time point (Hour)	0
Day of Visit	5
Celerion Study Number	AA99128-15
Date of Collection	2014-FEB-18
Timepoint-minutes	
Urine Start Day	5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 5

Form: Biomarker-Urine (Ames) (1)

Data signed: (hfarmer1) 26 Mar 2015 15:21:50

Generated On: 20 Jul 2016 12:37:46

Urine End Day

6

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 5

Form: Biomarker-Urine (1-OHP)

Data signed: (hfarmer1) 26 Mar 2015 15:21:50

Generated On: 20 Jul 2016 12:37:46

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 5

Form: Biomarker-Urine (1-OHP) (1)

Data signed: (hfarmer1) 26 Mar 2015 15:21:50

Generated On: 20 Jul 2016 12:37:46

Sample Barcode	05115190001328
Analyte	1-OHP
Sample type	URINE
Result	.
Result Unit	PG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	5
Celerion Study Number	AA99598-03
Date of Collection	2014-FEB-18
Timepoint-minutes	
Urine Start Day	5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 5

Form: Biomarker-Urine (1-OHP) (1)

Data signed: (hfarmer1) 26 Mar 2015 15:21:50

Generated On: 20 Jul 2016 12:37:46

Urine End Day

6

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 5

Form: Biomarker-Urine (SPMA, SBMA)

Data signed: (hfarmer1) 26 Mar 2015 15:21:48

Generated On: 20 Jul 2016 12:37:46

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 5

Form: Biomarker-Urine (SPMA, SBMA) (1)

Data signed: (hfarmer1) 26 Mar 2015 15:21:48

Generated On: 20 Jul 2016 12:37:46

Sample Barcode	05115170001284
Analyte	SBMA
Sample type	URINE
Result	.
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	5
Celerion Study Number	AA99598-01
Date of Collection	2014-FEB-18
Timepoint-minutes	
Urine Start Day	5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 5

Form: Biomarker-Urine (SPMA, SBMA) (1)

Data signed: (hfarmer1) 26 Mar 2015 15:21:48

Generated On: 20 Jul 2016 12:37:46

Urine End Day

6

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 5

Form: Biomarker-Urine (SPMA, SBMA) (2)

Data signed: (hfarmer1) 26 Mar 2015 15:21:48

Generated On: 20 Jul 2016 12:37:46

Sample Barcode	05115170001284
Analyte	SPMA
Sample type	URINE
Result	.
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	5
Celerion Study Number	AA99598-01
Date of Collection	2014-FEB-18
Timepoint-minutes	
Urine Start Day	5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 5

Form: Biomarker-Urine (SPMA, SBMA) (2)

Data signed: (hfarmer1) 26 Mar 2015 15:21:48

Generated On: 20 Jul 2016 12:37:46

Urine End Day

6

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 5

Form: Biomarker-Urine (MHBMA)

Data signed: (hfarmer1) 26 Mar 2015 15:21:49

Generated On: 20 Jul 2016 12:37:46

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 5

Form: Biomarker-Urine (MHBMA) (1)

Data signed: (hfarmer1) 26 Mar 2015 15:21:49

Generated On: 20 Jul 2016 12:37:46

Sample Barcode	05115180001328
Analyte	MHBMA
Sample type	URINE
Result	.
Result Unit	NG/ML
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	5
Celerion Study Number	AA99598-02
Date of Collection	2014-FEB-18
Timepoint-minutes	
Urine Start Day	5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 5

Form: Biomarker-Urine (MHBMA) (1)

Data signed: (hfarmer1) 26 Mar 2015 15:21:49

Generated On: 20 Jul 2016 12:37:46

Urine End Day

6

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 5

Form: Biomarker-Urine (Creatinine)

Data signed: (hfarmer1) 26 Mar 2015 15:21:50

Generated On: 20 Jul 2016 12:37:46

Sample type

URINE

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 5

Form: Biomarker-Urine (Creatinine) (1)

Data signed: (hfarmer1) 26 Mar 2015 15:21:50

Generated On: 20 Jul 2016 12:37:46

Sample Barcode	05115160000677
Analyte	CREATININE
Sample type	URINE
Result	.
Result Unit	MG/DL
Lab Status	OTHER
Sample comment	ANALYSIS NOT REQUIRED
Detection method	SPECTROPHOTOMETRIC
Planned time point (Hour)	0
Day of Visit	5
Celerion Study Number	AA99128-14
Date of Collection	2014-FEB-18
Timepoint-minutes	
Urine Start Day	5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 5

Form: Biomarker-Urine (Creatinine) (1)

Data signed: (hfarmer1) 26 Mar 2015 15:21:50

Generated On: 20 Jul 2016 12:37:46

Urine End Day

6

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot)

Data signed: (hfarmer1) 26 Mar 2015 15:21:49

Generated On: 20 Jul 2016 12:37:46

Sample type

PLASMA

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (1)

Data signed: (hfarmer1) 26 Mar 2015 15:21:49

Generated On: 20 Jul 2016 12:37:46

Sample Barcode	05112440000036
----------------	----------------

Analyte	COT
---------	-----

Sample type	PLASMA
-------------	--------

Result	.
--------	---

Result Unit	NG/ML
-------------	-------

Lab Status	OTHER
------------	-------

Sample comment	ANALYSIS NOT REQUIRED
----------------	-----------------------

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	5
--------------	---

Celerion Study Number	AA99128-02
-----------------------	------------

Date of Collection	2014-FEB-18
--------------------	-------------

Timepoint-minutes	0
-------------------	---

Urine Start Day	
-----------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (1)

Data signed: (hfarmer1) 26 Mar 2015 15:21:49

Generated On: 20 Jul 2016 12:37:46

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (2)

Data signed: (hfarmer1) 26 Mar 2015 15:21:49

Generated On: 20 Jul 2016 12:37:46

Sample Barcode	05112440000036
----------------	----------------

Analyte	NIC
---------	-----

Sample type	PLASMA
-------------	--------

Result	.
--------	---

Result Unit	NG/ML
-------------	-------

Lab Status	OTHER
------------	-------

Sample comment	ANALYSIS NOT REQUIRED
----------------	-----------------------

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	5
--------------	---

Celerion Study Number	AA99128-02
-----------------------	------------

Date of Collection	2014-FEB-18
--------------------	-------------

Timepoint-minutes	0
-------------------	---

Urine Start Day	
-----------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 5

Form: Biomarker-Plasma (Nic, Cot, tHCot) (2)

Data signed: (hfarmer1) 26 Mar 2015 15:21:49

Generated On: 20 Jul 2016 12:37:46

Urine End Day

5

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 6

Form: Date of Visit

Data signed: (hfarmer1) 26 Mar 2015 15:21:51

Generated On: 20 Jul 2016 12:37:46

Date of Visit

19 FEB 2014
DD/MMM/YYYY

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 6

Form: Plasma Nicotine Sample

Data signed: (hfarmer1) 26 Mar 2015 15:21:51

Generated On: 20 Jul 2016 12:37:46

Not Done	False
----------	-------

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	19 FEB 2014
---------------------	-------------

Time hour:min 24-hour clock	08:11
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 6

Form: Plasma Cotinine Sample

Data signed: (hfarmer1) 26 Mar 2015 15:21:51

Generated On: 20 Jul 2016 12:37:46

Not Done	False
----------	-------

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	19 FEB 2014
---------------------	-------------

Time hour:min 24-hour clock	08:11
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 6

Form: CoHb Blood Sample <prior to gas transfer>

Data signed: (hfarmer1) 26 Mar 2015 15:21:51

Generated On: 20 Jul 2016 12:37:46

Not Done	False
----------	-------

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	19 FEB 2014
---------------------	-------------

Timepoint	Prior to gas transfer assessment <input checked="" type="radio"/>
-----------	--

Time hour:min 24-hour clock	07:00
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 6

Form: Oxysterols

Data signed: (hfarmer1) 26 Mar 2015 15:21:51

Generated On: 20 Jul 2016 12:37:46

Not Done	False
----------	-------

If Not Done, please specify the reason: _____

Was the subject fasting for at least 10 hours at time of sample collection?	Yes <input checked="" type="radio"/>
--	--------------------------------------

Date DD/MMM/YYYY	19 FEB 2014
---------------------	-------------

Time hour:min 24-hour clock	07:00
--------------------------------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1077

Folder: Day 6

Form: CYP2A6 activity Sample

Data signed: (hfarmer1) 26 Mar 2015 15:21:50

Generated On: 20 Jul 2016 12:37:46

Not Done	False
----------	-------

If Not Done, please specify the reason: _____

Date of sample collection
DD/MMM/YYYY

Time of sample collection
hour:min 24-hour clock

Parameter

19 FEB 2014

07:00

trans-3'-hydroxyc
otinine

19 FEB 2014

07:00

cotinine

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 6

Form: Risk Marker: sICAM-1

Data signed: (hfarmer1) 26 Mar 2015 15:21:50

Generated On: 20 Jul 2016 12:37:46

Not Done	False
----------	-------

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	19 FEB 2014
---------------------	-------------

Time hour:min 24-hour clock	07:00
--------------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 6

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Data signed: (hfarmer1) 26 Mar 2015 15:21:51

Generated On: 20 Jul 2016 12:37:46

Date of Birth

(b) (6)

Date of assessment
DD/MMM/YYYY

2014 FEB 19
DD/MMM/YYYY

Time of assessment

06:03
hour:min 24-hour clock

Assessment Status

Completed ☒

Please indicate for each of the items below, how you have been feeling over the past 24 hours

How have you been feeling over the past 24 hours?

None ☐

1. Angry, irritable, frustrated

How have you been feeling over the past 24 hours?

None ☐

2. Anxious, nervous

How have you been feeling over the past 24 hours?

None ☐

3. Depressed Mood, sad

How have you been feeling over the past 24 hours?

Mild ☐

4. Desire or craving to smoke

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 6

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Data signed: (hfarmer1) 26 Mar 2015 15:21:51

Generated On: 20 Jul 2016 12:37:46

How have you been feeling over the past 24 hours? None ☐

5. Difficulty concentrating

How have you been feeling over the past 24 hours? None ☐

6. Increased appetite, hungry, weight gain

How have you been feeling over the past 24 hours? None ☐

7. Insomnia, sleep problems, awakening at night

How have you been feeling over the past 24 hours? None ☐

8. Restless

How have you been feeling over the past 24 hours? None ☐

9. Impatient

How have you been feeling over the past 24 hours? None ☐

10. Constipation

How have you been feeling over the past 24 hours? None ☐

11. Dizziness

How have you been feeling over the past 24 hours? None ☐

12. Coughing

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 6

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Data signed: (hfarmer1) 26 Mar 2015 15:21:51

Generated On: 20 Jul 2016 12:37:46

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: 1077

Folder: Day 6

Form: Cough Assessment

Data signed: (hfarmer1) 26 Mar 2015 15:21:52

Generated On: 20 Jul 2016 12:37:46

Date of Birth

(b) (6)

Date of assessment
DD/MMM/YYYY

2014 FEB 19
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?

No ☒

If YES, please answer the following questions:

First Question: Cough Impact Scale
How much is your cough bothering you?

-9

Second Question: Cough Intensity Scale:
How intense is your cough?

Not Applicable ☒

Third Question: Cough Frequency Scale:
How frequently do you normally have to cough each
day?

Not Applicable ☒

Fourth Question: Sputum Production
To what extent do you produce sputum when coughing?

Not Applicable ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 6

Form: Bio-banking (Transcriptomics)

Data signed: (hfarmer1) 26 Mar 2015 15:21:51

Generated On: 20 Jul 2016 12:37:46

Was a Bio-banking sample for transcriptomics taken?

Yes ☒

Time of Sample Collection

07:00
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: 1077**

Folder: Day 6

Form: Bio-banking (Biomarkers of exposure and risk markers)

Data signed: (hfarmer1) 26 Mar 2015 15:21:51

Generated On: 20 Jul 2016 12:37:46

Was a Bio-banking sample for biomarkers of exposure
and risk markers taken?

Yes ☒

Time of Sample Collection

07:00
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: 1077**

Folder: Day 6

Form: Bio-banking (nasal epithelial collection/buccal collection)

Data signed: (hfarmer1) 26 Mar 2015 15:21:51

Generated On: 20 Jul 2016 12:37:46

Was a Bio-banking sample for nasal epithelial collection/buccal collection taken?	Yes <input checked="" type="radio"/>
---	--------------------------------------

Time of Buccal Collection	10:30
	hour:min 24-hour clock

Time of Nasal Epithelial Collection	10:28
	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: 1077**

Folder: Day 6

Form: Oxysterol results (1)

Generated On: 20 Jul 2016 12:37:46

Sample Accession number	3194608415
-------------------------	------------

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: 1077**

Folder: Day 6

Form: Oxysterol results (2)

Generated On: 20 Jul 2016 12:37:46

Sample Accession number	3194608415
-------------------------	------------

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: 1077**

Folder: Day 6

Form: Oxysterol results (3)

Generated On: 20 Jul 2016 12:37:46

Sample Accession number	3194608415
-------------------------	------------

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: 1077**

Folder: Day 6

Form: Oxysterol results (4)

Generated On: 20 Jul 2016 12:37:46

Sample Accession number	3194608415
-------------------------	------------

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: 1077**

Folder: Day 6

Form: Oxysterol results (5)

Generated On: 20 Jul 2016 12:37:46

Sample Accession number	3194608415
-------------------------	------------

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: 1077**

Folder: Day 6

Form: Oxysterol results (6)

Generated On: 20 Jul 2016 12:37:46

Sample Accession number	3194608415
-------------------------	------------

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: 1077**

Folder: Day 6

Form: Oxysterol results (7)

Generated On: 20 Jul 2016 12:37:46

Sample Accession number	3194608415
-------------------------	------------

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: 1077**

Folder: Day 6

Form: Oxysterol results (8)

Generated On: 20 Jul 2016 12:37:46

Sample Accession number	3194608415
-------------------------	------------

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: 1077**

Folder: Day 6

Form: Oxysterol results (9)

Generated On: 20 Jul 2016 12:37:46

Sample Accession number	3194608415
-------------------------	------------

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: 1077**

Folder: Day 6

Form: Oxysterol results (10)

Generated On: 20 Jul 2016 12:37:46

Sample Accession number	3194608415
-------------------------	------------

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: 1077**

Folder: Day 6

Form: Oxysterol results (11)

Generated On: 20 Jul 2016 12:37:46

Sample Accession number	3194608415
-------------------------	------------

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: 1077**

Folder: Day 6

Form: Oxysterol results (12)

Generated On: 20 Jul 2016 12:37:46

Sample Accession number	3194608415
-------------------------	------------

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: 1077**

Folder: Day 6

Form: Lab_BU_COHB (1)

Data signed: (hfarmer1) 26 Mar 2015 15:21:53

Generated On: 20 Jul 2016 12:37:46

Sample Barcode	05115150000476
----------------	----------------

Analyte	CARBOXYHEMOGLOBIN
---------	-------------------

Sample type	BLOOD
-------------	-------

Result	.
--------	---

Result Unit	%
-------------	---

Lab Status	OTHER
------------	-------

Sample comment	ANALYSIS NOT REQUIRED
----------------	-----------------------

Detection method	SPECTROPHOTOMETRIC
------------------	--------------------

Lower limit of quantification	0.500
-------------------------------	-------

Planned time point (Hour)	6
---------------------------	---

Day of Visit	6
--------------	---

Celerion Study Number	AA99128-16
-----------------------	------------

Date of Collection	2014-FEB-19
--------------------	-------------

Timepoint-minutes	
-------------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 6

Form: Lab_BU_COHB (1)

Data signed: (hfarmer1) 26 Mar 2015 15:21:53

Generated On: 20 Jul 2016 12:37:46

Start Day (24 hour urine only)

End Day (24 hour Urine Only)

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1077

Folder: Day 6

Form: Questionnaire on smoking urges (QSU)

Data signed: (hfarmer1) 26 Mar 2015 15:21:52

Generated On: 20 Jul 2016 12:37:46

Type	QSU
------	-----

Date of Birth	(b) (6)
---------------	---------

Date of assessment	2014 FEB 19
--------------------	-------------

DD/MMM/YYYY

Time of assessment	06:04
--------------------	-------

hour:min 24-hour clock

Assessment Status	Completed <input type="radio"/>
-------------------	---------------------------------

1. I have a desire for a cigarette right now	Somewhat disagree <input type="radio"/>
--	---

2. Nothing would be better than smoking a cigarette right now	Strongly disagree <input type="radio"/>
---	---

3. If it were possible I would probably smoke now	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	Somewhat disagree <input type="radio"/>
--	---

6. I have an urge for a cigarette	Somewhat disagree <input type="radio"/>
-----------------------------------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 6

Form: Risk Markers(CCLS) (1)

Data signed: (hfarmer1) 26 Mar 2015 15:21:52

Generated On: 20 Jul 2016 12:37:46

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	1077
----------------------	------

Subject Sex	M
-------------	---

Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	DAY6
------------	------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	V946084
--------------	---------

Actual Collection Date	2014 02 19
------------------------	------------

Actual Collection Time	07:00
------------------------	-------

Specimen Condition	
--------------------	--

Battery ID	IM2293
------------	--------

Battery Name	SICAM-1
--------------	---------

Lab Test ID	IMT1768
-------------	---------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 6

Form: Risk Markers(CCLS) (1)

Data signed: (hfarmer1) 26 Mar 2015 15:21:52

Generated On: 20 Jul 2016 12:37:46

Lab Test Name	SICAM-1-RUO
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	236.6
Reported Numeric Result	236.6
Reference Range low	98.8
Reference Range high	320.0
Range Units	NG/ML
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 6

Form: Risk Markers(CCLS) (1)

Data signed: (hfarmer1) 26 Mar 2015 15:21:52

Generated On: 20 Jul 2016 12:37:46

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: 1077**

Folder: Day 6

Form: Biomarker-Plasma (Nic, Cot, tHCot)

Generated On: 20 Jul 2016 12:37:46

Sample type

PLASMA

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 6

Form: Biomarker-Plasma (Nic, Cot, tHCot) (1)

Generated On: 20 Jul 2016 12:37:46

Sample Barcode	05112440000037
----------------	----------------

Analyte	COT
---------	-----

Sample type	PLASMA
-------------	--------

Result	.
--------	---

Result Unit	NG/ML
-------------	-------

Lab Status	OTHER
------------	-------

Sample comment	ANALYSIS NOT REQUIRED
----------------	-----------------------

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	6
--------------	---

Celerion Study Number	AA99128-02
-----------------------	------------

Date of Collection	2014-FEB-19
--------------------	-------------

Timepoint-minutes	0
-------------------	---

Urine Start Day	
-----------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 6

Form: Biomarker-Plasma (Nic, Cot, tHCot) (1)

Generated On: 20 Jul 2016 12:37:46

Urine End Day

6

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 6

Form: Biomarker-Plasma (Nic, Cot, tHCot) (2)

Generated On: 20 Jul 2016 12:37:46

Sample Barcode	05112440000037
----------------	----------------

Analyte	NIC
---------	-----

Sample type	PLASMA
-------------	--------

Result	.
--------	---

Result Unit	NG/ML
-------------	-------

Lab Status	OTHER
------------	-------

Sample comment	ANALYSIS NOT REQUIRED
----------------	-----------------------

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	6
--------------	---

Celerion Study Number	AA99128-02
-----------------------	------------

Date of Collection	2014-FEB-19
--------------------	-------------

Timepoint-minutes	0
-------------------	---

Urine Start Day	
-----------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 6

Form: Biomarker-Plasma (Nic, Cot, tHCot) (2)

Generated On: 20 Jul 2016 12:37:46

Urine End Day

6

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 6

Form: Biomarker-Plasma (Nic, Cot, tHCot) (3)

Generated On: 20 Jul 2016 12:37:46

Sample Barcode	05112520000101
----------------	----------------

Analyte	COT
---------	-----

Sample type	PLASMA
-------------	--------

Result	.
--------	---

Result Unit	NG/ML
-------------	-------

Lab Status	OTHER
------------	-------

Sample comment	ANALYSIS NOT REQUIRED
----------------	-----------------------

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	6
--------------	---

Celerion Study Number	AA99128-10
-----------------------	------------

Date of Collection	2014-FEB-19
--------------------	-------------

Timepoint-minutes	0
-------------------	---

Urine Start Day	
-----------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 6

Form: Biomarker-Plasma (Nic, Cot, tHCot) (3)

Generated On: 20 Jul 2016 12:37:46

Urine End Day

6

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 6

Form: Biomarker-Plasma (Nic, Cot, tHCot) (4)

Generated On: 20 Jul 2016 12:37:46

Sample Barcode	05112520000101
----------------	----------------

Analyte	THCOT
---------	-------

Sample type	PLASMA
-------------	--------

Result	.
--------	---

Result Unit	NG/ML
-------------	-------

Lab Status	OTHER
------------	-------

Sample comment	ANALYSIS NOT REQUIRED
----------------	-----------------------

Detection method	LC-MS/MS
------------------	----------

Planned time point (Hour)	0
---------------------------	---

Day of Visit	6
--------------	---

Celerion Study Number	AA99128-10
-----------------------	------------

Date of Collection	2014-FEB-19
--------------------	-------------

Timepoint-minutes	0
-------------------	---

Urine Start Day	
-----------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Day 6

Form: Biomarker-Plasma (Nic, Cot, tHCot) (4)

Generated On: 20 Jul 2016 12:37:46

Urine End Day

6

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Discharge (Confinement)

Form: Date of Discharge

Data signed: (hfarmer1) 26 Mar 2015 15:21:57

Generated On: 20 Jul 2016 12:37:46

Date of Visit	19 FEB 2014 DD/MMM/YYYY
---------------	----------------------------

Discharge Time	11:26 hour:min 24-hour clock
----------------	---------------------------------

Is the subject continuing in the ambulatory period?	Yes <input type="radio"/>
---	---------------------------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Discharge (Confinement)

Form: Vital Signs

Data signed: (hcoleman1) 18 Jun 2015 20:00:11

Generated On: 20 Jul 2016 12:37:46

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 10:23
hour:min 24-hour clock

Pulse rate 59
beats per minute

Respiratory rate 16
breaths per minute

Blood Pressure (systolic) 109
mmHg

Blood Pressure (diastolic) 75
mmHg

Vital Signs Position of Subject Supine ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Discharge (Confinement)

Form: Advice on the risk of smoking and debriefing

Data signed: (hfarmer1) 26 Mar 2015 15:21:57

Generated On: 20 Jul 2016 12:37:46

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: 1077**

Folder: Discharge (Confinement)

Form: Physical Examination

Data signed: (hcoleman1) 18 Jun 2015 20:00:10

Generated On: 20 Jul 2016 12:37:46

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Discharge (Confinement)

Form: Physical Examination (1)

Data signed: (hcoleman1) 18 Jun 2015 20:00:10

Generated On: 20 Jul 2016 12:37:46

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: 1077**

Folder: Discharge (Confinement)

Form: Physical Examination (2)

Data signed: (hcoleman1) 18 Jun 2015 20:00:10

Generated On: 20 Jul 2016 12:37:46

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: 1077**

Folder: Discharge (Confinement)

Form: Physical Examination (3)

Data signed: (hcoleman1) 18 Jun 2015 20:00:10

Generated On: 20 Jul 2016 12:37:46

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: 1077**

Folder: Discharge (Confinement)

Form: Physical Examination (4)

Data signed: (hcoleman1) 18 Jun 2015 20:00:10

Generated On: 20 Jul 2016 12:37:46

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: 1077**

Folder: Discharge (Confinement)

Form: Physical Examination (5)

Data signed: (hcoleman1) 18 Jun 2015 20:00:10

Generated On: 20 Jul 2016 12:37:46

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: 1077**

Folder: Discharge (Confinement)

Form: Physical Examination (6)

Data signed: (hcoleman1) 18 Jun 2015 20:00:10

Generated On: 20 Jul 2016 12:37:46

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: 1077**

Folder: Discharge (Confinement)

Form: Physical Examination (7)

Data signed: (hcoleman1) 18 Jun 2015 20:00:10

Generated On: 20 Jul 2016 12:37:46

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: 1077

Folder: Discharge (Confinement)

Form: Physical Examination (8)

Data signed: (hcoleman1) 18 Jun 2015 20:00:10

Generated On: 20 Jul 2016 12:37:46

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: 1077**

Folder: Discharge (Confinement)

Form: Physical Examination (9)

Data signed: (hcoleman1) 18 Jun 2015 20:00:10

Generated On: 20 Jul 2016 12:37:46

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: 1077**

Folder: Discharge (Confinement)

Form: Physical Examination (10)

Data signed: (hcoleman1) 18 Jun 2015 20:00:10

Generated On: 20 Jul 2016 12:37:46

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: 1077**

Folder: Discharge (Confinement)

Form: Physical Examination (11)

Data signed: (hcoleman1) 18 Jun 2015 20:00:10

Generated On: 20 Jul 2016 12:37:46

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: 1077**

Folder: Discharge (Confinement)

Form: Physical Examination (12)

Data signed: (hcoleman1) 18 Jun 2015 20:00:10

Generated On: 20 Jul 2016 12:37:46

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

System Musculoskeletal ☒

Outcome Abnormal ☒

Abnormal, please specify ABRASION LEFT GREAT TOE

Clinically significant No ☒

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Discharge (Confinement)

Form: Physical Examination (13)

Data signed: (hcoleman1) 18 Jun 2015 20:00:10

Generated On: 20 Jul 2016 12:37:46

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: 1077**

Folder: Discharge (Confinement)

Form: Physical Examination (14)

Data signed: (hcoleman1) 18 Jun 2015 20:00:10

Generated On: 20 Jul 2016 12:37:46

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

System Dentition ☒

Outcome Abnormal ☒

Abnormal, please specify
DECAYING 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: 1077

Folder: Discharge (Confinement)

Form: Physical Examination (15)

Data signed: (hcoleman1) 18 Jun 2015 20:00:10

Generated On: 20 Jul 2016 12:37:46

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: 1077**

Folder: Discharge (Confinement)

Form: Physical Examination (16)

Data signed: (hcoleman1) 18 Jun 2015 20:00:10

Generated On: 20 Jul 2016 12:37:46

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: 1077**

Folder: Discharge (Confinement)

Form: Physical Examination (17)

Data signed: (hcoleman1) 18 Jun 2015 20:00:10

Generated On: 20 Jul 2016 12:37:46

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: 1077**

Folder: Discharge (Confinement)

Form: Physical Examination (18)

Data signed: (hcoleman1) 18 Jun 2015 20:00:10

Generated On: 20 Jul 2016 12:37:46

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: 1077**

Folder: Discharge (Confinement)

Form: Physical Examination (19)

Data signed: (hcoleman1) 18 Jun 2015 20:00:10

Generated On: 20 Jul 2016 12:37:46

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: 1077**

Folder: Discharge (Confinement)

Form: Weight

Data signed: (hfarmer1) 26 Mar 2015 15:21:57

Generated On: 20 Jul 2016 12:37:46

Measurement(s) assessed?

Yes ☒

If No, please specify the reason: _____

Date of Assessment

19 FEB 2014
DD/MMM/YYYY

Time of assessment

10:36
hour:min 24-hour clock

Weight

74.4
kg

BMI

21.7

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1077

Folder: Discharge (Confinement)

Form: ECG (12-Lead Standard)

Data signed: (hfarmer1) 26 Mar 2015 15:21:54

Generated On: 20 Jul 2016 12:37:46

Was the ECG performed? Yes ☒

If No, please specify the reason: _____

Position Supine ☒

Heart Rate 57
beats per minute

QRS Interval 106
msec

QT Interval 422
msec

QTcB Interval 414
msec

PR Interval 179
msec

QTcF Interval 417
msec

Interpretation Normal ☒

If Abnormal, Clinical Significance _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Discharge (Confinement)

Form: ECG (12-Lead Standard)

Data signed: (hfarmer1) 26 Mar 2015 15:21:54

Generated On: 20 Jul 2016 12:37:46

If Not Clinically significant or clinically Significant, Please
specify the finding(s)

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1077

Folder: Discharge (Confinement)

Form: Gas Transfer

Data signed: (hcoleman1) 18 Jun 2015 20:00:10

Generated On: 20 Jul 2016 12:37:46

Was the Gas Transfer performed?

No ☒

If No, please specify the reason:

TEST PERFORMED BUT THEY
WERE NOT RESULTED

Category

Position

SITTING

Date of assessment
DD/MMM/YYYY

Time of assessment

DLCO value

KCO value

DLCO/VA value

Interpretation

If Abnormal, Clinical Significance

If Not Clinically Significant or Clinically Significant, Please
specify the finding(s)

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1077

Folder: Discharge (Confinement)

Form: Lung Volume Measurements

Data signed: (hcoleman1) 18 Jun 2015 20:00:10

Generated On: 20 Jul 2016 12:37:46

Were the Lung Volume Measurements performed?

No ☒

If No, please specify the reason:

TEST PERFORMED BUT THEY
WERE NOT RESULTED

Category

Position

SITTING

Date of assessment
DD/MMM/YYYY

Time of assessment

VC value

TLC value

IC value

FRC value

Interpretation

If Abnormal, Clinical Significance

If Not Clinically Significant or Clinically Significant, Please
specify the finding(s)

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1077

Folder: Discharge (Confinement)

Form: Spirometry with a short-acting bronchodilator

Data signed: (hcoleman1) 18 Jun 2015 20:00:11

Generated On: 20 Jul 2016 12:37:46

Was the Spirometry with a short-acting bronchodilator performed?

No ☒

If No, please specify the reason:

TEST PERFORMED BUT THEY WERE NOT RESULTED

Category

With short-acting bronchodilator ☒

Position

SITTING

Date of assessment
DD/MMM/YYYY

Time of assessment

Name of bronchodilator

Dose

Predicted FVC value

Best measured FVC value

Percent of predicted FVC value

Best measured FEV1 value

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Discharge (Confinement)

Form: Spirometry with a short-acting bronchodilator

Data signed: (hcoleman1) 18 Jun 2015 20:00:11

Generated On: 20 Jul 2016 12:37:46

Predicted FEV1 value

Percent of predicted FEV1 value

Calculated ratio between FEV1/FVC

MEF 25/75 value

Interpretation

If Abnormal, Clinical Significance

If Not Clinically Significant or Clinically Significant, Please
specify the finding(s)

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Discharge (Confinement)

Form: Haematology

Data signed: (hfarmer1) 26 Mar 2015 15:21:54

Generated On: 20 Jul 2016 12:37:46

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: 1077**

Folder: Discharge (Confinement)

Form: Clinical Chemistry

Data signed: (hfarmer1) 26 Mar 2015 15:21:54

Generated On: 20 Jul 2016 12:37:46

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: 1077**

Folder: Discharge (Confinement)

Form: Urine analysis

Data signed: (hfarmer1) 26 Mar 2015 15:21:54

Generated On: 20 Jul 2016 12:37:46

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: 1077**

Folder: Discharge (Confinement)

Form: CO Breath Test

Data signed: (hfarmer1) 26 Mar 2015 15:21:54

Generated On: 20 Jul 2016 12:37:46

Assessment not done	False
---------------------	-------

If Not Done, please specify the reason: _____

Actual Time of Assessment	10:26
	hour:min 24-hour clock

Result	9
	ppm

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (1)

Data signed: (hfarmer1) 26 Mar 2015 15:21:57

Generated On: 20 Jul 2016 12:37:46

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	V946084
--------------	---------

Actual Collection Date	2014 02 19
------------------------	------------

Actual Collection Time	07:00
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	RC1029
------------	--------

Battery Name	TRIGLYCERIDES
--------------	---------------

Lab Test ID	RCT19
-------------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1077

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (1)

Data signed: (hfarmer1) 26 Mar 2015 15:21:57

Generated On: 20 Jul 2016 12:37:46

Lab Test Name	TRIGLYCERIDES (GPO)
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	302
Reported Numeric Result	302
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: 1077**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (1)

Data signed: (hfarmer1) 26 Mar 2015 15:21:57

Generated On: 20 Jul 2016 12:37:46

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (2)

Data signed: (hfarmer1) 26 Mar 2015 15:21:57

Generated On: 20 Jul 2016 12:37:46

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	V946084
--------------	---------

Actual Collection Date	2014 02 19
------------------------	------------

Actual Collection Time	07:00
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	RC1092
------------	--------

Battery Name	FASTING GLUCOSE
--------------	-----------------

Lab Test ID	RCT142
-------------	--------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (2)

Data signed: (hfarmer1) 26 Mar 2015 15:21:57

Generated On: 20 Jul 2016 12:37:46

Lab Test Name	FASTING GLUCOSE
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	92
Reported Numeric Result	92
Reference Range low	70
Reference Range high	100
Range Units	MG/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (2)

Data signed: (hfarmer1) 26 Mar 2015 15:21:57

Generated On: 20 Jul 2016 12:37:46

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (3)

Data signed: (hfarmer1) 26 Mar 2015 15:21:57

Generated On: 20 Jul 2016 12:37:46

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	V946084
--------------	---------

Actual Collection Date	2014 02 19
------------------------	------------

Actual Collection Time	07:00
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	RC272
------------	-------

Battery Name	TOTAL CHOLESTEROL
--------------	-------------------

Lab Test ID	RCT20
-------------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1077

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (3)

Data signed: (hfarmer1) 26 Mar 2015 15:21:57

Generated On: 20 Jul 2016 12:37:46

Lab Test Name	CHOLESTEROL (HIGH PERFORMANCE)
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	231
Reported Numeric Result	231
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: 1077**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (3)

Data signed: (hfarmer1) 26 Mar 2015 15:21:57

Generated On: 20 Jul 2016 12:37:46

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: 1077**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (4)

Data signed: (hfarmer1) 26 Mar 2015 15:21:57

Generated On: 20 Jul 2016 12:37:46

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	V946084
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Actual Collection Date	2014 02 19
------------------------	------------

Actual Collection Time	07:00
------------------------	-------

Specimen Condition	<hr/>
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Battery ID	RC9255
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Battery Name	CHEMISTRY PANEL
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Lab Test ID	RCT1
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (4)

Data signed: (hfarmer1) 26 Mar 2015 15:21:57

Generated On: 20 Jul 2016 12:37:46

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: 1077**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (4)

Data signed: (hfarmer1) 26 Mar 2015 15:21:57

Generated On: 20 Jul 2016 12:37:46

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (5)

Data signed: (hfarmer1) 26 Mar 2015 15:21:57

Generated On: 20 Jul 2016 12:37:46

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	M
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Subject Date of Birth	(b) (6)
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	V946084
--------------	---------

Actual Collection Date	2014 02 19
------------------------	------------

Actual Collection Time	07:00
------------------------	-------

Specimen Condition	<hr/>
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Battery ID	RC9255
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Battery Name	CHEMISTRY PANEL
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Lab Test ID	RCT12
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1077

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (5)

Data signed: (hfarmer1) 26 Mar 2015 15:21:57

Generated On: 20 Jul 2016 12:37:46

Lab Test Name	TOTAL PROTEIN
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	7.8
Reported Numeric Result	7.8
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: 1077**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (5)

Data signed: (hfarmer1) 26 Mar 2015 15:21:57

Generated On: 20 Jul 2016 12:37:46

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (6)

Data signed: (hfarmer1) 26 Mar 2015 15:21:57

Generated On: 20 Jul 2016 12:37:46

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	V946084
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Actual Collection Date	2014 02 19
------------------------	------------

Actual Collection Time	07:00
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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	RCT13
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1077

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (6)

Data signed: (hfarmer1) 26 Mar 2015 15:21:57

Generated On: 20 Jul 2016 12:37:46

Lab Test Name	ALBUMIN
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	4.6
Reported Numeric Result	4.6
Reference Range low	3.3
Reference Range high	4.9
Range Units	G/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (6)

Data signed: (hfarmer1) 26 Mar 2015 15:21:57

Generated On: 20 Jul 2016 12:37:46

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (7)

Data signed: (hfarmer1) 26 Mar 2015 15:21:57

Generated On: 20 Jul 2016 12:37:46

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	V946084
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Actual Collection Date	2014 02 19
------------------------	------------

Actual Collection Time	07:00
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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	RCT1407
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1077

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (7)

Data signed: (hfarmer1) 26 Mar 2015 15:21:57

Generated On: 20 Jul 2016 12:37:46

Lab Test Name	ALKALINE PHOSPHATASE
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	90
Reported Numeric Result	90
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: 1077**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (7)

Data signed: (hfarmer1) 26 Mar 2015 15:21:57

Generated On: 20 Jul 2016 12:37:46

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (8)

Data signed: (hfarmer1) 26 Mar 2015 15:21:57

Generated On: 20 Jul 2016 12:37:46

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	V946084
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Actual Collection Date	2014 02 19
------------------------	------------

Actual Collection Time	07:00
------------------------	-------

Specimen Condition	<hr/>
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Battery ID	RC9255
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Battery Name	CHEMISTRY PANEL
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Lab Test ID	RCT1408
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1077

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (8)

Data signed: (hfarmer1) 26 Mar 2015 15:21:57

Generated On: 20 Jul 2016 12:37:46

Lab Test Name	LDH
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	154
Reported Numeric Result	154
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: 1077**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (8)

Data signed: (hfarmer1) 26 Mar 2015 15:21:57

Generated On: 20 Jul 2016 12:37:46

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1077

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (9)

Data signed: (hfarmer1) 26 Mar 2015 15:21:57

Generated On: 20 Jul 2016 12:37:46

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	V946084
--------------	---------

Actual Collection Date	2014 02 19
------------------------	------------

Actual Collection Time	07:00
------------------------	-------

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: 1077

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (9)

Data signed: (hfarmer1) 26 Mar 2015 15:21:57

Generated On: 20 Jul 2016 12:37:46

Lab Test Name	SERUM SODIUM
Test ID	
Test Status	Done <input checked="" type="checkbox"/>
Reported Text Result	142
Reported Numeric Result	142
Reference Range low	132
Reference Range high	147
Range Units	MEQ/L
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (9)

Data signed: (hfarmer1) 26 Mar 2015 15:21:57

Generated On: 20 Jul 2016 12:37:46

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (10)

Data signed: (hfarmer1) 26 Mar 2015 15:21:57

Generated On: 20 Jul 2016 12:37:46

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	V946084
--------------	---------

Actual Collection Date	2014 02 19
------------------------	------------

Actual Collection Time	07:00
------------------------	-------

Specimen Condition	<hr/>
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Battery ID	RC9255
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Battery Name	CHEMISTRY PANEL
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Lab Test ID	RCT16
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1077

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (10)

Data signed: (hfarmer1) 26 Mar 2015 15:21:57

Generated On: 20 Jul 2016 12:37:46

Lab Test Name	SERUM POTASSIUM
Test ID	
Test Status	Done <input checked="" type="checkbox"/>
Reported Text Result	5.2
Reported Numeric Result	5.2
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: 1077**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (10)

Data signed: (hfarmer1) 26 Mar 2015 15:21:57

Generated On: 20 Jul 2016 12:37:46

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (11)

Data signed: (hfarmer1) 26 Mar 2015 15:21:57

Generated On: 20 Jul 2016 12:37:46

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	V946084
--------------	---------

Actual Collection Date	2014 02 19
------------------------	------------

Actual Collection Time	07:00
------------------------	-------

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: 1077

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (11)

Data signed: (hfarmer1) 26 Mar 2015 15:21:57

Generated On: 20 Jul 2016 12:37:46

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: 1077**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (11)

Data signed: (hfarmer1) 26 Mar 2015 15:21:57

Generated On: 20 Jul 2016 12:37:46

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (12)

Data signed: (hfarmer1) 26 Mar 2015 15:21:57

Generated On: 20 Jul 2016 12:37:46

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	<hr/>
----------------------	-------

Subject Sex	M
-------------	---

Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	V946084
--------------	---------

Actual Collection Date	2014 02 19
------------------------	------------

Actual Collection Time	07:00
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	RC9255
------------	--------

Battery Name	CHEMISTRY PANEL
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Lab Test ID	RCT3
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1077

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (12)

Data signed: (hfarmer1) 26 Mar 2015 15:21:57

Generated On: 20 Jul 2016 12:37:46

Lab Test Name	GGT
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	14
Reported Numeric Result	14
Reference Range low	10
Reference Range high	61
Range Units	U/L
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (12)

Data signed: (hfarmer1) 26 Mar 2015 15:21:57

Generated On: 20 Jul 2016 12:37:46

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (13)

Data signed: (hfarmer1) 26 Mar 2015 15:21:57

Generated On: 20 Jul 2016 12:37:46

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	V946084
--------------	---------

Actual Collection Date	2014 02 19
------------------------	------------

Actual Collection Time	07:00
------------------------	-------

Specimen Condition	<hr/>
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Battery ID	RC9255
------------	--------

Battery Name	CHEMISTRY PANEL
--------------	-----------------

Lab Test ID	RCT392
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1077

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (13)

Data signed: (hfarmer1) 26 Mar 2015 15:21:57

Generated On: 20 Jul 2016 12:37:46

Lab Test Name	CREATININE (RATE BLANKED)
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Test ID	<hr/>
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Test Status	Done <input checked="" type="radio"/>
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Reported Text Result	1.1
----------------------	-----

Reported Numeric Result	1.1
-------------------------	-----

Reference Range low	0.5
---------------------	-----

Reference Range high	1.2
----------------------	-----

Range Units	MG/DL
-------------	-------

Conventional Text Result	<hr/>
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Conventional Numeric Result	<hr/>
-----------------------------	-------

Conventional Reference Range Low	<hr/>
----------------------------------	-------

Conventional Reference Range High	<hr/>
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Conventional Units	<hr/>
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SI Text Result	<hr/>
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (13)

Data signed: (hfarmer1) 26 Mar 2015 15:21:57

Generated On: 20 Jul 2016 12:37:46

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (14)

Data signed: (hfarmer1) 26 Mar 2015 15:21:57

Generated On: 20 Jul 2016 12:37:46

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	<hr/>
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Subject Sex	M
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Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	V946084
--------------	---------

Actual Collection Date	2014 02 19
------------------------	------------

Actual Collection Time	07:00
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Specimen Condition	<hr/>
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Battery ID	RC9255
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Battery Name	CHEMISTRY PANEL
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Lab Test ID	RCT4
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1077

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (14)

Data signed: (hfarmer1) 26 Mar 2015 15:21:57

Generated On: 20 Jul 2016 12:37:46

Lab Test Name	ALT (SGPT)
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	22
Reported Numeric Result	22
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: 1077**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (14)

Data signed: (hfarmer1) 26 Mar 2015 15:21:57

Generated On: 20 Jul 2016 12:37:46

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1077

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (15)

Data signed: (hfarmer1) 26 Mar 2015 15:21:57

Generated On: 20 Jul 2016 12:37:46

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
----------------------	-------

Subject Sex	M
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Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	V946084
--------------	---------

Actual Collection Date	2014 02 19
------------------------	------------

Actual Collection Time	07:00
------------------------	-------

Specimen Condition	<hr/>
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Battery ID	RC9255
------------	--------

Battery Name	CHEMISTRY PANEL
--------------	-----------------

Lab Test ID	RCT5
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1077

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (15)

Data signed: (hfarmer1) 26 Mar 2015 15:21:57

Generated On: 20 Jul 2016 12:37:46

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: 1077**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (15)

Data signed: (hfarmer1) 26 Mar 2015 15:21:57

Generated On: 20 Jul 2016 12:37:46

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (16)

Data signed: (hfarmer1) 26 Mar 2015 15:21:57

Generated On: 20 Jul 2016 12:37:46

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
----------------------	-------

Subject Sex	M
-------------	---

Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	V946084
--------------	---------

Actual Collection Date	2014 02 19
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Actual Collection Time	07:00
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Specimen Condition	<hr/>
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Battery ID	RC9255
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Battery Name	CHEMISTRY PANEL
--------------	-----------------

Lab Test ID	RCT6
-------------	------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1077

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (16)

Data signed: (hfarmer1) 26 Mar 2015 15:21:57

Generated On: 20 Jul 2016 12:37:46

Lab Test Name	UREA NITROGEN
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	21
Reported Numeric Result	21
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: 1077**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (16)

Data signed: (hfarmer1) 26 Mar 2015 15:21:57

Generated On: 20 Jul 2016 12:37:46

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (17)

Data signed: (hfarmer1) 26 Mar 2015 15:21:57

Generated On: 20 Jul 2016 12:37:46

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	V946084
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Actual Collection Date	2014 02 19
------------------------	------------

Actual Collection Time	07:00
------------------------	-------

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: 1077

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (17)

Data signed: (hfarmer1) 26 Mar 2015 15:21:57

Generated On: 20 Jul 2016 12:37:46

Lab Test Name	MONOCYTES
Test ID	
Test Status	Done <input type="checkbox"/>
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: 1077**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (17)

Data signed: (hfarmer1) 26 Mar 2015 15:21:57

Generated On: 20 Jul 2016 12:37:46

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (18)

Data signed: (hfarmer1) 26 Mar 2015 15:21:57

Generated On: 20 Jul 2016 12:37:46

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	V946084
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Actual Collection Date	2014 02 19
------------------------	------------

Actual Collection Time	07:00
------------------------	-------

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: 1077**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (18)

Data signed: (hfarmer1) 26 Mar 2015 15:21:57

Generated On: 20 Jul 2016 12:37:46

Lab Test Name

MCH

Test ID

Test Status

Done ☒

Reported Text Result

29

Reported Numeric Result

29

Reference Range low

26

Reference Range high

34

Range Units

PG

Conventional Text Result

Conventional Numeric Result

Conventional Reference Range Low

Conventional Reference Range High

Conventional Units

SI Text Result

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (18)

Data signed: (hfarmer1) 26 Mar 2015 15:21:57

Generated On: 20 Jul 2016 12:37:46

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1077

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (19)

Data signed: (hfarmer1) 26 Mar 2015 15:21:57

Generated On: 20 Jul 2016 12:37:46

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	V946084
--------------	---------

Actual Collection Date	2014 02 19
------------------------	------------

Actual Collection Time	07:00
------------------------	-------

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: 1077

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (19)

Data signed: (hfarmer1) 26 Mar 2015 15:21:57

Generated On: 20 Jul 2016 12:37:46

Lab Test Name	MCHC
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	34
Reported Numeric Result	34
Reference Range low	31
Reference Range high	38
Range Units	G/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (19)

Data signed: (hfarmer1) 26 Mar 2015 15:21:57

Generated On: 20 Jul 2016 12:37:46

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (20)

Data signed: (hfarmer1) 26 Mar 2015 15:21:57

Generated On: 20 Jul 2016 12:37:46

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	V946084
--------------	---------

Actual Collection Date	2014 02 19
------------------------	------------

Actual Collection Time	07:00
------------------------	-------

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: 1077

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (20)

Data signed: (hfarmer1) 26 Mar 2015 15:21:57

Generated On: 20 Jul 2016 12:37:46

Lab Test Name	EOSINOPHILS
Test ID	
Test Status	Done <input checked="" type="checkbox"/>
Reported Text Result	0.31
Reported Numeric Result	0.31
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: 1077**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (20)

Data signed: (hfarmer1) 26 Mar 2015 15:21:57

Generated On: 20 Jul 2016 12:37:46

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1077

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (21)

Data signed: (hfarmer1) 26 Mar 2015 15:21:57

Generated On: 20 Jul 2016 12:37:46

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	V946084
--------------	---------

Actual Collection Date	2014 02 19
------------------------	------------

Actual Collection Time	07:00
------------------------	-------

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: 1077

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (21)

Data signed: (hfarmer1) 26 Mar 2015 15:21:57

Generated On: 20 Jul 2016 12:37:46

Lab Test Name	BASOPHILS
Test ID	
Test Status	Done <input checked="" type="checkbox"/>
Reported Text Result	0.03
Reported Numeric Result	0.03
Reference Range low	0.00
Reference Range high	0.20
Range Units	X10^3/UL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (21)

Data signed: (hfarmer1) 26 Mar 2015 15:21:57

Generated On: 20 Jul 2016 12:37:46

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1077

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (22)

Data signed: (hfarmer1) 26 Mar 2015 15:21:57

Generated On: 20 Jul 2016 12:37:46

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	M
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Subject Date of Birth	(b) (6)
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	V946084
--------------	---------

Actual Collection Date	2014 02 19
------------------------	------------

Actual Collection Time	07:00
------------------------	-------

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: 1077**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (22)

Data signed: (hfarmer1) 26 Mar 2015 15:21:57

Generated On: 20 Jul 2016 12:37:46

Lab Test Name	PLATELETS
Test ID	
Test Status	Done <input checked="" type="radio"/>
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: 1077**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (22)

Data signed: (hfarmer1) 26 Mar 2015 15:21:57

Generated On: 20 Jul 2016 12:37:46

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1077

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (23)

Data signed: (hfarmer1) 26 Mar 2015 15:21:57

Generated On: 20 Jul 2016 12:37:46

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	V946084
--------------	---------

Actual Collection Date	2014 02 19
------------------------	------------

Actual Collection Time	07:00
------------------------	-------

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: 1077

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (23)

Data signed: (hfarmer1) 26 Mar 2015 15:21:57

Generated On: 20 Jul 2016 12:37:46

Lab Test Name	NEUTROPHILS (%)
Test ID	
Test Status	Done <input checked="" type="checkbox"/>
Reported Text Result	56.4
Reported Numeric Result	56.4
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: 1077**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (23)

Data signed: (hfarmer1) 26 Mar 2015 15:21:57

Generated On: 20 Jul 2016 12:37:46

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (24)

Data signed: (hfarmer1) 26 Mar 2015 15:21:57

Generated On: 20 Jul 2016 12:37:46

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
----------------------	-------

Subject Sex	M
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Subject Date of Birth	(b) (6)
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Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	V946084
--------------	---------

Actual Collection Date	2014 02 19
------------------------	------------

Actual Collection Time	07:00
------------------------	-------

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: 1077

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (24)

Data signed: (hfarmer1) 26 Mar 2015 15:21:57

Generated On: 20 Jul 2016 12:37:46

Lab Test Name	LYMPHOCYTES (%)
Test ID	
Test Status	Done <input checked="" type="checkbox"/>
Reported Text Result	33.2
Reported Numeric Result	33.2
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: 1077**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (24)

Data signed: (hfarmer1) 26 Mar 2015 15:21:57

Generated On: 20 Jul 2016 12:37:46

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1077

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (25)

Data signed: (hfarmer1) 26 Mar 2015 15:21:57

Generated On: 20 Jul 2016 12:37:46

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/>
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	V946084
--------------	---------

Actual Collection Date	2014 02 19
------------------------	------------

Actual Collection Time	07:00
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	HM1604
------------	--------

Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
--------------	-----------------------------------

Lab Test ID	HMT17
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1077

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (25)

Data signed: (hfarmer1) 26 Mar 2015 15:21:57

Generated On: 20 Jul 2016 12:37:46

Lab Test Name	MONOCYTES (%)
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	6.0
Reported Numeric Result	6.0
Reference Range low	2.6
Reference Range high	10.1
Range Units	%
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (25)

Data signed: (hfarmer1) 26 Mar 2015 15:21:57

Generated On: 20 Jul 2016 12:37:46

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1077

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (26)

Data signed: (hfarmer1) 26 Mar 2015 15:21:57

Generated On: 20 Jul 2016 12:37:46

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	M
-------------	---

Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	V946084
--------------	---------

Actual Collection Date	2014 02 19
------------------------	------------

Actual Collection Time	07:00
------------------------	-------

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: 1077

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (26)

Data signed: (hfarmer1) 26 Mar 2015 15:21:57

Generated On: 20 Jul 2016 12:37:46

Lab Test Name	EOSINOPHILS (%)
Test ID	
Test Status	Done <input type="checkbox"/>
Reported Text Result	4.0
Reported Numeric Result	4.0
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: 1077**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (26)

Data signed: (hfarmer1) 26 Mar 2015 15:21:57

Generated On: 20 Jul 2016 12:37:46

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1077

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (27)

Data signed: (hfarmer1) 26 Mar 2015 15:21:57

Generated On: 20 Jul 2016 12:37:46

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6)

Visit Name _____

Visit Type Scheduled ☒

Accession ID V946084

Actual Collection Date 2014 02 19

Actual Collection Time 07:00

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: 1077

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (27)

Data signed: (hfarmer1) 26 Mar 2015 15:21:57

Generated On: 20 Jul 2016 12:37:46

Lab Test Name	BASOPHILS (%)
Test ID	
Test Status	Done <input type="checkbox"/>
Reported Text Result	0.4
Reported Numeric Result	0.4
Reference Range low	0.0
Reference Range high	2.0
Range Units	%
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (27)

Data signed: (hfarmer1) 26 Mar 2015 15:21:57

Generated On: 20 Jul 2016 12:37:46

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (28)

Data signed: (hfarmer1) 26 Mar 2015 15:21:57

Generated On: 20 Jul 2016 12:37:46

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	V946084
--------------	---------

Actual Collection Date	2014 02 19
------------------------	------------

Actual Collection Time	07:00
------------------------	-------

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: 1077

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (28)

Data signed: (hfarmer1) 26 Mar 2015 15:21:57

Generated On: 20 Jul 2016 12:37:46

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: 1077**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (28)

Data signed: (hfarmer1) 26 Mar 2015 15:21:57

Generated On: 20 Jul 2016 12:37:46

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (29)

Data signed: (hfarmer1) 26 Mar 2015 15:21:57

Generated On: 20 Jul 2016 12:37:46

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	<hr/>
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Subject Sex	M
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Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	V946084
--------------	---------

Actual Collection Date	2014 02 19
------------------------	------------

Actual Collection Time	07:00
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	HM1604
------------	--------

Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
--------------	-----------------------------------

Lab Test ID	HMT3
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1077

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (29)

Data signed: (hfarmer1) 26 Mar 2015 15:21:57

Generated On: 20 Jul 2016 12:37:46

Lab Test Name	RBC
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	5.2
Reported Numeric Result	5.2
Reference Range low	4.5
Reference Range high	6.4
Range Units	X10^6/UL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (29)

Data signed: (hfarmer1) 26 Mar 2015 15:21:57

Generated On: 20 Jul 2016 12:37:46

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1077

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (30)

Data signed: (hfarmer1) 26 Mar 2015 15:21:57

Generated On: 20 Jul 2016 12:37:46

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	V946084
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Actual Collection Date	2014 02 19
------------------------	------------

Actual Collection Time	07:00
------------------------	-------

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: 1077

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (30)

Data signed: (hfarmer1) 26 Mar 2015 15:21:57

Generated On: 20 Jul 2016 12:37:46

Lab Test Name	MCV
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	87
Reported Numeric Result	87
Reference Range low	79
Reference Range high	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: 1077**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (30)

Data signed: (hfarmer1) 26 Mar 2015 15:21:57

Generated On: 20 Jul 2016 12:37:46

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (31)

Data signed: (hfarmer1) 26 Mar 2015 15:21:57

Generated On: 20 Jul 2016 12:37:46

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	V946084
--------------	---------

Actual Collection Date	2014 02 19
------------------------	------------

Actual Collection Time	07:00
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	HM1604
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Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
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Lab Test ID	HMT40
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1077

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (31)

Data signed: (hfarmer1) 26 Mar 2015 15:21:57

Generated On: 20 Jul 2016 12:37:46

Lab Test Name	HEMOGLOBIN
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	15.2
Reported Numeric Result	15.2
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: 1077**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (31)

Data signed: (hfarmer1) 26 Mar 2015 15:21:57

Generated On: 20 Jul 2016 12:37:46

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (32)

Data signed: (hfarmer1) 26 Mar 2015 15:21:57

Generated On: 20 Jul 2016 12:37:46

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
----------------------	-------

Subject Sex	M
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Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	V946084
--------------	---------

Actual Collection Date	2014 02 19
------------------------	------------

Actual Collection Time	07:00
------------------------	-------

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: 1077**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (32)

Data signed: (hfarmer1) 26 Mar 2015 15:21:57

Generated On: 20 Jul 2016 12:37:46

Lab Test Name	WBC
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	7.72
Reported Numeric Result	7.72
Reference Range low	3.80
Reference Range high	10.70
Range Units	X10^3/UL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (32)

Data signed: (hfarmer1) 26 Mar 2015 15:21:57

Generated On: 20 Jul 2016 12:37:46

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (33)

Data signed: (hfarmer1) 26 Mar 2015 15:21:57

Generated On: 20 Jul 2016 12:37:46

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	<hr/>
----------------------	-------

Subject Sex	M
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Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	V946084
--------------	---------

Actual Collection Date	2014 02 19
------------------------	------------

Actual Collection Time	07:00
------------------------	-------

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: 1077

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (33)

Data signed: (hfarmer1) 26 Mar 2015 15:21:57


Generated On: 20 Jul 2016 12:37:46

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: 1077**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (33)

Data signed: (hfarmer1) 26 Mar 2015 15:21:57

Generated On: 20 Jul 2016 12:37:46

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1077

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (34)

Data signed: (hfarmer1) 26 Mar 2015 15:21:57

Generated On: 20 Jul 2016 12:37:46

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	V946084
--------------	---------

Actual Collection Date	2014 02 19
------------------------	------------

Actual Collection Time	07:00
------------------------	-------

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: 1077

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (34)

Data signed: (hfarmer1) 26 Mar 2015 15:21:57

Generated On: 20 Jul 2016 12:37:46

Lab Test Name	NEUTROPHILS
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	4.35
Reported Numeric Result	4.35
Reference Range low	1.96
Reference Range high	7.23
Range Units	X10^3/UL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (34)

Data signed: (hfarmer1) 26 Mar 2015 15:21:57

Generated On: 20 Jul 2016 12:37:46

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1077

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (35)

Data signed: (hfarmer1) 26 Mar 2015 15:21:57

Generated On: 20 Jul 2016 12:37:46

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	<hr/>
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Subject Sex	M
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Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	V946084
--------------	---------

Actual Collection Date	2014 02 19
------------------------	------------

Actual Collection Time	07:00
------------------------	-------

Specimen Condition	<hr/>
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Battery ID	HM1604
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Battery Name	HEMATOLOGY &DIFFERENTIAL PANEL
--------------	-----------------------------------

Lab Test ID	HMT9
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1077

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (35)

Data signed: (hfarmer1) 26 Mar 2015 15:21:57

Generated On: 20 Jul 2016 12:37:46

Lab Test Name	LYMPHOCYTES
Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	2.56
Reported Numeric Result	2.56
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: 1077**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (35)

Data signed: (hfarmer1) 26 Mar 2015 15:21:57

Generated On: 20 Jul 2016 12:37:46

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (36)

Data signed: (hfarmer1) 26 Mar 2015 15:21:57

Generated On: 20 Jul 2016 12:37:46

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	<hr/>
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Subject Sex	M
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Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	V946084
--------------	---------

Actual Collection Date	2014 02 19
------------------------	------------

Actual Collection Time	07:00
------------------------	-------

Specimen Condition	<hr/>
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Battery ID	UA1538
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Battery Name	URINE MACRO PANEL
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Lab Test ID	UAT10
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1077

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (36)

Data signed: (hfarmer1) 26 Mar 2015 15:21:57


Generated On: 20 Jul 2016 12:37:46

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: 1077**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (36)

Data signed: (hfarmer1) 26 Mar 2015 15:21:57

Generated On: 20 Jul 2016 12:37:46

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (37)

Data signed: (hfarmer1) 26 Mar 2015 15:21:57

Generated On: 20 Jul 2016 12:37:46

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	V946084
--------------	---------

Actual Collection Date	2014 02 19
------------------------	------------

Actual Collection Time	07:00
------------------------	-------

Specimen Condition	<hr/>
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Battery ID	UA1538
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Battery Name	URINE MACRO PANEL
--------------	-------------------

Lab Test ID	UAT2
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1077

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (37)

Data signed: (hfarmer1) 26 Mar 2015 15:21:57

Generated On: 20 Jul 2016 12:37:46

Lab Test Name	UR SPECIFIC GRAVITY
Test ID	
Test Status	Done <input checked="" type="checkbox"/>
Reported Text Result	1.020
Reported Numeric Result	1.020
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: 1077**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (37)

Data signed: (hfarmer1) 26 Mar 2015 15:21:57

Generated On: 20 Jul 2016 12:37:46

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (38)

Data signed: (hfarmer1) 26 Mar 2015 15:21:57

Generated On: 20 Jul 2016 12:37:46

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	V946084
--------------	---------

Actual Collection Date	2014 02 19
------------------------	------------

Actual Collection Time	07:00
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	UA1538
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Battery Name	URINE MACRO PANEL
--------------	-------------------

Lab Test ID	UAT3
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1077

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (38)

Data signed: (hfarmer1) 26 Mar 2015 15:21:57

Generated On: 20 Jul 2016 12:37:46

Lab Test Name	UR PH
Test ID	
Test Status	Done <input type="checkbox"/>
Reported Text Result	5.0
Reported Numeric Result	5.0
Reference Range low	5.0
Reference Range high	8.0
Range Units	
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (38)

Data signed: (hfarmer1) 26 Mar 2015 15:21:57

Generated On: 20 Jul 2016 12:37:46

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (39)

Data signed: (hfarmer1) 26 Mar 2015 15:21:57

Generated On: 20 Jul 2016 12:37:46

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	V946084
--------------	---------

Actual Collection Date	2014 02 19
------------------------	------------

Actual Collection Time	07:00
------------------------	-------

Specimen Condition	<hr/>
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Battery ID	UA1538
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Battery Name	URINE MACRO PANEL
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Lab Test ID	UAT43
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1077

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (39)

Data signed: (hfarmer1) 26 Mar 2015 15:21:57


Generated On: 20 Jul 2016 12:37:46

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: 1077**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (39)

Data signed: (hfarmer1) 26 Mar 2015 15:21:57

Generated On: 20 Jul 2016 12:37:46

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (40)

Data signed: (hfarmer1) 26 Mar 2015 15:21:57

Generated On: 20 Jul 2016 12:37:46

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	<hr/>
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Subject Sex	M
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Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
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Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	V946084
--------------	---------

Actual Collection Date	2014 02 19
------------------------	------------

Actual Collection Time	07:00
------------------------	-------

Specimen Condition	<hr/>
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Battery ID	UA1538
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Battery Name	URINE MACRO PANEL
--------------	-------------------

Lab Test ID	UAT49
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1077

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (40)

Data signed: (hfarmer1) 26 Mar 2015 15:21:57

Generated On: 20 Jul 2016 12:37:46

Lab Test Name	UR PROTEIN
Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	NEGATIVE
Reported Numeric Result	
Reference Range low	
Reference Range high	
Range Units	
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (40)

Data signed: (hfarmer1) 26 Mar 2015 15:21:57

Generated On: 20 Jul 2016 12:37:46

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (41)

Data signed: (hfarmer1) 26 Mar 2015 15:21:57

Generated On: 20 Jul 2016 12:37:46

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	V946084
--------------	---------

Actual Collection Date	2014 02 19
------------------------	------------

Actual Collection Time	07:00
------------------------	-------

Specimen Condition	<hr/>
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Battery ID	UA1538
------------	--------

Battery Name	URINE MACRO PANEL
--------------	-------------------

Lab Test ID	UAT5
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1077

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (41)

Data signed: (hfarmer1) 26 Mar 2015 15:21:57


Generated On: 20 Jul 2016 12:37:46

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: 1077**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (41)

Data signed: (hfarmer1) 26 Mar 2015 15:21:57

Generated On: 20 Jul 2016 12:37:46

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (42)

Data signed: (hfarmer1) 26 Mar 2015 15:21:57

Generated On: 20 Jul 2016 12:37:46

Transmission Type	Cumulative <input checked="" type="radio"/>
-------------------	---

Subject ID or Number	<hr/>
----------------------	-------

Subject Sex	M
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Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	<hr/>
------------	-------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	V946084
--------------	---------

Actual Collection Date	2014 02 19
------------------------	------------

Actual Collection Time	07:00
------------------------	-------

Specimen Condition	<hr/>
--------------------	-------

Battery ID	UA1538
------------	--------

Battery Name	URINE MACRO PANEL
--------------	-------------------

Lab Test ID	UAT7
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1077

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (42)

Data signed: (hfarmer1) 26 Mar 2015 15:21:57


Generated On: 20 Jul 2016 12:37:46

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: 1077**

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (42)

Data signed: (hfarmer1) 26 Mar 2015 15:21:57

Generated On: 20 Jul 2016 12:37:46

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Product Use

Form: Product administration-mCC

Data signed: (hfarmer1) 26 Mar 2015 15:22:24

Generated On: 20 Jul 2016 12:37:46

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: 1077**

Folder: Product Use

Form: Product administration-mCC (1)

Data signed: (hfarmer1) 26 Mar 2015 15:22:24

Generated On: 20 Jul 2016 12:37:46

Date of product use DD/MMM/YYYY	12 FEB 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	06:46
---------------------	-------

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: 1077

Folder: Product Use

Form: Product administration-mCC (1)

Data signed: (hfarmer1) 26 Mar 2015 15:22:24

Generated On: 20 Jul 2016 12:37:46

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: 1077**

Folder: Product Use

Form: Product administration-mCC (2)

Data signed: (hfarmer1) 26 Mar 2015 15:22:24

Generated On: 20 Jul 2016 12:37:46

Date of product use DD/MMM/YYYY	12 FEB 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	07:42
----------------------	-------

Time of butt return	07:50
---------------------	-------

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: 1077

Folder: Product Use

Form: Product administration-mCC (2)

Data signed: (hfarmer1) 26 Mar 2015 15:22:24

Generated On: 20 Jul 2016 12:37:46

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: 1077

Folder: Product Use

Form: Product administration-mCC (3)

Data signed: (hfarmer1) 26 Mar 2015 15:22:24

Generated On: 20 Jul 2016 12:37:46

Date of product use DD/MMM/YYYY	12 FEB 2014
------------------------------------	-------------

Visit	Day -1 <input checked="" type="radio"/>
-------	---

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	08:26
----------------------	-------

Time of butt return	08:35
---------------------	-------

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: 1077

Folder: Product Use

Form: Product administration-mCC (3)

Data signed: (hfarmer1) 26 Mar 2015 15:22:24

Generated On: 20 Jul 2016 12:37:46

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: 1077**

Folder: Product Use

Form: Product administration-mCC (4)

Data signed: (hfarmer1) 26 Mar 2015 15:22:24

Generated On: 20 Jul 2016 12:37:46

Date of product use DD/MMM/YYYY	12 FEB 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	10:10
----------------------	-------

Time of butt return	10:18
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1077

Folder: Product Use

Form: Product administration-mCC (4)

Data signed: (hfarmer1) 26 Mar 2015 15:22:24

Generated On: 20 Jul 2016 12:37:46

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: 1077**

Folder: Product Use

Form: Product administration-mCC (5)

Data signed: (hfarmer1) 26 Mar 2015 15:22:24

Generated On: 20 Jul 2016 12:37:46

Date of product use DD/MMM/YYYY	12 FEB 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	12:50
----------------------	-------

Time of butt return	12:57
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1077

Folder: Product Use

Form: Product administration-mCC (5)

Data signed: (hfarmer1) 26 Mar 2015 15:22:24

Generated On: 20 Jul 2016 12:37:46

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: 1077

Folder: Product Use

Form: Product administration-mCC (6)

Data signed: (hfarmer1) 26 Mar 2015 15:22:24

Generated On: 20 Jul 2016 12:37:46

Date of product use DD/MMM/YYYY	12 FEB 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	14:02
----------------------	-------

Time of butt return	14:14
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1077

Folder: Product Use

Form: Product administration-mCC (6)

Data signed: (hfarmer1) 26 Mar 2015 15:22:24

Generated On: 20 Jul 2016 12:37:46

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: 1077**

Folder: Product Use

Form: Product administration-mCC (7)

Data signed: (hfarmer1) 26 Mar 2015 15:22:24

Generated On: 20 Jul 2016 12:37:46

Date of product use DD/MMM/YYYY	12 FEB 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	15:09
----------------------	-------

Time of butt return	15:16
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1077

Folder: Product Use

Form: Product administration-mCC (7)

Data signed: (hfarmer1) 26 Mar 2015 15:22:24

Generated On: 20 Jul 2016 12:37:46

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: 1077

Folder: Product Use

Form: Product administration-mCC (8)

Data signed: (hfarmer1) 26 Mar 2015 15:22:24

Generated On: 20 Jul 2016 12:37:46

Date of product use DD/MMM/YYYY	12 FEB 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	16:26
----------------------	-------

Time of butt return	16:35
---------------------	-------

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: 1077

Folder: Product Use

Form: Product administration-mCC (8)

Data signed: (hfarmer1) 26 Mar 2015 15:22:24

Generated On: 20 Jul 2016 12:37:46

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: 1077**

Folder: Product Use

Form: Product administration-mCC (9)

Data signed: (hfarmer1) 26 Mar 2015 15:22:24

Generated On: 20 Jul 2016 12:37:46

Date of product use DD/MMM/YYYY	12 FEB 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	18:16
----------------------	-------

Time of butt return	18:22
---------------------	-------

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: 1077

Folder: Product Use

Form: Product administration-mCC (9)

Data signed: (hfarmer1) 26 Mar 2015 15:22:24

Generated On: 20 Jul 2016 12:37:46

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: 1077**

Folder: Product Use

Form: Product administration-mCC (10)

Data signed: (hfarmer1) 26 Mar 2015 15:22:24

Generated On: 20 Jul 2016 12:37:46

Date of product use DD/MMM/YYYY	12 FEB 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	19:01
----------------------	-------

Time of butt return	19:09
---------------------	-------

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: 1077

Folder: Product Use

Form: Product administration-mCC (10)

Data signed: (hfarmer1) 26 Mar 2015 15:22:24

Generated On: 20 Jul 2016 12:37:46

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: 1077**

Folder: Product Use

Form: Product administration-mCC (11)

Data signed: (hfarmer1) 26 Mar 2015 15:22:24

Generated On: 20 Jul 2016 12:37:46

Date of product use DD/MMM/YYYY	12 FEB 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	20:45
----------------------	-------

Time of butt return	20:54
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1077

Folder: Product Use

Form: Product administration-mCC (11)

Data signed: (hfarmer1) 26 Mar 2015 15:22:24

Generated On: 20 Jul 2016 12:37:46

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: 1077**

Folder: Product Use

Form: Product administration-mCC (12)

Data signed: (hfarmer1) 26 Mar 2015 15:22:24

Generated On: 20 Jul 2016 12:37:46

Date of product use DD/MMM/YYYY	12 FEB 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	21:38
----------------------	-------

Time of butt return	21:48
---------------------	-------

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: 1077

Folder: Product Use

Form: Product administration-mCC (12)

Data signed: (hfarmer1) 26 Mar 2015 15:22:24

Generated On: 20 Jul 2016 12:37:46

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: 1077**

Folder: Product Use

Form: Product administration-mCC (13)

Data signed: (hfarmer1) 26 Mar 2015 15:22:24

Generated On: 20 Jul 2016 12:37:46

Date of product use DD/MMM/YYYY	13 FEB 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	06:48
----------------------	-------

Time of butt return	06:58
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	164
---------------------	-----

SODIM sample holder number	0207
----------------------------	------

SODIM file number	08DY0164COHE10207001
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1077

Folder: Product Use

Form: Product administration-mCC (13)

Data signed: (hfarmer1) 26 Mar 2015 15:22:24

Generated On: 20 Jul 2016 12:37:46

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: 1077**

Folder: Product Use

Form: Product administration-mCC (14)

Data signed: (hfarmer1) 26 Mar 2015 15:22:24

Generated On: 20 Jul 2016 12:37:46

Date of product use DD/MMM/YYYY	13 FEB 2014
------------------------------------	-------------

Visit	Day 0 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	09:17
----------------------	-------

Time of butt return	09:26
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	164
---------------------	-----

SODIM sample holder number	0207
----------------------------	------

SODIM file number	08DY0164COHE10207002
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1077

Folder: Product Use

Form: Product administration-mCC (14)

Data signed: (hfarmer1) 26 Mar 2015 15:22:24

Generated On: 20 Jul 2016 12:37:46

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: 1077**

Folder: Product Use

Form: Product administration-mCC (15)

Data signed: (hfarmer1) 26 Mar 2015 15:22:24

Generated On: 20 Jul 2016 12:37:46

Date of product use DD/MMM/YYYY	13 FEB 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	11:22
----------------------	-------

Time of butt return	11:32
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	164
---------------------	-----

SODIM sample holder number	0207
----------------------------	------

SODIM file number	08DY0164COHE10207003
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1077

Folder: Product Use

Form: Product administration-mCC (15)

Data signed: (hfarmer1) 26 Mar 2015 15:22:24

Generated On: 20 Jul 2016 12:37:46

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: 1077**

Folder: Product Use

Form: Product administration-mCC (16)

Data signed: (hfarmer1) 26 Mar 2015 15:22:24

Generated On: 20 Jul 2016 12:37:46

Date of product use DD/MMM/YYYY	13 FEB 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	13:10
----------------------	-------

Time of butt return	_____
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	164
---------------------	-----

SODIM sample holder number	0207
----------------------------	------

SODIM file number	08DY0164COHE10207003
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1077

Folder: Product Use

Form: Product administration-mCC (16)

Data signed: (hfarmer1) 26 Mar 2015 15:22:24

Generated On: 20 Jul 2016 12:37:46

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: 1077**

Folder: Product Use

Form: Product administration-mCC (17)

Data signed: (hfarmer1) 26 Mar 2015 15:22:24

Generated On: 20 Jul 2016 12:37:46

Date of product use DD/MMM/YYYY	13 FEB 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	14:14
----------------------	-------

Time of butt return	14:24
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	164
---------------------	-----

SODIM sample holder number	0207
----------------------------	------

SODIM file number	08DY0164COHE10207005
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1077

Folder: Product Use

Form: Product administration-mCC (17)

Data signed: (hfarmer1) 26 Mar 2015 15:22:24

Generated On: 20 Jul 2016 12:37:46

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: 1077**

Folder: Product Use

Form: Product administration-mCC (18)

Data signed: (hfarmer1) 26 Mar 2015 15:22:24

Generated On: 20 Jul 2016 12:37:46

Date of product use DD/MMM/YYYY	13 FEB 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	15:27
----------------------	-------

Time of butt return	15:39
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	164
---------------------	-----

SODIM sample holder number	0207
----------------------------	------

SODIM file number	08DY0164COHE10207006
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1077

Folder: Product Use

Form: Product administration-mCC (18)

Data signed: (hfarmer1) 26 Mar 2015 15:22:24

Generated On: 20 Jul 2016 12:37:46

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: 1077**

Folder: Product Use

Form: Product administration-mCC (19)

Data signed: (hfarmer1) 26 Mar 2015 15:22:24

Generated On: 20 Jul 2016 12:37:46

Date of product use DD/MMM/YYYY	13 FEB 2014
------------------------------------	-------------

Visit	Day 0 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	16:01
----------------------	-------

Time of butt return	16:09
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	164
---------------------	-----

SODIM sample holder number	0207
----------------------------	------

SODIM file number	08DY0164COHE10207007
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1077

Folder: Product Use

Form: Product administration-mCC (19)

Data signed: (hfarmer1) 26 Mar 2015 15:22:24

Generated On: 20 Jul 2016 12:37:46

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: 1077**

Folder: Product Use

Form: Product administration-mCC (20)

Data signed: (hfarmer1) 26 Mar 2015 15:22:24

Generated On: 20 Jul 2016 12:37:46

Date of product use DD/MMM/YYYY	13 FEB 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	17:56
----------------------	-------

Time of butt return	18:05
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	164
---------------------	-----

SODIM sample holder number	0207
----------------------------	------

SODIM file number	08DY0164COHE10207008
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1077

Folder: Product Use

Form: Product administration-mCC (20)

Data signed: (hfarmer1) 26 Mar 2015 15:22:24

Generated On: 20 Jul 2016 12:37:46

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: 1077**

Folder: Product Use

Form: Product administration-mCC (21)

Data signed: (hfarmer1) 26 Mar 2015 15:22:24

Generated On: 20 Jul 2016 12:37:46

Date of product use DD/MMM/YYYY	13 FEB 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	19:39
----------------------	-------

Time of butt return	19:47
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	164
---------------------	-----

SODIM sample holder number	0207
----------------------------	------

SODIM file number	08DY0164COHE10207009
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1077

Folder: Product Use

Form: Product administration-mCC (21)

Data signed: (hfarmer1) 26 Mar 2015 15:22:24

Generated On: 20 Jul 2016 12:37:46

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: 1077**

Folder: Product Use

Form: Product administration-mCC (22)

Data signed: (hfarmer1) 26 Mar 2015 15:22:24

Generated On: 20 Jul 2016 12:37:46

Date of product use DD/MMM/YYYY	13 FEB 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	20:25
----------------------	-------

Time of butt return	20:34
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	164
---------------------	-----

SODIM sample holder number	0207
----------------------------	------

SODIM file number	08DY0164COHE10207009
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1077

Folder: Product Use

Form: Product administration-mCC (22)

Data signed: (hfarmer1) 26 Mar 2015 15:22:24

Generated On: 20 Jul 2016 12:37:46

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: 1077**

Folder: Product Use

Form: Product administration-mCC (23)

Data signed: (hfarmer1) 26 Mar 2015 15:22:24

Generated On: 20 Jul 2016 12:37:46

Date of product use DD/MMM/YYYY	13 FEB 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	21:45
----------------------	-------

Time of butt return	21:54
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	164
---------------------	-----

SODIM sample holder number	0207
----------------------------	------

SODIM file number	08DY0164COHE10207010
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1077

Folder: Product Use

Form: Product administration-mCC (23)

Data signed: (hfarmer1) 26 Mar 2015 15:22:24

Generated On: 20 Jul 2016 12:37:46

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: 1077**

Folder: Product Use

Form: Product administration-THS menthol

Data signed: (hfarmer1) 26 Mar 2015 15:22:28

Generated On: 20 Jul 2016 12:37:46

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: 1077**

Folder: Product Use

Form: Product administration-THS menthol (1)

Data signed: (hfarmer1) 26 Mar 2015 15:22:28

Generated On: 20 Jul 2016 12:37:46

Date of product use DD/MMM/YYYY	11 FEB 2014
------------------------------------	-------------

Visit	Day -2 <input type="radio"/>
-------	------------------------------

Type of Product Use	THS 2.2 Menthol <input type="radio"/>
---------------------	---------------------------------------

If type of Product Use different from the randomization please explain	PRODUCT TEST
---	--------------

Time of distribution	15:40
----------------------	-------

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/>
---------	-------

Batch Number	B08545
--------------	--------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1077

Folder: Product Use

Form: Product administration-THS menthol (1)

Data signed: (hfarmer1) 26 Mar 2015 15:22:28

Generated On: 20 Jul 2016 12:37:46

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: 1077**

Folder: Product Use

Form: HST 4 hours (1)

Data signed: (hfarmer1) 26 Mar 2015 15:22:29

Generated On: 20 Jul 2016 12:37:46

Visit	Day 30 <input checked="" type="radio"/>
-------	---

Not Done	True
----------	------

If Not Done, please specify	SUBJECT WITHDREW CONSENT
-----------------------------	-----------------------------

Date DD/MMM/YYYY	<hr/>
---------------------	-------

SODIM device distribution time hour:min 24-hour clock	<hr/>
--	-------

SODIM device collection time hour:min 24-hour clock	<hr/>
--	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Product Use

Form: HST 4 hours (2)

Data signed: (hfarmer1) 26 Mar 2015 15:22:29

Generated On: 20 Jul 2016 12:37:46

Visit	Day 60 <input checked="" type="radio"/>
-------	---

Not Done	True
----------	------

If Not Done, please specify	SUBJECT WITHDREW CONSENT
-----------------------------	-----------------------------

Date DD/MMM/YYYY	<hr/>
---------------------	-------

SODIM device distribution time hour:min 24-hour clock	<hr/>
--	-------

SODIM device collection time hour:min 24-hour clock	<hr/>
--	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Product Use

Form: HST 4 hours (3)

Data signed: (hfarmer1) 26 Mar 2015 15:22:29

Generated On: 20 Jul 2016 12:37:46

Visit	Day 90 <input checked="" type="radio"/>
-------	---

Not Done	True
----------	------

If Not Done, please specify	SUBJECT WITHDREW CONSENT
-----------------------------	-----------------------------

Date DD/MMM/YYYY	<hr/>
---------------------	-------

SODIM device distribution time hour:min 24-hour clock	<hr/>
--	-------

SODIM device collection time hour:min 24-hour clock	<hr/>
--	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Product Use

Form: Topography files status for mCC (1)

Generated On: 20 Jul 2016 12:37:46

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: 1077**

Folder: Product Use

Form: Topography files status for mCC (2)

Generated On: 20 Jul 2016 12:37:46

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: 1077**

Folder: Product Use

Form: Topography files status for mCC (3)

Generated On: 20 Jul 2016 12:37:46

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: 1077**

Folder: Product Use

Form: Topography files status for mCC (4)

Generated On: 20 Jul 2016 12:37:46

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: 1077**

Folder: Product Use

Form: Topography files status for mCC (5)

Generated On: 20 Jul 2016 12:37:46

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: 1077**

Folder: Product Use

Form: Topography files status for mCC (6)

Generated On: 20 Jul 2016 12:37:46

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: 1077**

Folder: Product Use

Form: Topography files status for mCC (7)

Generated On: 20 Jul 2016 12:37:46

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: 1077**

Folder: Product Use

Form: Topography files status for mCC (8)

Generated On: 20 Jul 2016 12:37:46

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: 1077**

Folder: Product Use

Form: Topography files status for mCC (9)

Generated On: 20 Jul 2016 12:37:46

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: 1077**

Folder: Product Use

Form: Topography files status for mCC (10)

Generated On: 20 Jul 2016 12:37:46

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: 1077**

Folder: Product Use

Form: Topography files status for mCC (11)

Generated On: 20 Jul 2016 12:37:46

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: 1077**

Folder: Product Use

Form: Topography files status for mCC (12)

Generated On: 20 Jul 2016 12:37:46

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: 1077**

Folder: Product Use

Form: Topography files status for mCC (13)

Generated On: 20 Jul 2016 12:37:46

SODIM file number	08DY0164COHE10207001
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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	25 AUG 2014
---------------------------------	-------------

Operator	Thierry Bachmann <input checked="" type="radio"/>
----------	---

Comment	<hr/>
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Modified File Number	<hr/>
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Product Use

Form: Topography files status for mCC (14)

Generated On: 20 Jul 2016 12:37:46

SODIM file number	08DY0164COHE10207002
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File Status	Accepted <input checked="" type="radio"/>
-------------	---

Rejection / Error reason	<hr/>
--------------------------	-------

Date of analysis DD/MMM/YYYY	25 AUG 2014
---------------------------------	-------------

Operator	Thierry Bachmann <input checked="" type="radio"/>
----------	---

Comment	<hr/>
---------	-------

Modified File Number	<hr/>
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Product Use

Form: Topography files status for mCC (15)

Generated On: 20 Jul 2016 12:37:46

SODIM file number	08DY0164COHE10207003
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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	25 AUG 2014
---------------------------------	-------------

Operator	Thierry Bachmann <input checked="" type="radio"/>
----------	---

Comment	<hr/>
---------	-------

Modified File Number	<hr/>
----------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Product Use

Form: Topography files status for mCC (17)

Generated On: 20 Jul 2016 12:37:46

SODIM file number	08DY0164COHE10207005
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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	25 AUG 2014
---------------------------------	-------------

Operator	Thierry Bachmann <input checked="" type="radio"/>
----------	---

Comment	<hr/>
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Modified File Number	<hr/>
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Product Use

Form: Topography files status for mCC (18)

Generated On: 20 Jul 2016 12:37:46

SODIM file number	08DY0164COHE10207006
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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	25 AUG 2014
---------------------------------	-------------

Operator	Thierry Bachmann <input checked="" type="radio"/>
----------	---

Comment	<hr/>
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Modified File Number	<hr/>
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Product Use

Form: Topography files status for mCC (19)

Generated On: 20 Jul 2016 12:37:46

SODIM file number	08DY0164COHE10207007
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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	25 AUG 2014
---------------------------------	-------------

Operator	Thierry Bachmann <input checked="" type="radio"/>
----------	---

Comment	<hr/>
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Modified File Number	<hr/>
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Product Use

Form: Topography files status for mCC (20)

Generated On: 20 Jul 2016 12:37:46

SODIM file number	08DY0164COHE10207008
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File Status	Accepted <input checked="" type="radio"/>
-------------	---

Rejection / Error reason	<hr/>
--------------------------	-------

Date of analysis DD/MMM/YYYY	25 AUG 2014
---------------------------------	-------------

Operator	Thierry Bachmann <input checked="" type="radio"/>
----------	---

Comment	<hr/>
---------	-------

Modified File Number	<hr/>
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Product Use

Form: Topography files status for mCC (21)

Generated On: 20 Jul 2016 12:37:46

SODIM file number	08DY0164COHE10207009
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File Status	Accepted <input checked="" type="radio"/>
-------------	---

Rejection / Error reason	<hr/>
--------------------------	-------

Date of analysis DD/MMM/YYYY	25 AUG 2014
---------------------------------	-------------

Operator	Thierry Bachmann <input checked="" type="radio"/>
----------	---

Comment	<hr/>
---------	-------

Modified File Number	<hr/>
----------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Product Use

Form: Topography files status for mCC (23)

Generated On: 20 Jul 2016 12:37:46

SODIM file number	08DY0164COHE10207010
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File Status	Rejected 
-------------	--

Rejection / Error reason	START RTD TOO HIGH
--------------------------	--------------------

Date of analysis DD/MMM/YYYY	25 AUG 2014
---------------------------------	-------------

Operator	Thierry Bachmann 
----------	--

Comment	<hr/>
---------	-------

Modified File Number	<hr/>
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Product Use

Form: Product use diary(Paper)

Data signed: (hcoleman1) 18 Jun 2015 20:00:11

Generated On: 20 Jul 2016 12:37:46

Was paper questionnaire used?

No ☒

Reason not done

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Product Use

Form: Product use diary(Paper) (1)

Data signed: (hcoleman1) 18 Jun 2015 20:00:11

Generated On: 20 Jul 2016 12:37:46

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: 1077**

Folder: Product Use

Form: Product use diary(Paper) (1)

Data signed: (hcoleman1) 18 Jun 2015 20:00:11

Generated On: 20 Jul 2016 12:37:46

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: 1077**

Folder: Adverse Events

Form: Adverse Events Y/N

Data signed: (hfarmer1) 26 Mar 2015 15:22:29

Generated On: 20 Jul 2016 12:37:46

Was there any Adverse Event for this subject?

Yes ☒

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1077

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (hcoleman1) 18 Jun 2015 20:00:11

Generated On: 20 Jul 2016 12:37:46

AE Identifier	1
---------------	---

Adverse Event	ABRASION RIGHT FIRST TOE
---------------	--------------------------

Start Date	11 FEB 2014
------------	-------------

DD/MMM/YYYY

End Date	26 FEB 2014
----------	-------------

DD/MMM/YYYY

Ongoing at final contact	No <input checked="" type="radio"/>
--------------------------	-------------------------------------

Severity	Mild Adverse Event <input checked="" type="radio"/>
----------	---

Serious AE	No <input checked="" type="radio"/>
------------	-------------------------------------

Seriousness Criteria

Treatment given	No <input checked="" type="radio"/>
-----------------	-------------------------------------

AE related to Study Procedure	Not Related <input checked="" type="radio"/>
-------------------------------	--

Relationship to mCC/THS	Not Related <input checked="" type="radio"/>
-------------------------	--

AE expectedness

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (hcoleman1) 18 Jun 2015 20:00:11

Generated On: 20 Jul 2016 12:37:46

Action taken with study product

Not Applicable ☒

Other action taken

Outcome

Recovered or Resolved ☒

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1077

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (hcoleman1) 18 Jun 2015 20:00:11

Generated On: 20 Jul 2016 12:37:46

AE Identifier	2
---------------	---

Adverse Event	INCREASED TRIGLYCERIDES
---------------	-------------------------

Start Date	19 FEB 2014
------------	-------------

DD/MMM/YYYY

End Date

DD/MMM/YYYY

Ongoing at final contact	Yes <input type="radio"/>
--------------------------	---------------------------

Severity	Moderate Adverse Event <input type="radio"/>
----------	--

Serious AE	No <input type="radio"/>
------------	--------------------------

Seriousness Criteria

Treatment given	No <input type="radio"/>
-----------------	--------------------------

AE related to Study Procedure	Not Related <input type="radio"/>
-------------------------------	-----------------------------------

Relationship to mCC/THS	Not Related <input type="radio"/>
-------------------------	-----------------------------------

AE expectedness

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (hcoleman1) 18 Jun 2015 20:00:11

Generated On: 20 Jul 2016 12:37:46

Action taken with study product

Not Applicable ☒

Other action taken

Outcome

Not Recovered or Not
Resolved ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Folder: Previous and Concomitant Medication

Form: Previous and Concomitant Medication Y/N

Data signed: (hfarmer1) 26 Mar 2015 15:22:30

Generated On: 20 Jul 2016 12:37:46

Has the subject taken previous or concomitant
medication?

No ☒

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1077

Form: Product use diary (1)

Data signed: (hfarmer1) 26 Mar 2015 15:20:47

Generated On: 20 Jul 2016 12:37:46

Date of Birth	(b) (6)
Date of completion DD/MMM/YYYY	2014 FEB 19
Time of completion hh:mm	20:00
Date the questionnaire was completed for DD/MMM/YYYY	2014 FEB 19
Assessment Status	Completed <input checked="" type="radio"/>
What tobacco/nicotine product did you use today?	CC <input checked="" type="radio"/>
How many THS 2.2 tobacco sticks did you use today?	-9
How many CC/ roll-your-own did you smoke today?	2
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: 1077

Form: Product use diary (1)

Data signed: (hfarmer1) 26 Mar 2015 15:20:47

Generated On: 20 Jul 2016 12:37:46

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: 1077

Form: Product use diary (2)

Data signed: (hfarmer1) 26 Mar 2015 15:20:47

Generated On: 20 Jul 2016 12:37:46

Date of Birth	(b) (6)
Date of completion DD/MMM/YYYY	2014 FEB 20
Time of completion hh:mm	20:00
Date the questionnaire was completed for DD/MMM/YYYY	2014 FEB 20
Assessment Status	Completed <input checked="" type="radio"/>
What tobacco/nicotine product did you use today?	CC <input checked="" type="radio"/>
How many THS 2.2 tobacco sticks did you use today?	-9
How many CC/ roll-your-own did you smoke today?	2
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: 1077

Form: Product use diary (2)

Data signed: (hfarmer1) 26 Mar 2015 15:20:47

Generated On: 20 Jul 2016 12:37:46

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: 1077

Form: Product use diary (3)

Data signed: (hfarmer1) 26 Mar 2015 15:20:47

Generated On: 20 Jul 2016 12:37:46

Date of Birth

(b) (6)

Date of completion
DD/MMM/YYYY

2014 FEB 21

Time of completion
hh:mm

20:00

Date the questionnaire was completed for
DD/MMM/YYYY

2014 FEB 21

Assessment Status

Completed ☒

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?

1

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: 1077

Form: Product use diary (3)

Data signed: (hfarmer1) 26 Mar 2015 15:20:47

Generated On: 20 Jul 2016 12:37:46

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: 1077

Form: Product use diary (4)

Data signed: (hfarmer1) 26 Mar 2015 15:20:47

Generated On: 20 Jul 2016 12:37:46

Date of Birth	(b) (6)
Date of completion DD/MMM/YYYY	2014 FEB 22
Time of completion hh:mm	20:00
Date the questionnaire was completed for DD/MMM/YYYY	2014 FEB 22
Assessment Status	Completed <input checked="" type="radio"/>
What tobacco/nicotine product did you use today?	CC <input checked="" type="radio"/>
How many THS 2.2 tobacco sticks did you use today?	-9
How many CC/ roll-your-own did you smoke today?	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: 1077

Form: Product use diary (4)

Data signed: (hfarmer1) 26 Mar 2015 15:20:47

Generated On: 20 Jul 2016 12:37:46

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: 1077

Form: Product use diary (5)

Data signed: (hfarmer1) 26 Mar 2015 15:20:47

Generated On: 20 Jul 2016 12:37:46

Date of Birth

(b) (6)

Date of completion
DD/MMM/YYYY

2014 FEB 23

Time of completion
hh:mm

20:00

Date the questionnaire was completed for
DD/MMM/YYYY

2014 FEB 23

Assessment Status

Completed ☒

What tobacco/nicotine product did you use today?

CC ☒

How many THS 2.2 tobacco sticks did you use today?

-9

How many CC/ roll-your-own did you smoke today?

1

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: 1077

Form: Product use diary (5)

Data signed: (hfarmer1) 26 Mar 2015 15:20:47

Generated On: 20 Jul 2016 12:37:46

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: 1077**

Form: End of study

Data signed: (hcoleman1) 18 Jun 2015 20:00:06

Generated On: 20 Jul 2016 12:37:46

End of study date

24 MAR 2014
DD/MMM/YYYY

Has the subject completed the study ?

No ☒

If No, please specify the reason:

Withdrawal by Subject ☒

Details:

SUBJECT CONTACTED SITE
STATING THEY HAVE A
FAMILY EMERGENCY AND
WILL BE MOVING OUT OF
STATE.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Form: Consent Withdrawal

Data signed: (hfarmer1) 26 Mar 2015 15:20:46

Generated On: 20 Jul 2016 12:37:46

Did the subject withdraw it's consent to the biobanking
for BoExp and risk markers?

No ☒

Date of withdrawal of consent for biobanking for BoEXP
and risk markers

Did the subject withdraw it's consent to the
transcriptomics analysis?

No ☒

Date of withdrawal of consent for transcriptomics
analysis

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1077**

Form: Withdrawal

Data signed: (hcoleman1) 18 Jun 2015 20:00:06

Generated On: 20 Jul 2016 12:37:46

Date of withdrawal	24 FEB 2014 DD/MMM/YYYY
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Did the subject withdraw it's consent from the main study?	No <input checked="" type="radio"/>
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If available, please provide details	<hr/>
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Did the subject withdraw from the Protected Health Information (PHI)?	No <input checked="" type="radio"/>
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Did the subject confirm that samples collected up to the time of withdrawal can be analysed?	<hr/>
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