

Subject Case Report Forms

0230 (Prod: Osaki Hospital Tokyo heart center)

Generated On: 18 Jul 2016 22:07:14

All time stamps listed in this document are displayed in GMT

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Form: Subject

Data signed: (Heart1) 29 Oct 2014 09:21:05

Generated On: 18 Jul 2016 22:07:14

Screening number	0230
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Site number	TOK
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ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Subject Status

Form: Subject Status

Data signed: (Heart1) 29 Oct 2014 09:21:05

Generated On: 18 Jul 2016 22:07:14

Date of 'Screen Failed' Event

Date of 'Discontinued From
Enrollment' Event

Randomization Date

24 JAN 2014
DD/MMM/YYYY

Randomization Time

12:54
hour:min 24-hour clock

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Date of Visit

Data signed: (Heart1) 29 Oct 2014 09:21:06

Generated On: 18 Jul 2016 22:07:14

Date of Visit

07 JAN 2014
DD/MMM/YYYY

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Additional Informed Consent

Data signed: (Heart1) 29 Oct 2014 09:21:06

Generated On: 18 Jul 2016 22:07:14

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

Yes ☒

Consent Date

07 JAN 2014
DD/MMM/YYYY

Has the subject given written informed consent for
Bio-banking for Transcriptomics (Pharmacogenomics)?

Yes ☒

Consent Date

07 JAN 2014
DD/MMM/YYYY

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Inclusion Criteria

Data signed: (Heart1) 29 Oct 2014 09:21:06

Generated On: 18 Jul 2016 22:07:14

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

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Inclusion Criteria (1)

Data signed: (Heart1) 29 Oct 2014 09:21:06

Generated On: 18 Jul 2016 22:07:14

Inclusion Criterion Number	1
----------------------------	---

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

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

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Inclusion Criteria (2)

Data signed: (Heart1) 29 Oct 2014 09:21:06

Generated On: 18 Jul 2016 22:07:14

Inclusion Criterion Number	2
----------------------------	---

Inclusion Criterion	Subject is aged from 23 to 65 years (inclusive).
---------------------	--

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

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

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Inclusion Criteria (3)

Data signed: (Heart1) 29 Oct 2014 09:21:06

Generated On: 18 Jul 2016 22:07:14

Inclusion Criterion Number	3
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Inclusion Criterion	Subject is Japanese. <input type="radio"/>
---------------------	--

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

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

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Inclusion Criteria (4)

Data signed: (Heart1) 29 Oct 2014 09:21:06

Generated On: 18 Jul 2016 22:07:14

Inclusion Criterion Number	4
Inclusion Criterion	Smoking, healthy subject as judged by the Investigator based on all available assessments from the Screening period/day of Admission (e.g. safety laboratory, spirometry[FEV1/FVC >0.7 at post-bronchodilator spirometry, post-bronchodilator FEV1 >80% predicted value, and post-bronchodilator FVC >80% predicted value], 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-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Inclusion Criteria (5)

Data signed: (Heart1) 29 Oct 2014 09:21:06

Generated On: 18 Jul 2016 22:07:14

Inclusion Criterion Number	5
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Inclusion Criterion	Subject smokes at least 10 commercially available menthol mCCs per day (no brand restrictions) with a maximum yield of 1 mg nicotine ISO/mCC, as labelled on the cigarette package, for the last 4 weeks, based on self-reporting. Furthermore, the subject has been smoking for at least the last three consecutive years. The smoking status will be verified based on a urinary cotinine test (cotinine \geq 200 ng/mL).
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Result	Yes
--------	-----

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

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Inclusion Criteria (6)

Data signed: (Heart1) 29 Oct 2014 09:21:06

Generated On: 18 Jul 2016 22:07:14

Inclusion Criterion Number	6
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Inclusion Criterion	The subject does not plan to quit smoking in the next 3 months.	<input checked="" type="radio"/>
---------------------	---	----------------------------------

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

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Inclusion Criteria (7)

Data signed: (Heart1) 29 Oct 2014 09:21:06

Generated On: 18 Jul 2016 22:07:14

Inclusion Criterion Number	7
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Inclusion Criterion	The subject is ready to accept interruptions of smoking for up to 90 days.
---------------------	--

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

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Exclusion Criteria

Data signed: (Heart1) 29 Oct 2014 09:21:07

Generated On: 18 Jul 2016 22:07:14

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

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Exclusion Criteria (1)

Data signed: (Heart1) 29 Oct 2014 09:21:07

Generated On: 18 Jul 2016 22:07:14

Exclusion Criterion Number	1
----------------------------	---

Exclusion Criterion	As per Investigator judgment, the subject cannot participate in the study for any reason (e.g. medical, psychiatric and/or social reason).
---------------------	--

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

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Exclusion Criteria (2)

Data signed: (Heart1) 29 Oct 2014 09:21:07

Generated On: 18 Jul 2016 22:07:14

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

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

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

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Exclusion Criteria (3)

Data signed: (Heart1) 29 Oct 2014 09:21:07

Generated On: 18 Jul 2016 22:07:14

Exclusion Criterion Number

3

Exclusion Criterion

The subject has medical condition requiring smoking cessation, or clinically relevant diseases (including but not limited to gastrointestinal, renal, hepatic, neurological, hematological, endocrine, oncological, urological, immunological, pulmonary and cardiovascular disease or any other medical condition [including but not limited to clinically relevant abnormal laboratory parameters]) in the judgment of the Investigator.

Result

No

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

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Exclusion Criteria (4)

Data signed: (Heart1) 29 Oct 2014 09:21:07

Generated On: 18 Jul 2016 22:07:14

Exclusion Criterion Number	4
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Exclusion Criterion	The subject has a body mass index (BMI) <18.5 or ≥ 32 kg/m ² . <input checked="" type="radio"/>
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Result	No <input checked="" type="radio"/>
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*If any has been answered Yes, subject must not be included in the study.

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Exclusion Criteria (5)

Data signed: (Heart1) 29 Oct 2014 09:21:07

Generated On: 18 Jul 2016 22:07:14

Exclusion Criterion Number	5
----------------------------	---

Exclusion Criterion	As per Investigator or designee 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-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Exclusion Criteria (6)

Data signed: (Heart1) 29 Oct 2014 09:21:07

Generated On: 18 Jul 2016 22:07:14

Exclusion Criterion Number	6
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Exclusion Criterion	The subject has used nicotine containing products other than commercially available mCC (either tobacco-based products or NRT) as well as electronic cigarettes and similar devices, within 4 weeks prior to assessment.
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Result	No <input checked="" type="radio"/>
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*If any has been answered Yes, subject must not be included in the study.

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Exclusion Criteria (7)

Data signed: (Heart1) 29 Oct 2014 09:21:07

Generated On: 18 Jul 2016 22:07:14

Exclusion Criterion Number	8
----------------------------	---

Exclusion Criterion	If a subject has received any medication (prescribed or over-the-counter) within 14 days prior to Screening or prior to the Admission Day (Day -2), it will be decided at the discretion of the Investigator if these can potentially interfere with the study objectives or subject's safety.
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Result	No <input type="radio"/>
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*If any has been answered Yes, subject must not be included in the study.

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Exclusion Criteria (8)

Data signed: (Heart1) 29 Oct 2014 09:21:07

Generated On: 18 Jul 2016 22:07:14

Exclusion Criterion Number	9
----------------------------	---

Exclusion Criterion	Concomitant use of NSAIDs <input type="radio"/> or acetylsalicylic acid.
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Result	No <input type="radio"/>
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*If any has been answered Yes, subject must not be included in the study.

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Exclusion Criteria (9)

Data signed: (Heart1) 29 Oct 2014 09:21:07

Generated On: 18 Jul 2016 22:07:14

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

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-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Exclusion Criteria (10)

Data signed: (Heart1) 29 Oct 2014 09:21:07

Generated On: 18 Jul 2016 22:07:14

Exclusion Criterion Number	11
----------------------------	----

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

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Exclusion Criteria (11)

Data signed: (Heart1) 29 Oct 2014 09:21:07

Generated On: 18 Jul 2016 22:07:14

Exclusion Criterion Number	12
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Exclusion Criterion	Positive serology test for HIV1/2, hepatitis B or hepatitis C.
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Result	No <input checked="" type="radio"/>
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*If any has been answered Yes, subject must not be included in the study.

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Exclusion Criteria (12)

Data signed: (Heart1) 29 Oct 2014 09:21:07

Generated On: 18 Jul 2016 22:07:14

Exclusion Criterion Number	13
----------------------------	----

Exclusion Criterion	Donation or receipt of whole blood or blood products within 3 months prior to Admission.
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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-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Exclusion Criteria (13)

Data signed: (Heart1) 29 Oct 2014 09:21:07

Generated On: 18 Jul 2016 22:07:14

Exclusion Criterion Number	14
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Exclusion Criterion	The subject is a current or former employee of the tobacco industry or of their first-degree relatives (parent, sibling, child).	<input checked="" type="radio"/>
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Result	No	<input checked="" type="radio"/>
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*If any has been answered Yes, subject must not be included in the study.

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Exclusion Criteria (14)

Data signed: (Heart1) 29 Oct 2014 09:21:07

Generated On: 18 Jul 2016 22:07:14

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

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, child).
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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-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Exclusion Criteria (15)

Data signed: (Heart1) 29 Oct 2014 09:21:07

Generated On: 18 Jul 2016 22:07:14

Exclusion Criterion Number	16
----------------------------	----

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

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Exclusion Criteria (16)

Data signed: (Heart1) 29 Oct 2014 09:21:07

Generated On: 18 Jul 2016 22:07:14

Exclusion Criterion Number	17
----------------------------	----

Exclusion Criterion	The subject has previously participated in the same study at a different time (i.e. each subject can be included in the study population only once).
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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-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Exclusion Criteria (17)

Data signed: (Heart1) 29 Oct 2014 09:21:07

Generated On: 18 Jul 2016 22:07:14

Exclusion Criterion Number	18
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-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Exclusion Criteria (18)

Data signed: (Heart1) 29 Oct 2014 09:21:07

Generated On: 18 Jul 2016 22:07:14

Exclusion Criterion Number	19
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Exclusion Criterion	For women only: Subject does not agree to use an acceptable method of effective contraception
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Result	NA
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*If any has been answered Yes, subject must not be included in the study.

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Demographics

Data signed: (Heart1) 29 Oct 2014 09:21:06

Generated On: 18 Jul 2016 22:07:14

Date of Birth	(b) (6)
Sex	Male <input checked="" type="radio"/>
Is the subject Japanese?	Yes <input checked="" type="radio"/>
Date the Subject signed the Main Informed Consent	07 JAN 2014 DD/MMM/YYYY
Time the Subject signed the Main Informed Consent	09:51 hour:min 24-hour clock
Age(Derived)	31

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Medical History/Concomitant Disease

Data signed: (Heart1) 29 Oct 2014 09:21:08

Generated On: 18 Jul 2016 22:07:14

Date of collection

07 JAN 2014
DD/MMM/YYYY

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

No ☒

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Medical History/Concomitant Disease (1)

Data signed: (Heart1) 29 Oct 2014 09:21:08

Generated On: 18 Jul 2016 22:07:14

Date of collection

07 JAN 2014
DD/MMM/YYYY

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

No ☒

Number

Diagnosis Description

Onset Date
DD/MMM/YYYY

Stop Date
DD/MMM/YYYY

Ongoing?

False

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Vital Signs

Data signed: (Heart1) 29 Oct 2014 09:21:08

Generated On: 18 Jul 2016 22:07:14

Were Vitals Signs assessed?

Yes ☒

If No, please specify the reason: _____

Has the subject smoked within 15 minutes prior to assessment

No ☒

Date of assessment

07 JAN 2014
DD/MMM/YYYY

Time of assessment

10:30
hour:min 24-hour clock

Pulse rate

52
beats per minute

Respiratory rate

16
breaths per minute

Blood Pressure (systolic)

109
mmHg

Blood Pressure (diastolic)

63
mmHg

Vital Signs Position of Subject

Supine ☒

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Physical Examination

Data signed: (Heart1) 29 Oct 2014 09:21:09

Generated On: 18 Jul 2016 22:07:14

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

07 JAN 2014
DD/MMM/YYYY

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Physical Examination (1)

Data signed: (Heart1) 29 Oct 2014 09:21:09

Generated On: 18 Jul 2016 22:07:14

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

07 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-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Physical Examination (2)

Data signed: (Heart1) 29 Oct 2014 09:21:09

Generated On: 18 Jul 2016 22:07:14

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

07 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-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Physical Examination (3)

Data signed: (Heart1) 29 Oct 2014 09:21:09

Generated On: 18 Jul 2016 22:07:14

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

07 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-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Physical Examination (4)

Data signed: (Heart1) 29 Oct 2014 09:21:09

Generated On: 18 Jul 2016 22:07:14

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

07 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-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Physical Examination (5)

Data signed: (Heart1) 29 Oct 2014 09:21:09

Generated On: 18 Jul 2016 22:07:14

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

07 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-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Physical Examination (6)

Data signed: (Heart1) 29 Oct 2014 09:21:09

Generated On: 18 Jul 2016 22:07:14

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

07 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-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Physical Examination (7)

Data signed: (Heart1) 29 Oct 2014 09:21:09

Generated On: 18 Jul 2016 22:07:14

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

07 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-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Physical Examination (8)

Data signed: (Heart1) 29 Oct 2014 09:21:09

Generated On: 18 Jul 2016 22:07:14

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

07 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-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Physical Examination (9)

Data signed: (Heart1) 29 Oct 2014 09:21:09

Generated On: 18 Jul 2016 22:07:14

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

07 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-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Physical Examination (10)

Data signed: (Heart1) 29 Oct 2014 09:21:09

Generated On: 18 Jul 2016 22:07:14

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

07 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-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Physical Examination (11)

Data signed: (Heart1) 29 Oct 2014 09:21:09

Generated On: 18 Jul 2016 22:07:14

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

07 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-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Physical Examination (12)

Data signed: (Heart1) 29 Oct 2014 09:21:09

Generated On: 18 Jul 2016 22:07:14

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

07 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-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Physical Examination (13)

Data signed: (Heart1) 29 Oct 2014 09:21:09

Generated On: 18 Jul 2016 22:07:14

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

07 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-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Physical Examination (14)

Data signed: (Heart1) 29 Oct 2014 09:21:09

Generated On: 18 Jul 2016 22:07:14

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

07 JAN 2014
DD/MMM/YYYY

System

Dentition ☒

Outcome

Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done

False

Not Done; please specify the reason: _____

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Physical Examination (15)

Data signed: (Heart1) 29 Oct 2014 09:21:09

Generated On: 18 Jul 2016 22:07:14

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

07 JAN 2014
DD/MMM/YYYY

System

Other ☒

Other, Specify _____

Outcome _____

Abnormal, please specify _____

Clinically significant _____

Not Done

True

Not Done; please specify the reason: _____

THERE IS NO SPECIFIC.

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Physical Examination (16)

Data signed: (Heart1) 29 Oct 2014 09:21:09

Generated On: 18 Jul 2016 22:07:14

Was the physical examination performed?

Yes ☒

If No, please specify the reason:

Date of assessment

07 JAN 2014
DD/MMM/YYYY

System

Other ☒

Other, Specify

Outcome

Abnormal, please specify

Clinically significant

Not Done

True

Not Done; please specify the reason:

THERE IS NO SPECIFIC.

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Physical Examination (17)

Data signed: (Heart1) 29 Oct 2014 09:21:09

Generated On: 18 Jul 2016 22:07:14

Was the physical examination performed?

Yes ☒

If No, please specify the reason:

Date of assessment

07 JAN 2014
DD/MMM/YYYY

System

Other ☒

Other, Specify

Outcome

Abnormal, please specify

Clinically significant

Not Done

True

Not Done; please specify the reason:

THERE IS NO SPECIFIC.

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Physical Examination (18)

Data signed: (Heart1) 29 Oct 2014 09:21:09

Generated On: 18 Jul 2016 22:07:14

Was the physical examination performed?

Yes ☒

If No, please specify the reason:

Date of assessment

07 JAN 2014
DD/MMM/YYYY

System

Other ☒

Other, Specify

Outcome

Abnormal, please specify

Clinically significant

Not Done

True

Not Done; please specify the reason:

THERE IS NO SPECIFIC.

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Physical Examination (19)

Data signed: (Heart1) 29 Oct 2014 09:21:09

Generated On: 18 Jul 2016 22:07:14

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

07 JAN 2014
DD/MMM/YYYY

System

Other ☒

Other, Specify _____

Outcome _____

Abnormal, please specify _____

Clinically significant _____

Not Done

True

Not Done; please specify the reason: _____

THERE IS NO SPECIFIC.

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Advice on the risk of smoking and debriefing

Data signed: (Heart1) 29 Oct 2014 09:21:12

Generated On: 18 Jul 2016 22:07:14

Has the subject received advices on the risks of
smoking?

Yes ☒

Has a debriefing been performed about THS 2.2?

Yes ☒

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Identification of Current Cigarette Brand

Data signed: (Heart1) 29 Oct 2014 09:21:12

Generated On: 18 Jul 2016 22:07:14

Date	07 JAN 2014 DD/MMM/YYYY
------	----------------------------

Brand name	MARLBORO ICE BLAST 1
------------	----------------------

ISO Tar Yield	1 MG
---------------	---------

ISO Nicotine Yield	0.1 MG
--------------------	-----------

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: THS 2.2 menthol product demonstration

Data signed: (Heart1) 29 Oct 2014 09:21:12

Generated On: 18 Jul 2016 22:07:14

Has the subject seen a THS 2.2 menthol product demonstration?

Yes ☒

If the subject did not see the demonstration please explain

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Smoking History

Data signed: (Heart1) 29 Oct 2014 09:21:12

Generated On: 18 Jul 2016 22:07:14

Date of Assessment

07 JAN 2014
DD/MMM/YYYY

1. Does the subject plan to quit smoking during the next 3 months?

No ☐

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

Yes ☐

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

10 to 19 ☐

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

Yes ☐

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

No ☐

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: FTND Questionnaire

Data signed: (Heart1) 29 Oct 2014 09:21:12

Generated On: 18 Jul 2016 22:07:14

Type	FTND
Was paper questionnaire used?	Yes <input type="radio"/>
Reason not done	
Date of assessment	07 JAN 2014 DD/MMM/YYYY
Time of assessment	10:05 hour:min 24-hour clock
1. How soon after you wake up do you smoke your first cigarette?	31-60 minutes <input type="radio"/>
2. Do you find it difficult to refrain from smoking in places where it is forbidden?	No <input type="radio"/>
3. Which cigarette would you hate most to give up?	Any other <input type="radio"/>
4. How many cigarettes per day do you smoke?	11-20 <input type="radio"/>
5. Do you smoke more frequently during the first hours after awakening than during the rest of the day?	Yes <input type="radio"/>
6. Do you smoke even if you are so ill that you are in bed most of the day?	Yes <input type="radio"/>

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Weight and Height

Data signed: (Heart1) 29 Oct 2014 09:21:12

Generated On: 18 Jul 2016 22:07:14

Measurement(s) assessed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

07 JAN 2014
DD/MMM/YYYY

Weight

83.4
kg

Height

171
cm

BMI (Derived)

28.5
kg/m2

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: ECG (12-Lead Standard)

Data signed: (Heart1) 29 Oct 2014 09:21:13

Generated On: 18 Jul 2016 22:07:14

Was the ECG performed?

Yes ☒

If No, please specify the reason: _____

Date of assessment:

07 JAN 2014
DD/MMM/YYYY

Position

Supine ☒

Heart Rate

54
beats per minute

QRS Interval

92
msec

QT Interval

428
msec

QTcB Interval

408
msec

PR Interval

164
msec

Interpretation

Normal ☒

If Abnormal, Clinical Significance _____

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: ECG (12-Lead Standard)

Data signed: (Heart1) 29 Oct 2014 09:21:13

Generated On: 18 Jul 2016 22:07:14

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

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Spirometry (1)

Data signed: (Heart1) 29 Oct 2014 09:21:13

Generated On: 18 Jul 2016 22:07:14

Was the spirometry performed? Yes ☒

If No, please specify the reason: _____

Category Without short-acting bronchodilator ☒

Date of assessment DD/MMM/YYYY 07 JAN 2014

Time of assessment 11:27

Predicted FVC value 4.65 L

Best measured FVC value 4.88 L

Percent of predicted FVC value 104.9 %

Best measured FEV1 value 3.98 L

Predicted FEV1 value 4.11 L

Percent of predicted FEV1 value 96.8 %

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Spirometry (1)

Data signed: (Heart1) 29 Oct 2014 09:21:13

Generated On: 18 Jul 2016 22:07:14

Calculated ratio between FEV1/FVC	0.82
-----------------------------------	------

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

If Abnormal, Clinical Significance

If Not Clinically Significant or Clinically Significant, Please
specify the finding(s)

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Spirometry (2)

Data signed: (Heart1) 29 Oct 2014 09:21:13

Generated On: 18 Jul 2016 22:07:14

Was the spirometry performed? Yes ☒

If No, please specify the reason: _____

Category With short-acting bronchodilator ☒

Date of assessment 07 JAN 2014
DD/MMM/YYYY

Time of assessment 11:51

Name of bronchodilator SULTANOL INHALER

Dose 100MG

Predicted FVC value 4.65
L

Best measured FVC value 4.84
L

Percent of predicted FVC value 104.0
%

Best measured FEV1 value 3.95
L

Predicted FEV1 value 4.11
L

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Spirometry (2)

Data signed: (Heart1) 29 Oct 2014 09:21:13

Generated On: 18 Jul 2016 22:07:14

Percent of predicted FEV1 value	96.1 %
---------------------------------	-----------

Calculated ratio between FEV1/FVC	0.82
-----------------------------------	------

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-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Chest X-Ray

Data signed: (Heart1) 29 Oct 2014 09:21:13

Generated On: 18 Jul 2016 22:07:14

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

Yes ☒

If No, please specify the reason: _____

Date of assessment

07 JAN 2014
DD/MMM/YYYY

System

Chest ☒

Interpretation

Normal ☒

Clinically significant _____

Abnormal, please specify: _____

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Haematology

Data signed: (Heart1) 29 Oct 2014 09:21:13

Generated On: 18 Jul 2016 22:07:14

Were samples collected?

Yes ☒

If No, please specify the reason: _____

Was the subject fasting for at least 10 hours at time of
sample collection?

Yes ☒

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Clinical Chemistry

Data signed: (Heart1) 29 Oct 2014 09:21:13

Generated On: 18 Jul 2016 22:07:14

Were samples collected?

Yes ☒

If No, please specify the reason: _____

Was the subject fasting for at least 10 hours at time of
sample collection?

Yes ☒

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Urine analysis

Data signed: (Heart1) 29 Oct 2014 09:21:13

Generated On: 18 Jul 2016 22:07:14

Were samples collected?

Yes ☒

If No, please specify the reason:

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Serology for HIV and Hepatitis B and C

Data signed: (Heart1) 29 Oct 2014 09:21:13

Generated On: 18 Jul 2016 22:07:14

Category

Serology ☒

Not Done

False

If Not Done, please specify the reason:

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Urine Drug Screen

Data signed: (Heart1) 29 Oct 2014 09:21:13

Generated On: 18 Jul 2016 22:07:14

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

If Not Done, please specify the reason: _____

Date of sample collection	07 JAN 2014 DD/MMM/YYYY
---------------------------	----------------------------

Time of sample collection	09:55 hour:min 24-hour clock
---------------------------	---------------------------------

Drug type	Result
Amphetamines	Negative
Barbiturates	Negative
Benzodiazepines	Negative

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Urine Drug Screen (4)

Data signed: (Heart1) 29 Oct 2014 09:21:13

Generated On: 18 Jul 2016 22:07:14

Drug type	Result
Cannabinoids	Negative
Cocaine	Negative
Opiates	Negative

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Alcohol Breath Test

Data signed: (Heart1) 29 Oct 2014 09:21:13

Generated On: 18 Jul 2016 22:07:14

Was the alcohol breath test performed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

07 JAN 2014
DD/MMM/YYYY

Time of assessment

10:24
hour:min 24-hour clock

Result

Negative ☒

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Urine Cotinine Test

Data signed: (Heart1) 29 Oct 2014 09:21:13

Generated On: 18 Jul 2016 22:07:14

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

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

If Not Done, please specify the reason:	<hr/>
---	-------

Date of Sample Collection	07 JAN 2014 DD/MMM/YYYY
---------------------------	----------------------------

Time of Sample Collection	09:55 hour:min 24-hour clock
---------------------------	---------------------------------

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

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Lab-BU (1)

Data signed: (Heart1) 29 Oct 2014 09:21:14

Generated On: 18 Jul 2016 22:07:14

Blood Sample time(BU)	1122
Urine Sample time(BU)	0955
Time of Blood Sample Collection	11:22
Time of Urine Sample Collection	09:55
Test Name	POS/NEG_HC
Result	
Text Result	NEGATIVE
Unit	
Lower limit	
Upper limit	NEGATIVE
Flag	
Clinically Significant?	
Comment	
Result Category	S

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Lab-BU (1)

Data signed: (Heart1) 29 Oct 2014 09:21:14

Generated On: 18 Jul 2016 22:07:14

Text Result Code	066
Reference Value Category	S
Timepoint(COHB)	
Material Code	SERUM
Chyle Comment Code	
Chyle Comment English	
Hemolysis Comment Code	
Hemolysis Comment English	
Specimen Comment Code 1	
Specimen English Comment 1	
Specimen Comment Code 2	
Specimen English Comment 2	
Result Supplementary Comment Code 1	
Result Supplementary English Comment Code 1	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Lab-BU (1)

Data signed: (Heart1) 29 Oct 2014 09:21:14

Generated On: 18 Jul 2016 22:07:14

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004671920

Please document clinically relevant abnormalities in the AE form

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Lab-BU (2)

Data signed: (Heart1) 29 Oct 2014 09:21:14

Generated On: 18 Jul 2016 22:07:14

Blood Sample time(BU)	1122
Urine Sample time(BU)	0955
Time of Blood Sample Collection	11:22
Time of Urine Sample Collection	09:55
Test Name	POS/NEG_HBS
Result	
Text Result	-
Unit	
Lower limit	
Upper limit	-
Flag	
Clinically Significant?	
Comment	
Result Category	S

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Lab-BU (2)

Data signed: (Heart1) 29 Oct 2014 09:21:14

Generated On: 18 Jul 2016 22:07:14

Text Result Code	168
Reference Value Category	S
Timepoint(COHB)	
Material Code	SERUM
Chyle Comment Code	
Chyle Comment English	
Hemolysis Comment Code	
Hemolysis Comment English	
Specimen Comment Code 1	
Specimen English Comment 1	
Specimen Comment Code 2	
Specimen English Comment 2	
Result Supplementary Comment Code 1	
Result Supplementary English Comment Code 1	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Lab-BU (2)

Data signed: (Heart1) 29 Oct 2014 09:21:14

Generated On: 18 Jul 2016 22:07:14

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004671920

Please document clinically relevant abnormalities in the AE form

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Lab-BU BLOOD CHEMISTRY(2014 JAN 07)

Data signed: (Heart1) 29 Oct 2014 09:21:14

Generated On: 18 Jul 2016 22:07:14

Test Category

BLOOD CHEMISTRY

Date of Sample Collection

2014 JAN 07

Date (BU)

2014/01/07

Please document clinically relevant abnormalities in the AE form

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Lab-BU BLOOD CHEMISTRY(2014 JAN 07)

Data signed: (Heart1) 29 Oct 2014 09:21:14

Generated On: 18 Jul 2016 22:07:14

Test Category	BLOOD CHEMISTRY
Date of Sample Collection	2014 JAN 07
Date (BU)	2014/01/07
Blood Sample time(BU)	1122
Urine Sample time(BU)	0955
Time of Blood Sample Collection	11:22
Time of Urine Sample Collection	09:55
Test Name	TOTAL PROTEIN
Result	7.7
Text Result	
Unit	G/DL
Lower limit	6.7
Upper limit	8.3
Flag	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Lab-BU BLOOD CHEMISTRY(2014 JAN 07)

Data signed: (Heart1) 29 Oct 2014 09:21:14

Generated On: 18 Jul 2016 22:07:14

Clinically Significant? _____

Comment _____

Result Category

N

Text Result Code _____

Reference Value Category

-

Timepoint(COHB) _____

Material Code

SERUM

Chyle Comment Code _____

Chyle Comment English

Hemolysis Comment Code _____

Hemolysis Comment English

Specimen Comment Code 1 _____

Specimen English Comment 1

Specimen Comment Code 2 _____

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Lab-BU BLOOD CHEMISTRY(2014 JAN 07)

Data signed: (Heart1) 29 Oct 2014 09:21:14

Generated On: 18 Jul 2016 22:07:14

Specimen English Comment 2

Result Supplementary Comment Code 1

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004671920

Please document clinically relevant abnormalities in the AE form

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Lab-BU (2)

Data signed: (Heart1) 29 Oct 2014 09:21:14

Generated On: 18 Jul 2016 22:07:14

Test Category	BLOOD CHEMISTRY
Date of Sample Collection	2014 JAN 07
Date (BU)	2014/01/07
Blood Sample time(BU)	1122
Urine Sample time(BU)	0955
Time of Blood Sample Collection	11:22
Time of Urine Sample Collection	09:55
Test Name	ALBUMIN
Result	5.2
Text Result	
Unit	G/DL
Lower limit	3.8
Upper limit	5.3
Flag	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Lab-BU (2)

Data signed: (Heart1) 29 Oct 2014 09:21:14

Generated On: 18 Jul 2016 22:07:14

Clinically Significant? _____

Comment _____

Result Category

N

Text Result Code _____

Reference Value Category

-

Timepoint(COHB) _____

Material Code

SERUM

Chyle Comment Code _____

Chyle Comment English

Hemolysis Comment Code _____

Hemolysis Comment English

Specimen Comment Code 1 _____

Specimen English Comment 1

Specimen Comment Code 2 _____

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Lab-BU (2)

Data signed: (Heart1) 29 Oct 2014 09:21:14

Generated On: 18 Jul 2016 22:07:14

Specimen English Comment 2

Result Supplementary Comment Code 1

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004671920

Please document clinically relevant abnormalities in the AE form

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Lab-BU (3)

Data signed: (Heart1) 29 Oct 2014 09:21:14

Generated On: 18 Jul 2016 22:07:14

Test Category	BLOOD CHEMISTRY
Date of Sample Collection	2014 JAN 07
Date (BU)	2014/01/07
Blood Sample time(BU)	1122
Urine Sample time(BU)	0955
Time of Blood Sample Collection	11:22
Time of Urine Sample Collection	09:55
Test Name	TOTAL BILIRUBIN
Result	0.9
Text Result	
Unit	MG/DL
Lower limit	0.2
Upper limit	1.2
Flag	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Lab-BU (3)

Data signed: (Heart1) 29 Oct 2014 09:21:14

Generated On: 18 Jul 2016 22:07:14

Clinically Significant? _____

Comment _____

Result Category

N

Text Result Code _____

Reference Value Category

-

Timepoint(COHB) _____

Material Code

SERUM

Chyle Comment Code _____

Chyle Comment English

Hemolysis Comment Code _____

Hemolysis Comment English

Specimen Comment Code 1 _____

Specimen English Comment 1

Specimen Comment Code 2 _____

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Lab-BU (3)

Data signed: (Heart1) 29 Oct 2014 09:21:14

Generated On: 18 Jul 2016 22:07:14

Specimen English Comment 2

Result Supplementary Comment Code 1

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004671920

Please document clinically relevant abnormalities in the AE form

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Lab-BU (4)

Data signed: (Heart1) 29 Oct 2014 09:21:14

Generated On: 18 Jul 2016 22:07:14

Test Category	BLOOD CHEMISTRY
Date of Sample Collection	2014 JAN 07
Date (BU)	2014/01/07
Blood Sample time(BU)	1122
Urine Sample time(BU)	0955
Time of Blood Sample Collection	11:22
Time of Urine Sample Collection	09:55
Test Name	DIRECT BILIRUBIN
Result	0.2
Text Result	
Unit	MG/DL
Lower limit	0.0
Upper limit	0.3
Flag	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Lab-BU (4)

Data signed: (Heart1) 29 Oct 2014 09:21:14

Generated On: 18 Jul 2016 22:07:14

Clinically Significant? _____

Comment _____

Result Category

N

Text Result Code _____

Reference Value Category

-

Timepoint(COHB) _____

Material Code

SERUM

Chyle Comment Code _____

Chyle Comment English

Hemolysis Comment Code _____

Hemolysis Comment English

Specimen Comment Code 1 _____

Specimen English Comment 1

Specimen Comment Code 2 _____

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Lab-BU (4)

Data signed: (Heart1) 29 Oct 2014 09:21:14

Generated On: 18 Jul 2016 22:07:14

Specimen English Comment 2

Result Supplementary Comment Code 1

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004671920

Please document clinically relevant abnormalities in the AE form

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Lab-BU (5)

Data signed: (Heart1) 29 Oct 2014 09:21:14

Generated On: 18 Jul 2016 22:07:14

Test Category	BLOOD CHEMISTRY
Date of Sample Collection	2014 JAN 07
Date (BU)	2014/01/07
Blood Sample time(BU)	1122
Urine Sample time(BU)	0955
Time of Blood Sample Collection	11:22
Time of Urine Sample Collection	09:55
Test Name	AST
Result	22
Text Result	
Unit	U/L
Lower limit	10
Upper limit	40
Flag	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Lab-BU (5)

Data signed: (Heart1) 29 Oct 2014 09:21:14

Generated On: 18 Jul 2016 22:07:14

Clinically Significant? _____

Comment _____

Result Category

N

Text Result Code _____

Reference Value Category

-

Timepoint(COHB) _____

Material Code

SERUM

Chyle Comment Code _____

Chyle Comment English

Hemolysis Comment Code _____

Hemolysis Comment English

Specimen Comment Code 1 _____

Specimen English Comment 1

Specimen Comment Code 2 _____

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Lab-BU (5)

Data signed: (Heart1) 29 Oct 2014 09:21:14

Generated On: 18 Jul 2016 22:07:14

Specimen English Comment 2

Result Supplementary Comment Code 1

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004671920

Please document clinically relevant abnormalities in the AE form

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Lab-BU (6)

Data signed: (Heart1) 29 Oct 2014 09:21:14

Generated On: 18 Jul 2016 22:07:14

Test Category	BLOOD CHEMISTRY
Date of Sample Collection	2014 JAN 07
Date (BU)	2014/01/07
Blood Sample time(BU)	1122
Urine Sample time(BU)	0955
Time of Blood Sample Collection	11:22
Time of Urine Sample Collection	09:55
Test Name	ALT
Result	31
Text Result	
Unit	U/L
Lower limit	5
Upper limit	45
Flag	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Lab-BU (6)

Data signed: (Heart1) 29 Oct 2014 09:21:14

Generated On: 18 Jul 2016 22:07:14

Clinically Significant? _____

Comment _____

Result Category

N

Text Result Code _____

Reference Value Category

-

Timepoint(COHB) _____

Material Code

SERUM

Chyle Comment Code _____

Chyle Comment English

Hemolysis Comment Code _____

Hemolysis Comment English

Specimen Comment Code 1 _____

Specimen English Comment 1

Specimen Comment Code 2 _____

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Lab-BU (6)

Data signed: (Heart1) 29 Oct 2014 09:21:14

Generated On: 18 Jul 2016 22:07:14

Specimen English Comment 2

Result Supplementary Comment Code 1

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004671920

Please document clinically relevant abnormalities in the AE form

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Lab-BU (7)

Data signed: (Heart1) 29 Oct 2014 09:21:14

Generated On: 18 Jul 2016 22:07:14

Test Category	BLOOD CHEMISTRY
Date of Sample Collection	2014 JAN 07
Date (BU)	2014/01/07
Blood Sample time(BU)	1122
Urine Sample time(BU)	0955
Time of Blood Sample Collection	11:22
Time of Urine Sample Collection	09:55
Test Name	LDH
Result	131
Text Result	
Unit	U/L
Lower limit	120
Upper limit	240
Flag	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Lab-BU (7)

Data signed: (Heart1) 29 Oct 2014 09:21:14

Generated On: 18 Jul 2016 22:07:14

Clinically Significant? _____

Comment _____

Result Category

N

Text Result Code _____

Reference Value Category

-

Timepoint(COHB) _____

Material Code

SERUM

Chyle Comment Code _____

Chyle Comment English

Hemolysis Comment Code _____

Hemolysis Comment English

Specimen Comment Code 1 _____

Specimen English Comment 1

Specimen Comment Code 2 _____

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Lab-BU (7)

Data signed: (Heart1) 29 Oct 2014 09:21:14

Generated On: 18 Jul 2016 22:07:14

Specimen English Comment 2

Result Supplementary Comment Code 1

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004671920

Please document clinically relevant abnormalities in the AE form

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Lab-BU (8)

Data signed: (Heart1) 29 Oct 2014 09:21:14

Generated On: 18 Jul 2016 22:07:14

Test Category	BLOOD CHEMISTRY
Date of Sample Collection	2014 JAN 07
Date (BU)	2014/01/07
Blood Sample time(BU)	1122
Urine Sample time(BU)	0955
Time of Blood Sample Collection	11:22
Time of Urine Sample Collection	09:55
Test Name	AP
Result	321
Text Result	
Unit	U/L
Lower limit	100
Upper limit	325
Flag	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Lab-BU (8)

Data signed: (Heart1) 29 Oct 2014 09:21:14

Generated On: 18 Jul 2016 22:07:14

Clinically Significant? _____

Comment _____

Result Category

N

Text Result Code _____

Reference Value Category

-

Timepoint(COHB) _____

Material Code

SERUM

Chyle Comment Code _____

Chyle Comment English

Hemolysis Comment Code _____

Hemolysis Comment English

Specimen Comment Code 1 _____

Specimen English Comment 1

Specimen Comment Code 2 _____

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Lab-BU (8)

Data signed: (Heart1) 29 Oct 2014 09:21:14

Generated On: 18 Jul 2016 22:07:14

Specimen English Comment 2

Result Supplementary Comment Code 1

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004671920

Please document clinically relevant abnormalities in the AE form

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Lab-BU (9)

Data signed: (Heart1) 29 Oct 2014 09:21:14

Generated On: 18 Jul 2016 22:07:14

Test Category	BLOOD CHEMISTRY
Date of Sample Collection	2014 JAN 07
Date (BU)	2014/01/07
Blood Sample time(BU)	1122
Urine Sample time(BU)	0955
Time of Blood Sample Collection	11:22
Time of Urine Sample Collection	09:55
Test Name	GGT
Result	35
Text Result	
Unit	U/L
Lower limit	
Upper limit	80
Flag	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Lab-BU (9)

Data signed: (Heart1) 29 Oct 2014 09:21:14

Generated On: 18 Jul 2016 22:07:14

Clinically Significant? _____

Comment _____

Result Category

N

Text Result Code _____

Reference Value Category

E

Timepoint(COHB) _____

Material Code

SERUM

Chyle Comment Code _____

Chyle Comment English

Hemolysis Comment Code _____

Hemolysis Comment English

Specimen Comment Code 1 _____

Specimen English Comment 1

Specimen Comment Code 2 _____

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Lab-BU (9)

Data signed: (Heart1) 29 Oct 2014 09:21:14

Generated On: 18 Jul 2016 22:07:14

Specimen English Comment 2

Result Supplementary Comment Code 1

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004671920

Please document clinically relevant abnormalities in the AE form

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Lab-BU (10)

Data signed: (Heart1) 29 Oct 2014 09:21:14

Generated On: 18 Jul 2016 22:07:14

Test Category	BLOOD CHEMISTRY
Date of Sample Collection	2014 JAN 07
Date (BU)	2014/01/07
Blood Sample time(BU)	1122
Urine Sample time(BU)	0955
Time of Blood Sample Collection	11:22
Time of Urine Sample Collection	09:55
Test Name	FASTING GLUCOSE
Result	92
Text Result	
Unit	MG/DL
Lower limit	70
Upper limit	109
Flag	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Lab-BU (10)

Data signed: (Heart1) 29 Oct 2014 09:21:14

Generated On: 18 Jul 2016 22:07:14

Clinically Significant? _____

Comment _____

Result Category

N

Text Result Code _____

Reference Value Category

-

Timepoint(COHB) _____

Material Code

SERUM

Chyle Comment Code _____

Chyle Comment English

Hemolysis Comment Code _____

Hemolysis Comment English

Specimen Comment Code 1 _____

Specimen English Comment 1

Specimen Comment Code 2 _____

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Lab-BU (10)

Data signed: (Heart1) 29 Oct 2014 09:21:14

Generated On: 18 Jul 2016 22:07:14

Specimen English Comment 2

Result Supplementary Comment Code 1

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004671920

Please document clinically relevant abnormalities in the AE form

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Lab-BU (11)

Data signed: (Heart1) 29 Oct 2014 09:21:14

Generated On: 18 Jul 2016 22:07:14

Test Category	BLOOD CHEMISTRY
Date of Sample Collection	2014 JAN 07
Date (BU)	2014/01/07
Blood Sample time(BU)	1122
Urine Sample time(BU)	0955
Time of Blood Sample Collection	11:22
Time of Urine Sample Collection	09:55
Test Name	CREATININE
Result	0.83
Text Result	
Unit	MG/DL
Lower limit	0.61
Upper limit	1.04
Flag	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Lab-BU (11)

Data signed: (Heart1) 29 Oct 2014 09:21:14

Generated On: 18 Jul 2016 22:07:14

Clinically Significant? _____

Comment _____

Result Category

N

Text Result Code _____

Reference Value Category

-

Timepoint(COHB) _____

Material Code

SERUM

Chyle Comment Code _____

Chyle Comment English

Hemolysis Comment Code _____

Hemolysis Comment English

Specimen Comment Code 1 _____

Specimen English Comment 1

Specimen Comment Code 2 _____

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Lab-BU (11)

Data signed: (Heart1) 29 Oct 2014 09:21:14

Generated On: 18 Jul 2016 22:07:14

Specimen English Comment 2

Result Supplementary Comment Code 1

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004671920

Please document clinically relevant abnormalities in the AE form

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Lab-BU (12)

Data signed: (Heart1) 29 Oct 2014 09:21:14

Generated On: 18 Jul 2016 22:07:14

Test Category	BLOOD CHEMISTRY
Date of Sample Collection	2014 JAN 07
Date (BU)	2014/01/07
Blood Sample time(BU)	1122
Urine Sample time(BU)	0955
Time of Blood Sample Collection	11:22
Time of Urine Sample Collection	09:55
Test Name	BUN
Result	15
Text Result	
Unit	MG/DL
Lower limit	8
Upper limit	23
Flag	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Lab-BU (12)

Data signed: (Heart1) 29 Oct 2014 09:21:14

Generated On: 18 Jul 2016 22:07:14

Clinically Significant? _____

Comment _____

Result Category

N

Text Result Code _____

Reference Value Category

-

Timepoint(COHB) _____

Material Code

SERUM

Chyle Comment Code _____

Chyle Comment English

Hemolysis Comment Code _____

Hemolysis Comment English

Specimen Comment Code 1 _____

Specimen English Comment 1

Specimen Comment Code 2 _____

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Lab-BU (12)

Data signed: (Heart1) 29 Oct 2014 09:21:14

Generated On: 18 Jul 2016 22:07:14

Specimen English Comment 2

Result Supplementary Comment Code 1

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004671920

Please document clinically relevant abnormalities in the AE form


ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Lab-BU (13)

Data signed: (Heart1) 29 Oct 2014 09:21:14

Generated On: 18 Jul 2016 22:07:14

Test Category	BLOOD CHEMISTRY
Date of Sample Collection	2014 JAN 07
Date (BU)	2014/01/07
Blood Sample time(BU)	1122
Urine Sample time(BU)	0955
Time of Blood Sample Collection	11:22
Time of Urine Sample Collection	09:55
Test Name	TRIGLYCERIDES
Result	226
Text Result	
Unit	MG/DL
Lower limit	30
Upper limit	149
Flag	High 

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Lab-BU (13)

Data signed: (Heart1) 29 Oct 2014 09:21:14

Generated On: 18 Jul 2016 22:07:14

Clinically Significant?

No ☒

Comment

Result Category

N

Text Result Code

Reference Value Category

-

Timepoint(COHB)

Material Code

SERUM

Chyle Comment Code

Chyle Comment English

Hemolysis Comment Code

Hemolysis Comment English

Specimen Comment Code 1

Specimen English Comment 1

Specimen Comment Code 2

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Lab-BU (13)

Data signed: (Heart1) 29 Oct 2014 09:21:14

Generated On: 18 Jul 2016 22:07:14

Specimen English Comment 2

Result Supplementary Comment Code 1

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004671920

Please document clinically relevant abnormalities in the AE form


ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Lab-BU (14)

Data signed: (Heart1) 29 Oct 2014 09:21:14

Generated On: 18 Jul 2016 22:07:14

Test Category	BLOOD CHEMISTRY
Date of Sample Collection	2014 JAN 07
Date (BU)	2014/01/07
Blood Sample time(BU)	1122
Urine Sample time(BU)	0955
Time of Blood Sample Collection	11:22
Time of Urine Sample Collection	09:55
Test Name	TOTAL CHOLESTEROL
Result	227
Text Result	
Unit	MG/DL
Lower limit	120
Upper limit	219
Flag	High 

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Lab-BU (14)

Data signed: (Heart1) 29 Oct 2014 09:21:14

Generated On: 18 Jul 2016 22:07:14

Clinically Significant?

No ☒

Comment

Result Category

N

Text Result Code

Reference Value Category

-

Timepoint(COHB)

Material Code

SERUM

Chyle Comment Code

Chyle Comment English

Hemolysis Comment Code

Hemolysis Comment English

Specimen Comment Code 1

Specimen English Comment 1

Specimen Comment Code 2

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Lab-BU (14)

Data signed: (Heart1) 29 Oct 2014 09:21:14

Generated On: 18 Jul 2016 22:07:14

Specimen English Comment 2

Result Supplementary Comment Code 1

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004671920

Please document clinically relevant abnormalities in the AE form

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Lab-BU (15)

Data signed: (Heart1) 29 Oct 2014 09:21:14

Generated On: 18 Jul 2016 22:07:14

Test Category	BLOOD CHEMISTRY
Date of Sample Collection	2014 JAN 07
Date (BU)	2014/01/07
Blood Sample time(BU)	1122
Urine Sample time(BU)	0955
Time of Blood Sample Collection	11:22
Time of Urine Sample Collection	09:55
Test Name	SODIUM
Result	142
Text Result	
Unit	MEQ/L
Lower limit	137
Upper limit	147
Flag	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Lab-BU (15)

Data signed: (Heart1) 29 Oct 2014 09:21:14

Generated On: 18 Jul 2016 22:07:14

Clinically Significant? _____

Comment _____

Result Category

N

Text Result Code _____

Reference Value Category

-

Timepoint(COHB) _____

Material Code

SERUM

Chyle Comment Code _____

Chyle Comment English

Hemolysis Comment Code _____

Hemolysis Comment English

Specimen Comment Code 1 _____

Specimen English Comment 1

Specimen Comment Code 2 _____

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Lab-BU (15)

Data signed: (Heart1) 29 Oct 2014 09:21:14

Generated On: 18 Jul 2016 22:07:14

Specimen English Comment 2

Result Supplementary Comment Code 1

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004671920

Please document clinically relevant abnormalities in the AE form

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Lab-BU (16)

Data signed: (Heart1) 29 Oct 2014 09:21:14

Generated On: 18 Jul 2016 22:07:14

Test Category	BLOOD CHEMISTRY
Date of Sample Collection	2014 JAN 07
Date (BU)	2014/01/07
Blood Sample time(BU)	1122
Urine Sample time(BU)	0955
Time of Blood Sample Collection	11:22
Time of Urine Sample Collection	09:55
Test Name	POTASSIUM
Result	5.0
Text Result	
Unit	MEQ/L
Lower limit	3.5
Upper limit	5.0
Flag	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Lab-BU (16)

Data signed: (Heart1) 29 Oct 2014 09:21:14

Generated On: 18 Jul 2016 22:07:14

Clinically Significant? _____

Comment _____

Result Category _____ N

Text Result Code _____

Reference Value Category _____ -

Timepoint(COHB) _____

Material Code _____ SERUM

Chyle Comment Code _____

Chyle Comment English _____

Hemolysis Comment Code _____

Hemolysis Comment English _____

Specimen Comment Code 1 _____

Specimen English Comment 1 _____

Specimen Comment Code 2 _____

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Lab-BU (16)

Data signed: (Heart1) 29 Oct 2014 09:21:14

Generated On: 18 Jul 2016 22:07:14

Specimen English Comment 2

Result Supplementary Comment Code 1

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004671920

Please document clinically relevant abnormalities in the AE form

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Lab-BU HEMATOLOGY(2014 JAN 07)

Data signed: (Heart1) 29 Oct 2014 09:21:23

Generated On: 18 Jul 2016 22:07:14

Test Category	HEMATOLOGY
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Date of Sample Collection	2014 JAN 07
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Date (BU)	2014/01/07
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Please document clinically relevant abnormalities in the AE form	
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ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Lab-BU HEMATOLOGY(2014 JAN 07)

Data signed: (Heart1) 29 Oct 2014 09:21:23

Generated On: 18 Jul 2016 22:07:14

Test Category	HEMATOLOGY
Date of Sample Collection	2014 JAN 07
Date (BU)	2014/01/07
Blood Sample time(BU)	1122
Urine Sample time(BU)	0955
Time of Blood Sample Collection	11:22
Time of Urine Sample Collection	09:55
Test Name	WBC COUNT
Result	8200
Text Result	
Unit	/UL
Lower limit	3300
Upper limit	9000
Flag	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Lab-BU HEMATOLOGY(2014 JAN 07)

Data signed: (Heart1) 29 Oct 2014 09:21:23

Generated On: 18 Jul 2016 22:07:14

Clinically Significant? _____

Comment _____

Result Category _____ N

Text Result Code _____

Reference Value Category _____ -

Timepoint(COHB) _____

Material Code _____ BLOOD

Chyle Comment Code _____

Chyle Comment English _____

Hemolysis Comment Code _____

Hemolysis Comment English _____

Specimen Comment Code 1 _____

Specimen English Comment 1 _____

Specimen Comment Code 2 _____

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Lab-BU HEMATOLOGY(2014 JAN 07)

Data signed: (Heart1) 29 Oct 2014 09:21:23

Generated On: 18 Jul 2016 22:07:14

Specimen English Comment 2

Result Supplementary Comment Code 1

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004671920

Please document clinically relevant abnormalities in the AE form

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Lab-BU (2)

Data signed: (Heart1) 29 Oct 2014 09:21:23

Generated On: 18 Jul 2016 22:07:14

Test Category	HEMATOLOGY
Date of Sample Collection	2014 JAN 07
Date (BU)	2014/01/07
Blood Sample time(BU)	1122
Urine Sample time(BU)	0955
Time of Blood Sample Collection	11:22
Time of Urine Sample Collection	09:55
Test Name	RBC COUNT
Result	502
Text Result	
Unit	10 ⁴ /UL
Lower limit	430
Upper limit	570
Flag	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Lab-BU (2)

Data signed: (Heart1) 29 Oct 2014 09:21:23

Generated On: 18 Jul 2016 22:07:14

Clinically Significant? _____

Comment _____

Result Category

N

Text Result Code _____

Reference Value Category

-

Timepoint(COHB) _____

Material Code

BLOOD

Chyle Comment Code _____

Chyle Comment English

Hemolysis Comment Code _____

Hemolysis Comment English

Specimen Comment Code 1 _____

Specimen English Comment 1

Specimen Comment Code 2 _____

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Lab-BU (2)

Data signed: (Heart1) 29 Oct 2014 09:21:23

Generated On: 18 Jul 2016 22:07:14

Specimen English Comment 2

Result Supplementary Comment Code 1

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004671920

Please document clinically relevant abnormalities in the AE form

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Lab-BU (3)

Data signed: (Heart1) 29 Oct 2014 09:21:23

Generated On: 18 Jul 2016 22:07:14

Test Category	HEMATOLOGY
Date of Sample Collection	2014 JAN 07
Date (BU)	2014/01/07
Blood Sample time(BU)	1122
Urine Sample time(BU)	0955
Time of Blood Sample Collection	11:22
Time of Urine Sample Collection	09:55
Test Name	HEMOGLOBIN
Result	16.4
Text Result	
Unit	G/DL
Lower limit	13.5
Upper limit	17.5
Flag	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Lab-BU (3)

Data signed: (Heart1) 29 Oct 2014 09:21:23

Generated On: 18 Jul 2016 22:07:14

Clinically Significant? _____

Comment _____

Result Category

N

Text Result Code _____

Reference Value Category

-

Timepoint(COHB) _____

Material Code

BLOOD

Chyle Comment Code _____

Chyle Comment English _____

Hemolysis Comment Code _____

Hemolysis Comment English _____

Specimen Comment Code 1 _____

Specimen English Comment 1 _____

Specimen Comment Code 2 _____

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Lab-BU (3)

Data signed: (Heart1) 29 Oct 2014 09:21:23

Generated On: 18 Jul 2016 22:07:14

Specimen English Comment 2

Result Supplementary Comment Code 1

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004671920

Please document clinically relevant abnormalities in the AE form

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Lab-BU (4)

Data signed: (Heart1) 29 Oct 2014 09:21:23

Generated On: 18 Jul 2016 22:07:14

Test Category	HEMATOLOGY
Date of Sample Collection	2014 JAN 07
Date (BU)	2014/01/07
Blood Sample time(BU)	1122
Urine Sample time(BU)	0955
Time of Blood Sample Collection	11:22
Time of Urine Sample Collection	09:55
Test Name	HEMATOCRIT
Result	47.6
Text Result	
Unit	%
Lower limit	39.7
Upper limit	52.4
Flag	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Lab-BU (4)

Data signed: (Heart1) 29 Oct 2014 09:21:23

Generated On: 18 Jul 2016 22:07:14

Clinically Significant? _____

Comment _____

Result Category

N

Text Result Code _____

Reference Value Category

-

Timepoint(COHB) _____

Material Code

BLOOD

Chyle Comment Code _____

Chyle Comment English _____

Hemolysis Comment Code _____

Hemolysis Comment English _____

Specimen Comment Code 1 _____

Specimen English Comment 1 _____

Specimen Comment Code 2 _____

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Lab-BU (4)

Data signed: (Heart1) 29 Oct 2014 09:21:23

Generated On: 18 Jul 2016 22:07:14

Specimen English Comment 2

Result Supplementary Comment Code 1

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004671920

Please document clinically relevant abnormalities in the AE form

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Lab-BU (5)

Data signed: (Heart1) 29 Oct 2014 09:21:23

Generated On: 18 Jul 2016 22:07:14

Test Category	HEMATOLOGY
Date of Sample Collection	2014 JAN 07
Date (BU)	2014/01/07
Blood Sample time(BU)	1122
Urine Sample time(BU)	0955
Time of Blood Sample Collection	11:22
Time of Urine Sample Collection	09:55
Test Name	MCV
Result	95
Text Result	
Unit	FL
Lower limit	85
Upper limit	102
Flag	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Lab-BU (5)

Data signed: (Heart1) 29 Oct 2014 09:21:23

Generated On: 18 Jul 2016 22:07:14

Clinically Significant? _____

Comment _____

Result Category

N

Text Result Code _____

Reference Value Category

-

Timepoint(COHB) _____

Material Code

BLOOD

Chyle Comment Code _____

Chyle Comment English _____

Hemolysis Comment Code _____

Hemolysis Comment English _____

Specimen Comment Code 1 _____

Specimen English Comment 1 _____

Specimen Comment Code 2 _____

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Lab-BU (5)

Data signed: (Heart1) 29 Oct 2014 09:21:23

Generated On: 18 Jul 2016 22:07:14

Specimen English Comment 2

Result Supplementary Comment Code 1

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004671920

Please document clinically relevant abnormalities in the AE form

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Lab-BU (6)

Data signed: (Heart1) 29 Oct 2014 09:21:23

Generated On: 18 Jul 2016 22:07:14

Test Category	HEMATOLOGY
Date of Sample Collection	2014 JAN 07
Date (BU)	2014/01/07
Blood Sample time(BU)	1122
Urine Sample time(BU)	0955
Time of Blood Sample Collection	11:22
Time of Urine Sample Collection	09:55
Test Name	MCH
Result	32.7
Text Result	
Unit	PG
Lower limit	28.0
Upper limit	34.0
Flag	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Lab-BU (6)

Data signed: (Heart1) 29 Oct 2014 09:21:23

Generated On: 18 Jul 2016 22:07:14

Clinically Significant? _____

Comment _____

Result Category

N

Text Result Code _____

Reference Value Category

-

Timepoint(COHB) _____

Material Code

BLOOD

Chyle Comment Code _____

Chyle Comment English

Hemolysis Comment Code _____

Hemolysis Comment English

Specimen Comment Code 1 _____

Specimen English Comment 1

Specimen Comment Code 2 _____

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Lab-BU (6)

Data signed: (Heart1) 29 Oct 2014 09:21:23

Generated On: 18 Jul 2016 22:07:14

Specimen English Comment 2

Result Supplementary Comment Code 1

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004671920

Please document clinically relevant abnormalities in the AE form

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Lab-BU (7)

Data signed: (Heart1) 29 Oct 2014 09:21:23

Generated On: 18 Jul 2016 22:07:14

Test Category	HEMATOLOGY
Date of Sample Collection	2014 JAN 07
Date (BU)	2014/01/07
Blood Sample time(BU)	1122
Urine Sample time(BU)	0955
Time of Blood Sample Collection	11:22
Time of Urine Sample Collection	09:55
Test Name	MCHC
Result	34.5
Text Result	
Unit	%
Lower limit	30.2
Upper limit	35.1
Flag	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Lab-BU (7)

Data signed: (Heart1) 29 Oct 2014 09:21:23

Generated On: 18 Jul 2016 22:07:14

Clinically Significant? _____

Comment _____

Result Category

N

Text Result Code _____

Reference Value Category

-

Timepoint(COHB) _____

Material Code

BLOOD

Chyle Comment Code _____

Chyle Comment English

Hemolysis Comment Code _____

Hemolysis Comment English

Specimen Comment Code 1 _____

Specimen English Comment 1

Specimen Comment Code 2 _____

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Lab-BU (7)

Data signed: (Heart1) 29 Oct 2014 09:21:23

Generated On: 18 Jul 2016 22:07:14

Specimen English Comment 2

Result Supplementary Comment Code 1

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004671920

Please document clinically relevant abnormalities in the AE form

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Lab-BU (8)

Data signed: (Heart1) 29 Oct 2014 09:21:23

Generated On: 18 Jul 2016 22:07:14

Test Category	HEMATOLOGY
Date of Sample Collection	2014 JAN 07
Date (BU)	2014/01/07
Blood Sample time(BU)	1122
Urine Sample time(BU)	0955
Time of Blood Sample Collection	11:22
Time of Urine Sample Collection	09:55
Test Name	PLATELET COUNT
Result	20.8
Text Result	
Unit	10 ⁴ /UL
Lower limit	14.0
Upper limit	34.0
Flag	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Lab-BU (8)

Data signed: (Heart1) 29 Oct 2014 09:21:23

Generated On: 18 Jul 2016 22:07:14

Clinically Significant? _____

Comment _____

Result Category

N

Text Result Code _____

Reference Value Category

-

Timepoint(COHB) _____

Material Code

BLOOD

Chyle Comment Code _____

Chyle Comment English

Hemolysis Comment Code _____

Hemolysis Comment English

Specimen Comment Code 1 _____

Specimen English Comment 1

Specimen Comment Code 2 _____

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Lab-BU (8)

Data signed: (Heart1) 29 Oct 2014 09:21:23

Generated On: 18 Jul 2016 22:07:14

Specimen English Comment 2

Result Supplementary Comment Code 1

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004671920

Please document clinically relevant abnormalities in the AE form

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Lab-BU (9)

Data signed: (Heart1) 29 Oct 2014 09:21:23

Generated On: 18 Jul 2016 22:07:14

Test Category	HEMATOLOGY
Date of Sample Collection	2014 JAN 07
Date (BU)	2014/01/07
Blood Sample time(BU)	1122
Urine Sample time(BU)	0955
Time of Blood Sample Collection	11:22
Time of Urine Sample Collection	09:55
Test Name	DIFFERENTIAL WBC
Result	
Text Result	
Unit	
Lower limit	
Upper limit	
Flag	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Lab-BU (9)

Data signed: (Heart1) 29 Oct 2014 09:21:23

Generated On: 18 Jul 2016 22:07:14

Clinically Significant? _____

Comment _____

Result Category _____

Text Result Code _____

Reference Value Category _____

Timepoint(COHB) _____

Material Code

BLOOD

Chyle Comment Code _____

Chyle Comment English _____

Hemolysis Comment Code _____

Hemolysis Comment English _____

Specimen Comment Code 1 _____

Specimen English Comment 1 _____

Specimen Comment Code 2 _____

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Lab-BU (9)

Data signed: (Heart1) 29 Oct 2014 09:21:23

Generated On: 18 Jul 2016 22:07:14

Specimen English Comment 2

Result Supplementary Comment Code 1

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004671920

Please document clinically relevant abnormalities in the AE form

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Lab-BU (10)

Data signed: (Heart1) 29 Oct 2014 09:21:23

Generated On: 18 Jul 2016 22:07:14

Test Category	HEMATOLOGY
Date of Sample Collection	2014 JAN 07
Date (BU)	2014/01/07
Blood Sample time(BU)	1122
Urine Sample time(BU)	0955
Time of Blood Sample Collection	11:22
Time of Urine Sample Collection	09:55
Test Name	NEUTROPHILS (REL)
Result	60.9
Text Result	
Unit	%
Lower limit	40.0
Upper limit	75.0
Flag	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Lab-BU (10)

Data signed: (Heart1) 29 Oct 2014 09:21:23

Generated On: 18 Jul 2016 22:07:14

Clinically Significant? _____

Comment _____

Result Category

N

Text Result Code _____

Reference Value Category

-

Timepoint(COHB) _____

Material Code

BLOOD

Chyle Comment Code _____

Chyle Comment English

Hemolysis Comment Code _____

Hemolysis Comment English

Specimen Comment Code 1 _____

Specimen English Comment 1

Specimen Comment Code 2 _____

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Lab-BU (10)

Data signed: (Heart1) 29 Oct 2014 09:21:23

Generated On: 18 Jul 2016 22:07:14

Specimen English Comment 2

Result Supplementary Comment Code 1

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004671920

Please document clinically relevant abnormalities in the AE form

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Lab-BU (11)

Data signed: (Heart1) 29 Oct 2014 09:21:23

Generated On: 18 Jul 2016 22:07:14

Test Category	HEMATOLOGY
Date of Sample Collection	2014 JAN 07
Date (BU)	2014/01/07
Blood Sample time(BU)	1122
Urine Sample time(BU)	0955
Time of Blood Sample Collection	11:22
Time of Urine Sample Collection	09:55
Test Name	LYMPHOCYTES (REL)
Result	30.7
Text Result	
Unit	%
Lower limit	18.0
Upper limit	49.0
Flag	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Lab-BU (11)

Data signed: (Heart1) 29 Oct 2014 09:21:23

Generated On: 18 Jul 2016 22:07:14

Clinically Significant? _____

Comment _____

Result Category

N

Text Result Code _____

Reference Value Category

-

Timepoint(COHB) _____

Material Code

BLOOD

Chyle Comment Code _____

Chyle Comment English

Hemolysis Comment Code _____

Hemolysis Comment English

Specimen Comment Code 1 _____

Specimen English Comment 1

Specimen Comment Code 2 _____

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Lab-BU (11)

Data signed: (Heart1) 29 Oct 2014 09:21:23

Generated On: 18 Jul 2016 22:07:14

Specimen English Comment 2

Result Supplementary Comment Code 1

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004671920

Please document clinically relevant abnormalities in the AE form

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Lab-BU (12)

Data signed: (Heart1) 29 Oct 2014 09:21:23

Generated On: 18 Jul 2016 22:07:14

Test Category	HEMATOLOGY
Date of Sample Collection	2014 JAN 07
Date (BU)	2014/01/07
Blood Sample time(BU)	1122
Urine Sample time(BU)	0955
Time of Blood Sample Collection	11:22
Time of Urine Sample Collection	09:55
Test Name	MONOCYTES (REL)
Result	5.0
Text Result	
Unit	%
Lower limit	2.0
Upper limit	10.0
Flag	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Lab-BU (12)

Data signed: (Heart1) 29 Oct 2014 09:21:23

Generated On: 18 Jul 2016 22:07:14

Clinically Significant? _____

Comment _____

Result Category

N

Text Result Code _____

Reference Value Category

-

Timepoint(COHB) _____

Material Code

BLOOD

Chyle Comment Code _____

Chyle Comment English

Hemolysis Comment Code _____

Hemolysis Comment English

Specimen Comment Code 1 _____

Specimen English Comment 1

Specimen Comment Code 2 _____

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Lab-BU (12)

Data signed: (Heart1) 29 Oct 2014 09:21:23

Generated On: 18 Jul 2016 22:07:14

Specimen English Comment 2

Result Supplementary Comment Code 1

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004671920

Please document clinically relevant abnormalities in the AE form

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Lab-BU (13)

Data signed: (Heart1) 29 Oct 2014 09:21:23

Generated On: 18 Jul 2016 22:07:14

Test Category	HEMATOLOGY
Date of Sample Collection	2014 JAN 07
Date (BU)	2014/01/07
Blood Sample time(BU)	1122
Urine Sample time(BU)	0955
Time of Blood Sample Collection	11:22
Time of Urine Sample Collection	09:55
Test Name	EOSINOPHILS (REL)
Result	3.1
Text Result	
Unit	%
Lower limit	0.0
Upper limit	8.0
Flag	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Lab-BU (13)

Data signed: (Heart1) 29 Oct 2014 09:21:23

Generated On: 18 Jul 2016 22:07:14

Clinically Significant? _____

Comment _____

Result Category _____ N

Text Result Code _____

Reference Value Category _____ -

Timepoint(COHB) _____

Material Code _____ BLOOD

Chyle Comment Code _____

Chyle Comment English _____

Hemolysis Comment Code _____

Hemolysis Comment English _____

Specimen Comment Code 1 _____

Specimen English Comment 1 _____

Specimen Comment Code 2 _____

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Lab-BU (13)

Data signed: (Heart1) 29 Oct 2014 09:21:23

Generated On: 18 Jul 2016 22:07:14

Specimen English Comment 2

Result Supplementary Comment Code 1

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004671920

Please document clinically relevant abnormalities in the AE form

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Lab-BU (14)

Data signed: (Heart1) 29 Oct 2014 09:21:23

Generated On: 18 Jul 2016 22:07:14

Test Category	HEMATOLOGY
Date of Sample Collection	2014 JAN 07
Date (BU)	2014/01/07
Blood Sample time(BU)	1122
Urine Sample time(BU)	0955
Time of Blood Sample Collection	11:22
Time of Urine Sample Collection	09:55
Test Name	BASOPHILS (REL)
Result	0.3
Text Result	
Unit	%
Lower limit	0.0
Upper limit	2.0
Flag	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Lab-BU (14)

Data signed: (Heart1) 29 Oct 2014 09:21:23

Generated On: 18 Jul 2016 22:07:14

Clinically Significant? _____

Comment _____

Result Category _____ N

Text Result Code _____

Reference Value Category _____ -

Timepoint(COHB) _____

Material Code _____ BLOOD

Chyle Comment Code _____

Chyle Comment English _____

Hemolysis Comment Code _____

Hemolysis Comment English _____

Specimen Comment Code 1 _____

Specimen English Comment 1 _____

Specimen Comment Code 2 _____

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Lab-BU (14)

Data signed: (Heart1) 29 Oct 2014 09:21:23

Generated On: 18 Jul 2016 22:07:14

Specimen English Comment 2

Result Supplementary Comment Code 1

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004671920

Please document clinically relevant abnormalities in the AE form

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Lab-BU (15)

Data signed: (Heart1) 29 Oct 2014 09:21:23

Generated On: 18 Jul 2016 22:07:14

Test Category	HEMATOLOGY
Date of Sample Collection	2014 JAN 07
Date (BU)	2014/01/07
Blood Sample time(BU)	1122
Urine Sample time(BU)	0955
Time of Blood Sample Collection	11:22
Time of Urine Sample Collection	09:55
Test Name	NEUTROPHILS (ABS)
Result	5000
Text Result	
Unit	/UL
Lower limit	
Upper limit	
Flag	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Lab-BU (15)

Data signed: (Heart1) 29 Oct 2014 09:21:23

Generated On: 18 Jul 2016 22:07:14

Clinically Significant? _____

Comment _____

Result Category

N

Text Result Code _____

Reference Value Category _____

Timepoint(COHB) _____

Material Code

BLOOD

Chyle Comment Code _____

Chyle Comment English _____

Hemolysis Comment Code _____

Hemolysis Comment English _____

Specimen Comment Code 1 _____

Specimen English Comment 1 _____

Specimen Comment Code 2 _____

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Lab-BU (15)

Data signed: (Heart1) 29 Oct 2014 09:21:23

Generated On: 18 Jul 2016 22:07:14

Specimen English Comment 2

Result Supplementary Comment Code 1

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004671920

Please document clinically relevant abnormalities in the AE form

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Lab-BU (16)

Data signed: (Heart1) 29 Oct 2014 09:21:23

Generated On: 18 Jul 2016 22:07:14

Test Category	HEMATOLOGY
Date of Sample Collection	2014 JAN 07
Date (BU)	2014/01/07
Blood Sample time(BU)	1122
Urine Sample time(BU)	0955
Time of Blood Sample Collection	11:22
Time of Urine Sample Collection	09:55
Test Name	LYMPHOCYTES (ABS)
Result	2500
Text Result	
Unit	/UL
Lower limit	
Upper limit	
Flag	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Lab-BU (16)

Data signed: (Heart1) 29 Oct 2014 09:21:23

Generated On: 18 Jul 2016 22:07:14

Clinically Significant? _____

Comment _____

Result Category

N

Text Result Code _____

Reference Value Category _____

Timepoint(COHB) _____

Material Code

BLOOD

Chyle Comment Code _____

Chyle Comment English _____

Hemolysis Comment Code _____

Hemolysis Comment English _____

Specimen Comment Code 1 _____

Specimen English Comment 1 _____

Specimen Comment Code 2 _____

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Lab-BU (16)

Data signed: (Heart1) 29 Oct 2014 09:21:23

Generated On: 18 Jul 2016 22:07:14

Specimen English Comment 2

Result Supplementary Comment Code 1

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004671920

Please document clinically relevant abnormalities in the AE form

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Lab-BU (17)

Data signed: (Heart1) 29 Oct 2014 09:21:23

Generated On: 18 Jul 2016 22:07:14

Test Category	HEMATOLOGY
Date of Sample Collection	2014 JAN 07
Date (BU)	2014/01/07
Blood Sample time(BU)	1122
Urine Sample time(BU)	0955
Time of Blood Sample Collection	11:22
Time of Urine Sample Collection	09:55
Test Name	MONOCYTES (ABS)
Result	410
Text Result	
Unit	/UL
Lower limit	
Upper limit	
Flag	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Lab-BU (17)

Data signed: (Heart1) 29 Oct 2014 09:21:23

Generated On: 18 Jul 2016 22:07:14

Clinically Significant? _____

Comment _____

Result Category

N

Text Result Code _____

Reference Value Category _____

Timepoint(COHB) _____

Material Code

BLOOD

Chyle Comment Code _____

Chyle Comment English _____

Hemolysis Comment Code _____

Hemolysis Comment English _____

Specimen Comment Code 1 _____

Specimen English Comment 1 _____

Specimen Comment Code 2 _____

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Lab-BU (17)

Data signed: (Heart1) 29 Oct 2014 09:21:23

Generated On: 18 Jul 2016 22:07:14

Specimen English Comment 2

Result Supplementary Comment Code 1

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004671920

Please document clinically relevant abnormalities in the AE form

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Lab-BU (18)

Data signed: (Heart1) 29 Oct 2014 09:21:23

Generated On: 18 Jul 2016 22:07:14

Test Category	HEMATOLOGY
Date of Sample Collection	2014 JAN 07
Date (BU)	2014/01/07
Blood Sample time(BU)	1122
Urine Sample time(BU)	0955
Time of Blood Sample Collection	11:22
Time of Urine Sample Collection	09:55
Test Name	EOSINOPHILS (ABS)
Result	250
Text Result	
Unit	/UL
Lower limit	
Upper limit	
Flag	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Lab-BU (18)

Data signed: (Heart1) 29 Oct 2014 09:21:23

Generated On: 18 Jul 2016 22:07:14

Clinically Significant? _____

Comment _____

Result Category

N

Text Result Code _____

Reference Value Category _____

Timepoint(COHB) _____

Material Code

BLOOD

Chyle Comment Code _____

Chyle Comment English _____

Hemolysis Comment Code _____

Hemolysis Comment English _____

Specimen Comment Code 1 _____

Specimen English Comment 1 _____

Specimen Comment Code 2 _____

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Lab-BU (18)

Data signed: (Heart1) 29 Oct 2014 09:21:23

Generated On: 18 Jul 2016 22:07:14

Specimen English Comment 2

Result Supplementary Comment Code 1

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004671920

Please document clinically relevant abnormalities in the AE form

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Lab-BU (19)

Data signed: (Heart1) 29 Oct 2014 09:21:23

Generated On: 18 Jul 2016 22:07:14

Test Category	HEMATOLOGY
Date of Sample Collection	2014 JAN 07
Date (BU)	2014/01/07
Blood Sample time(BU)	1122
Urine Sample time(BU)	0955
Time of Blood Sample Collection	11:22
Time of Urine Sample Collection	09:55
Test Name	BASOPHILS (ABS)
Result	25
Text Result	
Unit	/UL
Lower limit	
Upper limit	
Flag	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Lab-BU (19)

Data signed: (Heart1) 29 Oct 2014 09:21:23

Generated On: 18 Jul 2016 22:07:14

Clinically Significant? _____

Comment _____

Result Category

N

Text Result Code _____

Reference Value Category _____

Timepoint(COHB) _____

Material Code

BLOOD

Chyle Comment Code _____

Chyle Comment English _____

Hemolysis Comment Code _____

Hemolysis Comment English _____

Specimen Comment Code 1 _____

Specimen English Comment 1 _____

Specimen Comment Code 2 _____

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Lab-BU (19)

Data signed: (Heart1) 29 Oct 2014 09:21:23

Generated On: 18 Jul 2016 22:07:14

Specimen English Comment 2

Result Supplementary Comment Code 1

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004671920

Please document clinically relevant abnormalities in the AE form

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Lab-BU URINALYSIS(2014 JAN 07)

Data signed: (Heart1) 29 Oct 2014 09:21:32

Generated On: 18 Jul 2016 22:07:14

Test Category	URINALYSIS
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Date of Sample Collection	2014 JAN 07
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Date (BU)	2014/01/07
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ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Lab-BU URINALYSIS(2014 JAN 07)

Data signed: (Heart1) 29 Oct 2014 09:21:32

Generated On: 18 Jul 2016 22:07:14

Test Category	URINALYSIS
Date of Sample Collection	2014 JAN 07
Date (BU)	2014/01/07
Blood Sample time(BU)	1122
Urine Sample time(BU)	0955
Time of Blood Sample Collection	11:22
Time of Urine Sample Collection	09:55
Test Name	SPECIFIC GRAVITY
Result	1.027
Text Result	
Unit	
Lower limit	1.002
Upper limit	1.030
Flag	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Lab-BU URINALYSIS(2014 JAN 07)

Data signed: (Heart1) 29 Oct 2014 09:21:32

Generated On: 18 Jul 2016 22:07:14

Clinically Significant? _____

Comment _____

Result Category _____ N

Text Result Code _____

Reference Value Category _____ -

Timepoint(COHB) _____

Material Code _____ URINE

Chyle Comment Code _____

Chyle Comment English _____

Hemolysis Comment Code _____

Hemolysis Comment English _____

Specimen Comment Code 1 _____

Specimen English Comment 1 _____

Specimen Comment Code 2 _____

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Lab-BU URINALYSIS(2014 JAN 07)

Data signed: (Heart1) 29 Oct 2014 09:21:32

Generated On: 18 Jul 2016 22:07:14

Specimen English Comment 2

Result Supplementary Comment Code 1

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004671920

Please document clinically relevant abnormalities in the AE form

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Lab-BU (2)

Data signed: (Heart1) 29 Oct 2014 09:21:32

Generated On: 18 Jul 2016 22:07:14

Test Category	URINALYSIS
Date of Sample Collection	2014 JAN 07
Date (BU)	2014/01/07
Blood Sample time(BU)	1122
Urine Sample time(BU)	0955
Time of Blood Sample Collection	11:22
Time of Urine Sample Collection	09:55
Test Name	PH
Result	6.0
Text Result	
Unit	
Lower limit	5.0
Upper limit	8.0
Flag	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Lab-BU (2)

Data signed: (Heart1) 29 Oct 2014 09:21:32

Generated On: 18 Jul 2016 22:07:14

Clinically Significant? _____

Comment _____

Result Category

N

Text Result Code _____

Reference Value Category

-

Timepoint(COHB) _____

Material Code

URINE

Chyle Comment Code _____

Chyle Comment English

Hemolysis Comment Code _____

Hemolysis Comment English

Specimen Comment Code 1 _____

Specimen English Comment 1

Specimen Comment Code 2 _____

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Lab-BU (2)

Data signed: (Heart1) 29 Oct 2014 09:21:32

Generated On: 18 Jul 2016 22:07:14

Specimen English Comment 2

Result Supplementary Comment Code 1

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004671920

Please document clinically relevant abnormalities in the AE form

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Lab-BU (3)

Data signed: (Heart1) 29 Oct 2014 09:21:32

Generated On: 18 Jul 2016 22:07:14

Test Category	URINALYSIS
Date of Sample Collection	2014 JAN 07
Date (BU)	2014/01/07
Blood Sample time(BU)	1122
Urine Sample time(BU)	0955
Time of Blood Sample Collection	11:22
Time of Urine Sample Collection	09:55
Test Name	GLUCOSE
Result	
Text Result	-
Unit	
Lower limit	
Upper limit	-
Flag	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Lab-BU (3)

Data signed: (Heart1) 29 Oct 2014 09:21:32

Generated On: 18 Jul 2016 22:07:14

Clinically Significant?	_____
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Comment	_____
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Result Category	S
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Text Result Code	168
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Reference Value Category	S
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Timepoint(COHB)	_____
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Material Code	URINE
---------------	-------

Chyle Comment Code	_____
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Chyle Comment English	_____
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Hemolysis Comment Code	_____
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Hemolysis Comment English	_____
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Specimen Comment Code 1	_____
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Specimen English Comment 1	_____
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Specimen Comment Code 2	_____
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ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Lab-BU (3)

Data signed: (Heart1) 29 Oct 2014 09:21:32

Generated On: 18 Jul 2016 22:07:14

Specimen English Comment 2

Result Supplementary Comment Code 1

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004671920

Please document clinically relevant abnormalities in the AE form

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Lab-BU (4)

Data signed: (Heart1) 29 Oct 2014 09:21:32

Generated On: 18 Jul 2016 22:07:14

Test Category	URINALYSIS
Date of Sample Collection	2014 JAN 07
Date (BU)	2014/01/07
Blood Sample time(BU)	1122
Urine Sample time(BU)	0955
Time of Blood Sample Collection	11:22
Time of Urine Sample Collection	09:55
Test Name	PROTEIN
Result	
Text Result	-
Unit	
Lower limit	
Upper limit	-
Flag	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Lab-BU (4)

Data signed: (Heart1) 29 Oct 2014 09:21:32

Generated On: 18 Jul 2016 22:07:14

Clinically Significant?	_____
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Comment	_____
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Result Category	S
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Text Result Code	168
------------------	-----

Reference Value Category	S
--------------------------	---

Timepoint(COHB)	_____
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Material Code	URINE
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Chyle Comment Code	_____
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Chyle Comment English	_____
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Hemolysis Comment Code	_____
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Hemolysis Comment English	_____
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Specimen Comment Code 1	_____
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Specimen English Comment 1	_____
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Specimen Comment Code 2	_____
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ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Lab-BU (4)

Data signed: (Heart1) 29 Oct 2014 09:21:32

Generated On: 18 Jul 2016 22:07:14

Specimen English Comment 2

Result Supplementary Comment Code 1

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004671920

Please document clinically relevant abnormalities in the AE form

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Lab-BU (5)

Data signed: (Heart1) 29 Oct 2014 09:21:32

Generated On: 18 Jul 2016 22:07:14

Test Category	URINALYSIS
Date of Sample Collection	2014 JAN 07
Date (BU)	2014/01/07
Blood Sample time(BU)	1122
Urine Sample time(BU)	0955
Time of Blood Sample Collection	11:22
Time of Urine Sample Collection	09:55
Test Name	BILIRUBIN
Result	
Text Result	-
Unit	
Lower limit	
Upper limit	-
Flag	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Lab-BU (5)

Data signed: (Heart1) 29 Oct 2014 09:21:32

Generated On: 18 Jul 2016 22:07:14

Clinically Significant?	_____
-------------------------	-------

Comment	_____
---------	-------

Result Category	S
-----------------	---

Text Result Code	168
------------------	-----

Reference Value Category	S
--------------------------	---

Timepoint(COHB)	_____
-----------------	-------

Material Code	URINE
---------------	-------

Chyle Comment Code	_____
--------------------	-------

Chyle Comment English	_____
-----------------------	-------

Hemolysis Comment Code	_____
------------------------	-------

Hemolysis Comment English	_____
---------------------------	-------

Specimen Comment Code 1	_____
-------------------------	-------

Specimen English Comment 1	_____
----------------------------	-------

Specimen Comment Code 2	_____
-------------------------	-------

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Lab-BU (5)

Data signed: (Heart1) 29 Oct 2014 09:21:32

Generated On: 18 Jul 2016 22:07:14

Specimen English Comment 2

Result Supplementary Comment Code 1

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004671920

Please document clinically relevant abnormalities in the AE form

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Lab-BU (6)

Data signed: (Heart1) 29 Oct 2014 09:21:32

Generated On: 18 Jul 2016 22:07:14

Test Category	URINALYSIS
Date of Sample Collection	2014 JAN 07
Date (BU)	2014/01/07
Blood Sample time(BU)	1122
Urine Sample time(BU)	0955
Time of Blood Sample Collection	11:22
Time of Urine Sample Collection	09:55
Test Name	NITRITE
Result	
Text Result	-
Unit	
Lower limit	
Upper limit	-
Flag	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Lab-BU (6)

Data signed: (Heart1) 29 Oct 2014 09:21:32

Generated On: 18 Jul 2016 22:07:14

Clinically Significant?	_____
-------------------------	-------

Comment	_____
---------	-------

Result Category	S
-----------------	---

Text Result Code	168
------------------	-----

Reference Value Category	S
--------------------------	---

Timepoint(COHB)	_____
-----------------	-------

Material Code	URINE
---------------	-------

Chyle Comment Code	_____
--------------------	-------

Chyle Comment English	_____
-----------------------	-------

Hemolysis Comment Code	_____
------------------------	-------

Hemolysis Comment English	_____
---------------------------	-------

Specimen Comment Code 1	_____
-------------------------	-------

Specimen English Comment 1	_____
----------------------------	-------

Specimen Comment Code 2	_____
-------------------------	-------

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Lab-BU (6)

Data signed: (Heart1) 29 Oct 2014 09:21:32

Generated On: 18 Jul 2016 22:07:14

Specimen English Comment 2

Result Supplementary Comment Code 1

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004671920

Please document clinically relevant abnormalities in the AE form

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Lab-BU (7)

Data signed: (Heart1) 29 Oct 2014 09:21:32

Generated On: 18 Jul 2016 22:07:14

Test Category	URINALYSIS
Date of Sample Collection	2014 JAN 07
Date (BU)	2014/01/07
Blood Sample time(BU)	1122
Urine Sample time(BU)	0955
Time of Blood Sample Collection	11:22
Time of Urine Sample Collection	09:55
Test Name	OCCULT BLOOD
Result	
Text Result	-
Unit	
Lower limit	
Upper limit	-
Flag	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Lab-BU (7)

Data signed: (Heart1) 29 Oct 2014 09:21:32

Generated On: 18 Jul 2016 22:07:14

Clinically Significant? _____

Comment _____

Result Category S

Text Result Code 168

Reference Value Category S

Timepoint(COHB) _____

Material Code URINE

Chyle Comment Code _____

Chyle Comment English _____

Hemolysis Comment Code _____

Hemolysis Comment English _____

Specimen Comment Code 1 _____

Specimen English Comment 1 _____

Specimen Comment Code 2 _____

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Screening

Form: Lab-BU (7)

Data signed: (Heart1) 29 Oct 2014 09:21:32

Generated On: 18 Jul 2016 22:07:14

Specimen English Comment 2

Result Supplementary Comment Code 1

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004671920

Please document clinically relevant abnormalities in the AE form

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Admission (Day -2)

Form: Date of Visit

Data signed: (Heart1) 29 Oct 2014 09:21:36

Generated On: 18 Jul 2016 22:07:14

Date of Visit

22 JAN 2014
DD/MMM/YYYY

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Admission (Day -2)

Form: Inclusion Criteria

Data signed: (Heart1) 29 Oct 2014 09:21:36

Generated On: 18 Jul 2016 22:07:14

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

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Admission (Day -2)

Form: Inclusion Criteria (1)

Data signed: (Heart1) 29 Oct 2014 09:21:36

Generated On: 18 Jul 2016 22:07:14

Inclusion Criterion Number	4
Inclusion Criterion	Smoking, healthy subject as judged by the Investigator based on all available assessments from the Screening period/day of Admission (e.g. safety laboratory, spirometry[FEV1/FVC >0.7 at post-bronchodilator spirometry, post-bronchodilator FEV1 >80% predicted value, and post-bronchodilator FVC >80% predicted value], 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-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Admission (Day -2)

Form: Inclusion Criteria (2)

Data signed: (Heart1) 29 Oct 2014 09:21:36

Generated On: 18 Jul 2016 22:07:14

Inclusion Criterion Number	5
----------------------------	---

Inclusion Criterion	Subject smokes at least 10 commercially available menthol mCCs per day (no brand restrictions) with a maximum yield of 1 mg nicotine ISO/mCC, as labelled on the cigarette package, for the last 4 weeks, based on self-reporting. Furthermore, the subject has been smoking for at least the last three 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-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Admission (Day -2)

Form: Inclusion Criteria (3)

Data signed: (Heart1) 29 Oct 2014 09:21:36

Generated On: 18 Jul 2016 22:07:14

Inclusion Criterion Number	7
----------------------------	---

Inclusion Criterion	The subject is ready to accept interruptions of smoking for up to 90 days.
---------------------	--

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

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

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Admission (Day -2)

Form: Inclusion Criteria (4)

Data signed: (Heart1) 29 Oct 2014 09:21:36

Generated On: 18 Jul 2016 22:07:14

Inclusion Criterion Number	8
----------------------------	---

Inclusion Criterion	The subject is ready to accept using the THS 2.2 Menthol.
---------------------	---

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

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

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Admission (Day -2)

Form: Exclusion Criteria

Data signed: (Heart1) 29 Oct 2014 09:21:36

Generated On: 18 Jul 2016 22:07:14

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

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Admission (Day -2)

Form: Exclusion Criteria (1)

Data signed: (Heart1) 29 Oct 2014 09:21:36

Generated On: 18 Jul 2016 22:07:14

Exclusion Criterion Number	1
----------------------------	---

Exclusion Criterion	As per Investigator judgment, the subject cannot participate in the study for any reason (e.g. medical, psychiatric and/or social reason).	<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-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Admission (Day -2)

Form: Exclusion Criteria (2)

Data signed: (Heart1) 29 Oct 2014 09:21:36

Generated On: 18 Jul 2016 22:07:14

Exclusion Criterion Number

3

Exclusion Criterion

The subject has medical condition requiring smoking cessation, or clinically relevant diseases (including but not limited to gastrointestinal, renal, hepatic, neurological, hematological, endocrine, oncological, urological, immunological, pulmonary and cardiovascular disease or any other medical condition [including but not limited to clinically relevant abnormal laboratory parameters]) in the judgment of the Investigator.

Result

No

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

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Admission (Day -2)

Form: Exclusion Criteria (3)

Data signed: (Heart1) 29 Oct 2014 09:21:36

Generated On: 18 Jul 2016 22:07:14

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

Exclusion Criterion	The subject has a body mass index (BMI) <18.5 or ≥ 32 kg/m ² . <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-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Admission (Day -2)

Form: Exclusion Criteria (4)

Data signed: (Heart1) 29 Oct 2014 09:21:36

Generated On: 18 Jul 2016 22:07:14

Exclusion Criterion Number	5
----------------------------	---

Exclusion Criterion	As per Investigator or designee 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-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Admission (Day -2)

Form: Exclusion Criteria (5)

Data signed: (Heart1) 29 Oct 2014 09:21:36

Generated On: 18 Jul 2016 22:07:14

Exclusion Criterion Number	6
----------------------------	---

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

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

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

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Admission (Day -2)

Form: Exclusion Criteria (6)

Data signed: (Heart1) 29 Oct 2014 09:21:36

Generated On: 18 Jul 2016 22:07:14

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

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

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

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Admission (Day -2)

Form: Exclusion Criteria (7)

Data signed: (Heart1) 29 Oct 2014 09:21:36

Generated On: 18 Jul 2016 22:07:14

Exclusion Criterion Number	8
----------------------------	---

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

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

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

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Admission (Day -2)

Form: Exclusion Criteria (8)

Data signed: (Heart1) 29 Oct 2014 09:21:36

Generated On: 18 Jul 2016 22:07:14

Exclusion Criterion Number	9
----------------------------	---

Exclusion Criterion	Concomitant use of NSAIDs <input checked="" type="radio"/> 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-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Admission (Day -2)

Form: Exclusion Criteria (9)

Data signed: (Heart1) 29 Oct 2014 09:21:36

Generated On: 18 Jul 2016 22:07:14

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

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-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Admission (Day -2)

Form: Exclusion Criteria (10)

Data signed: (Heart1) 29 Oct 2014 09:21:36

Generated On: 18 Jul 2016 22:07:14

Exclusion Criterion Number	11
----------------------------	----

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-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Admission (Day -2)

Form: Exclusion Criteria (11)

Data signed: (Heart1) 29 Oct 2014 09:21:36

Generated On: 18 Jul 2016 22:07:14

Exclusion Criterion Number	13
----------------------------	----

Exclusion Criterion	Donation or receipt of whole blood or blood products within 3 months prior to Admission.
---------------------	--

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

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

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Admission (Day -2)

Form: Exclusion Criteria (12)

Data signed: (Heart1) 29 Oct 2014 09:21:36

Generated On: 18 Jul 2016 22:07:14

Exclusion Criterion Number	18
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-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Admission (Day -2)

Form: Exclusion Criteria (13)

Data signed: (Heart1) 29 Oct 2014 09:21:36

Generated On: 18 Jul 2016 22:07:14

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

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-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Admission (Day -2)

Form: Vital Signs

Data signed: (Heart1) 29 Oct 2014 09:21:37

Generated On: 18 Jul 2016 22:07:14

Were Vitals Signs assessed?

Yes ☒

If No, please specify the reason: _____

Has the subject smoked within 15 minutes prior to
assessment

No ☒

Time of assessment

15:46
hour:min 24-hour clock

Pulse rate

54
beats per minute

Respiratory rate

16
breaths per minute

Blood Pressure (systolic)

108
mmHg

Blood Pressure (diastolic)

64
mmHg

Vital Signs Position of Subject

Supine ☒

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Admission (Day -2)

Form: Product preference

Data signed: (Heart1) 29 Oct 2014 09:21:37

Generated On: 18 Jul 2016 22:07:14

Which product would you prefer to be randomized to:

mCC ☐

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Admission (Day -2)

Form: Advice on the risk of smoking and debriefing

Data signed: (Heart1) 29 Oct 2014 09:21:37

Generated On: 18 Jul 2016 22:07:14

Has the subject received advices on the risks of smoking?

Yes ☐

Has a debriefing been performed about THS 2.2?

Yes ☐

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Admission (Day -2)

Form: Physical Examination

Data signed: (Heart1) 29 Oct 2014 09:21:38

Generated On: 18 Jul 2016 22:07:14

Was the physical examination performed?

Yes ☒

If No, please specify the reason:

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Admission (Day -2)

Form: Physical Examination (1)

Data signed: (Heart1) 29 Oct 2014 09:21:38

Generated On: 18 Jul 2016 22:07:14

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

System

General Appearance ☒

Outcome

Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done

False

Not Done; please specify the reason: _____

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Admission (Day -2)

Form: Physical Examination (2)

Data signed: (Heart1) 29 Oct 2014 09:21:38

Generated On: 18 Jul 2016 22:07:14

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

System

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

Outcome

Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done

False

Not Done; please specify the reason: _____

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Admission (Day -2)

Form: Physical Examination (3)

Data signed: (Heart1) 29 Oct 2014 09:21:38

Generated On: 18 Jul 2016 22:07:14

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

System

Thyroid Gland ☒

Outcome

Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done

False

Not Done; please specify the reason: _____

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Admission (Day -2)

Form: Physical Examination (4)

Data signed: (Heart1) 29 Oct 2014 09:21:38

Generated On: 18 Jul 2016 22:07:14

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

System

Heart ☒

Outcome

Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done

False

Not Done; please specify the reason: _____

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Admission (Day -2)

Form: Physical Examination (5)

Data signed: (Heart1) 29 Oct 2014 09:21:38

Generated On: 18 Jul 2016 22:07:14

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

System

Chest ☒

Outcome

Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done

False

Not Done; please specify the reason: _____

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Admission (Day -2)

Form: Physical Examination (6)

Data signed: (Heart1) 29 Oct 2014 09:21:38

Generated On: 18 Jul 2016 22:07:14

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

System

Lungs ☒

Outcome

Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done

False

Not Done; please specify the reason: _____

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Admission (Day -2)

Form: Physical Examination (7)

Data signed: (Heart1) 29 Oct 2014 09:21:38

Generated On: 18 Jul 2016 22:07:14

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

System

Gastrointestinal ☒

Outcome

Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done

False

Not Done; please specify the reason: _____

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Admission (Day -2)

Form: Physical Examination (8)

Data signed: (Heart1) 29 Oct 2014 09:21:38

Generated On: 18 Jul 2016 22:07:14

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

System

Cardiovascular System ☒

Outcome

Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done

False

Not Done; please specify the reason: _____

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Admission (Day -2)

Form: Physical Examination (9)

Data signed: (Heart1) 29 Oct 2014 09:21:38

Generated On: 18 Jul 2016 22:07:14

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

System

Neurologic ☒

Outcome

Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done

False

Not Done; please specify the reason: _____

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Admission (Day -2)

Form: Physical Examination (10)

Data signed: (Heart1) 29 Oct 2014 09:21:38

Generated On: 18 Jul 2016 22:07:14

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

System

Skin ☒

Outcome

Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done

False

Not Done; please specify the reason: _____

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Admission (Day -2)

Form: Physical Examination (11)

Data signed: (Heart1) 29 Oct 2014 09:21:38

Generated On: 18 Jul 2016 22:07:14

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

System

Back ☒

Outcome

Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done

False

Not Done; please specify the reason: _____

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Admission (Day -2)

Form: Physical Examination (12)

Data signed: (Heart1) 29 Oct 2014 09:21:38

Generated On: 18 Jul 2016 22:07:14

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

System

Musculoskeletal ☒

Outcome

Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done

False

Not Done; please specify the reason: _____

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Admission (Day -2)

Form: Physical Examination (13)

Data signed: (Heart1) 29 Oct 2014 09:21:38

Generated On: 18 Jul 2016 22:07:14

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

System

Abdomen ☒

Outcome

Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done

False

Not Done; please specify the reason: _____

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Admission (Day -2)

Form: Physical Examination (14)

Data signed: (Heart1) 29 Oct 2014 09:21:38

Generated On: 18 Jul 2016 22:07:14

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

System

Dentition ☒

Outcome

Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done

False

Not Done; please specify the reason: _____

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Admission (Day -2)

Form: Physical Examination (15)

Data signed: (Heart1) 29 Oct 2014 09:21:38

Generated On: 18 Jul 2016 22:07:14

Was the physical examination performed?

Yes ☒

If No, please specify the reason:

System

Other ☒

Other, Specify

Outcome

Abnormal, please specify

Clinically significant

Not Done

True

Not Done; please specify the reason:

THERE IS NO SPECIFIC.

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Admission (Day -2)

Form: Physical Examination (16)

Data signed: (Heart1) 29 Oct 2014 09:21:38

Generated On: 18 Jul 2016 22:07:14

Was the physical examination performed?

Yes ☒

If No, please specify the reason:

System

Other ☒

Other, Specify

Outcome

Abnormal, please specify

Clinically significant

Not Done

True

Not Done; please specify the reason:

THERE IS NO SPECIFIC.

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Admission (Day -2)

Form: Physical Examination (17)

Data signed: (Heart1) 29 Oct 2014 09:21:38

Generated On: 18 Jul 2016 22:07:14

Was the physical examination performed?

Yes ☒

If No, please specify the reason:

System

Other ☒

Other, Specify

Outcome

Abnormal, please specify

Clinically significant

Not Done

True

Not Done; please specify the reason:

THERE IS NO SPECIFIC.

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Admission (Day -2)

Form: Physical Examination (18)

Data signed: (Heart1) 29 Oct 2014 09:21:38

Generated On: 18 Jul 2016 22:07:14

Was the physical examination performed?

Yes ☒

If No, please specify the reason:

System

Other ☒

Other, Specify

Outcome

Abnormal, please specify

Clinically significant

Not Done

True

Not Done; please specify the reason:

THERE IS NO SPECIFIC.

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Admission (Day -2)

Form: Physical Examination (19)

Data signed: (Heart1) 29 Oct 2014 09:21:38

Generated On: 18 Jul 2016 22:07:14

Was the physical examination performed?

Yes ☒

If No, please specify the reason:

System

Other ☒

Other, Specify

Outcome

Abnormal, please specify

Clinically significant

Not Done

True

Not Done; please specify the reason:

THERE IS NO SPECIFIC.

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Admission (Day -2)

Form: Identification of Current Cigarette Brand

Data signed: (Heart1) 29 Oct 2014 09:21:42

Generated On: 18 Jul 2016 22:07:14

Brand name	MARLBORO ICE BLAST 1
------------	----------------------

ISO Tar Yield	1 MG
---------------	---------

ISO Nicotine Yield	0.1 MG
--------------------	-----------

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Admission (Day -2)

Form: THS 2.2 menthol product test

Data signed: (Heart1) 29 Oct 2014 09:21:42

Generated On: 18 Jul 2016 22:07:14

Was the THS 2.2 menthol product trial performed?

Yes ☒

If the THS 2.2 menthol product trial was not performed,
please explain _____

How many THS 2.2 menthol tobacco sticks did the
subject use on this day?

1

Is the subject willing and able to use the product during
the study?

Yes ☒

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Admission (Day -2)

Form: Smoking History

Data signed: (Heart1) 29 Oct 2014 09:21:42

Generated On: 18 Jul 2016 22:07:14

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

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

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

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

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Admission (Day -2)

Form: Weight

Data signed: (Heart1) 29 Oct 2014 09:21:42

Generated On: 18 Jul 2016 22:07:14

Measurement(s) assessed?

Yes ☒

If No, please specify the reason: _____

Date of Assessment

22 JAN 2014
DD/MMM/YYYY

Time of assessment

16:10
hour:min 24-hour clock

Weight

84.4
kg

Waist circumference

99
cm

BMI

28.9

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Admission (Day -2)

Form: Urine Drug Screen

Data signed: (Heart1) 29 Oct 2014 09:21:43

Generated On: 18 Jul 2016 22:07:14

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

If Not Done, please specify the reason: _____

Time of sample collection	16:06
	hour:min 24-hour clock

Drug type	Result
-----------	--------

Amphetamines	Negative
--------------	----------

Barbiturates	Negative
--------------	----------

Benzodiazepines	Negative
-----------------	----------

Cannabinoids	Negative
--------------	----------

Cocaine	Negative
---------	----------

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Admission (Day -2)

Form: Urine Drug Screen (6)

Data signed: (Heart1) 29 Oct 2014 09:21:43

Generated On: 18 Jul 2016 22:07:14

Drug type	Result
Opiates	Negative

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Admission (Day -2)

Form: Alcohol Breath Test

Data signed: (Heart1) 29 Oct 2014 09:21:43

Generated On: 18 Jul 2016 22:07:14

Was the alcohol breath test performed?

Yes ☒

If No, please specify the reason: _____

Time of assessment

15:36
hour:min 24-hour clock

Result

Negative ☒

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Admission (Day -2)

Form: Urine Cotinine Test

Data signed: (Heart1) 29 Oct 2014 09:21:43

Generated On: 18 Jul 2016 22:07:14

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

If Not Done, please specify the reason: _____

Time of Sample Collection	16:06
	hour:min 24-hour clock

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

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Admission (Day -2)

Form: CO Breath Test

Data signed: (Heart1) 29 Oct 2014 09:21:43

Generated On: 18 Jul 2016 22:07:14

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

If Not Done, please specify the reason: _____

Actual Time of Assessment	15:37
	hour:min 24-hour clock

Result	4
	ppm

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day -1)

Form: Date of Visit

Data signed: (Heart1) 29 Oct 2014 09:21:43

Generated On: 18 Jul 2016 22:07:14

Date of Visit

23 JAN 2014
DD/MMM/YYYY

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day -1)

Form: Vital Signs

Data signed: (Heart1) 29 Oct 2014 09:21:43

Generated On: 18 Jul 2016 22:07:14

Were Vitals Signs assessed?

Yes ☒

If No, please specify the reason: _____

Has the subject smoked within 15 minutes prior to assessment

No ☒

Time of assessment

10:09
hour:min 24-hour clock

Pulse rate

60
beats per minute

Respiratory rate

17
breaths per minute

Blood Pressure (systolic)

101
mmHg

Blood Pressure (diastolic)

53
mmHg

Vital Signs Position of Subject

Supine ☒

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day -1)

Form: CoHb Blood Sample

Data signed: (Heart1) 29 Oct 2014 09:21:43

Generated On: 18 Jul 2016 22:07:14

Not Done

False

If Not Done, please specify the reason:

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day -1)

Form: CO Breath Test (1)

Data signed: (Heart1) 29 Oct 2014 09:21:43

Generated On: 18 Jul 2016 22:07:14

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

If Not Done, please specify the reason: _____

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

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

Result(ppm)	5
-------------	---

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day -1)

Form: CO Breath Test (2)

Data signed: (Heart1) 29 Oct 2014 09:21:43

Generated On: 18 Jul 2016 22:07:14

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

If Not Done, please specify the reason: _____

Scheduled Time	12:00 - 13:30 <input checked="" type="radio"/>
----------------	--

Actual Time of Assessment hour:min 24-hour clock	12:03
---	-------

Result(ppm)	1
-------------	---

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day -1)

Form: CO Breath Test (3)

Data signed: (Heart1) 29 Oct 2014 09:21:43

Generated On: 18 Jul 2016 22:07:14

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

If Not Done, please specify the reason: _____

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

Actual Time of Assessment hour:min 24-hour clock	16:03
---	-------

Result(ppm)	6
-------------	---

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day -1)

Form: CO Breath Test (4)

Data signed: (Heart1) 29 Oct 2014 09:21:43

Generated On: 18 Jul 2016 22:07:14

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

If Not Done, please specify the reason: _____

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

Actual Time of Assessment hour:min 24-hour clock	20:04
---	-------

Result(ppm)	3
-------------	---

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day -1)

Form: 24 hour urine collections

Data signed: (Heart1) 29 Oct 2014 09:21:44

Generated On: 18 Jul 2016 22:07:14

Start Time	06:30
	hour:min 24-hour clock

End Date	24 JAN 2014
	DD/MMM/YYYY

End Time	06:29
	hour:min 24-hour clock

Volume	702
--------	-----

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day -1)

Form: Sample Urine Collection

Data signed: (Heart1) 29 Oct 2014 09:21:44

Generated On: 18 Jul 2016 22:07:14

Were samples 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-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day -1)

Form: Questionnaire on smoking urges (QSU)

Generated On: 18 Jul 2016 22:07:14

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

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

Date of assessment	2014 JAN 23
--------------------	-------------

DD/MMM/YYYY

Time of assessment	20:01
--------------------	-------

hour:min 24-hour clock

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

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

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

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

6. I have an urge for a cigarette	Somewhat disagree <input type="radio"/>
-----------------------------------	---

7. A cigarette would taste good now	Somewhat disagree <input type="radio"/>
-------------------------------------	---

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day -1)

Form: Questionnaire on smoking urges (QSU)

Generated On: 18 Jul 2016 22:07:14

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

9. Smoking would make me less depressed Do not agree or disagree ☐

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

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day -1)

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)

Generated On: 18 Jul 2016 22:07:14

Date of Birth

(b) (6)

Date of assessment=
DD/MMM/YYYY

2014 JAN 23
DD/MMM/YYYY

Time of assessment

20:04
hour:min 24-hour clock

Assessment Status

Completed ☒

1. Was smoking satisfying?

Moderately ☒

2. Did cigarettes taste good?

Quite a lot ☒

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

A lot ☒

4. Did smoking calm you down?

A lot ☒

5. Did smoking make you feel more awake?

Little ☒

6. Did smoking make you feel less irritable?

Little ☒

7. Did smoking help you concentrate?

Little ☒

8. Did smoking reduce your hunger for food?

Quite a lot ☒

9. Did smoking make you dizzy?

Not at all ☒

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230
Folder: Baseline (Day -1)
Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)
Generated On: 18 Jul 2016 22:07:14

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? Moderately ☐

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day -1)

Form: Biomarker(Urine)

Data signed: (Heart1) 04 Nov 2014 08:52:38

Generated On: 18 Jul 2016 22:07:14

Sample type

URINE

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day -1)

Form: Biomarker(Urine) (23)

Data signed: (Heart1) 04 Nov 2014 08:52:38

Generated On: 18 Jul 2016 22:07:14

Sample type	URINE
Sample Barcode	05112190003261
Analyte	3-HPMA
Result	429
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	-1
Celerion Study Number	AA99127-03
Date of Collection	2014-JAN-23
Timepoint-minutes	
Urine Start Day	-1

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day -1)

Form: Biomarker(Urine) (23)

Data signed: (Heart1) 04 Nov 2014 08:52:38

Generated On: 18 Jul 2016 22:07:14

Urine End Day	0
---------------	---

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day -1)

Form: Biomarker(Urine) (24)

Data signed: (Heart1) 04 Nov 2014 08:52:38

Generated On: 18 Jul 2016 22:07:14

Sample type	URINE
Sample Barcode	05112190003261
Analyte	CEMA
Result	52.5
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	-1
Celerion Study Number	AA99127-03
Date of Collection	2014-JAN-23
Timepoint-minutes	
Urine Start Day	-1

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day -1)

Form: Biomarker(Urine) (24)

Data signed: (Heart1) 04 Nov 2014 08:52:38

Generated On: 18 Jul 2016 22:07:14

Urine End Day	0
---------------	---

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day -1)

Form: Biomarker(Urine) (25)

Data signed: (Heart1) 04 Nov 2014 08:52:38

Generated On: 18 Jul 2016 22:07:14

Sample type	URINE
Sample Barcode	05112190003261
Analyte	HBMA
Result	194
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	-1
Celerion Study Number	AA99127-03
Date of Collection	2014-JAN-23
Timepoint-minutes	
Urine Start Day	-1

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day -1)

Form: Biomarker(Urine) (25)

Data signed: (Heart1) 04 Nov 2014 08:52:38

Generated On: 18 Jul 2016 22:07:14

Urine End Day	0
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ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day -1)

Form: Biomarker(Urine) (26)

Data signed: (Heart1) 04 Nov 2014 08:52:38

Generated On: 18 Jul 2016 22:07:14

Sample type	URINE
Sample Barcode	05112200003831
Analyte	NNAL
Result	99.7
Result Unit	PG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	-1
Celerion Study Number	AA99127-04
Date of Collection	2014-JAN-23
Timepoint-minutes	
Urine Start Day	-1

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day -1)

Form: Biomarker(Urine) (26)

Data signed: (Heart1) 04 Nov 2014 08:52:38

Generated On: 18 Jul 2016 22:07:14

Urine End Day	0
---------------	---

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day -1)

Form: Biomarker(Urine) (27)

Data signed: (Heart1) 04 Nov 2014 08:52:38

Generated On: 18 Jul 2016 22:07:14

Sample type	URINE
Sample Barcode	05112200003831
Analyte	NNN
Result	2.87
Result Unit	PG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	-1
Celerion Study Number	AA99127-04
Date of Collection	2014-JAN-23
Timepoint-minutes	
Urine Start Day	-1

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day -1)

Form: Biomarker(Urine) (27)

Data signed: (Heart1) 04 Nov 2014 08:52:38

Generated On: 18 Jul 2016 22:07:14

Urine End Day	0
---------------	---

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day -1)

Form: Biomarker(Urine) (28)

Data signed: (Heart1) 04 Nov 2014 08:52:38

Generated On: 18 Jul 2016 22:07:14

Sample type	URINE
Sample Barcode	05112210001911
Analyte	HEMA
Result	1.67
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	-1
Celerion Study Number	AA99127-05
Date of Collection	2014-JAN-23
Timepoint-minutes	
Urine Start Day	-1

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day -1)

Form: Biomarker(Urine) (28)

Data signed: (Heart1) 04 Nov 2014 08:52:38

Generated On: 18 Jul 2016 22:07:14

Urine End Day	0
---------------	---

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day -1)

Form: Biomarker(Urine) (29)

Data signed: (Heart1) 04 Nov 2014 08:52:38

Generated On: 18 Jul 2016 22:07:14

Sample type	URINE
Sample Barcode	05112220001271
Analyte	COT
Result	833
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	-1
Celerion Study Number	AA99127-06
Date of Collection	2014-JAN-23
Timepoint-minutes	
Urine Start Day	-1

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day -1)

Form: Biomarker(Urine) (29)

Data signed: (Heart1) 04 Nov 2014 08:52:38

Generated On: 18 Jul 2016 22:07:14

Urine End Day	0
---------------	---

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day -1)

Form: Biomarker(Urine) (30)

Data signed: (Heart1) 04 Nov 2014 08:52:38

Generated On: 18 Jul 2016 22:07:14

Sample type	URINE
Sample Barcode	05112220001271
Analyte	NIC
Result	495
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	-1
Celerion Study Number	AA99127-06
Date of Collection	2014-JAN-23
Timepoint-minutes	
Urine Start Day	-1

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day -1)

Form: Biomarker(Urine) (30)

Data signed: (Heart1) 04 Nov 2014 08:52:38

Generated On: 18 Jul 2016 22:07:14

Urine End Day	0
---------------	---

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day -1)

Form: Biomarker(Urine) (31)

Data signed: (Heart1) 04 Nov 2014 08:52:38

Generated On: 18 Jul 2016 22:07:14

Sample type	URINE
Sample Barcode	05112220001271
Analyte	NIC-GLUC
Result	725
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	-1
Celerion Study Number	AA99127-06
Date of Collection	2014-JAN-23
Timepoint-minutes	
Urine Start Day	-1

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day -1)

Form: Biomarker(Urine) (31)

Data signed: (Heart1) 04 Nov 2014 08:52:38

Generated On: 18 Jul 2016 22:07:14

Urine End Day	0
---------------	---

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day -1)

Form: Biomarker(Urine) (32)

Data signed: (Heart1) 04 Nov 2014 08:52:38

Generated On: 18 Jul 2016 22:07:14

Sample type	URINE
Sample Barcode	05112220001271
Analyte	THCOT
Result	1560
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	-1
Celerion Study Number	AA99127-06
Date of Collection	2014-JAN-23
Timepoint-minutes	
Urine Start Day	-1

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day -1)

Form: Biomarker(Urine) (32)

Data signed: (Heart1) 04 Nov 2014 08:52:38

Generated On: 18 Jul 2016 22:07:14

Urine End Day	0
---------------	---

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day -1)

Form: Biomarker(Urine) (33)

Data signed: (Heart1) 04 Nov 2014 08:52:38

Generated On: 18 Jul 2016 22:07:14

Sample type	URINE
Sample Barcode	05112220001271
Analyte	COT-GLUC
Result	5230
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	-1
Celerion Study Number	AA99127-06
Date of Collection	2014-JAN-23
Timepoint-minutes	
Urine Start Day	-1

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day -1)

Form: Biomarker(Urine) (33)

Data signed: (Heart1) 04 Nov 2014 08:52:38

Generated On: 18 Jul 2016 22:07:14

Urine End Day	0
---------------	---

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day -1)

Form: Biomarker(Urine) (34)

Data signed: (Heart1) 04 Nov 2014 08:52:38

Generated On: 18 Jul 2016 22:07:14

Sample type	URINE
Sample Barcode	05112220001271
Analyte	THCOT-GLUC
Result	610
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	-1
Celerion Study Number	AA99127-06
Date of Collection	2014-JAN-23
Timepoint-minutes	
Urine Start Day	-1

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day -1)

Form: Biomarker(Urine) (34)

Data signed: (Heart1) 04 Nov 2014 08:52:38

Generated On: 18 Jul 2016 22:07:14

Urine End Day	0
---------------	---

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day -1)

Form: Biomarker(Urine) (35)

Data signed: (Heart1) 04 Nov 2014 08:52:38

Generated On: 18 Jul 2016 22:07:14

Sample type	URINE
Sample Barcode	05112230001911
Analyte	3-OH BAP
Result	25.5
Result Unit	FG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	-1
Celerion Study Number	AA99127-07
Date of Collection	2014-JAN-23
Timepoint-minutes	
Urine Start Day	-1

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day -1)

Form: Biomarker(Urine) (35)

Data signed: (Heart1) 04 Nov 2014 08:52:38

Generated On: 18 Jul 2016 22:07:14

Urine End Day	0
---------------	---

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day -1)

Form: Biomarker(Urine) (36)

Data signed: (Heart1) 04 Nov 2014 08:52:38

Generated On: 18 Jul 2016 22:07:14

Sample type	URINE
Sample Barcode	05112250001911
Analyte	1-NA
Result	48.9
Result Unit	PG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	-1
Celerion Study Number	AA99127-09
Date of Collection	2014-JAN-23
Timepoint-minutes	
Urine Start Day	-1

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day -1)

Form: Biomarker(Urine) (36)

Data signed: (Heart1) 04 Nov 2014 08:52:38

Generated On: 18 Jul 2016 22:07:14

Urine End Day	0
---------------	---

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day -1)

Form: Biomarker(Urine) (37)

Data signed: (Heart1) 04 Nov 2014 08:52:38

Generated On: 18 Jul 2016 22:07:14

Sample type	URINE
Sample Barcode	05112250001911
Analyte	2-NA
Result	13.2
Result Unit	PG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	-1
Celerion Study Number	AA99127-09
Date of Collection	2014-JAN-23
Timepoint-minutes	
Urine Start Day	-1

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day -1)

Form: Biomarker(Urine) (37)

Data signed: (Heart1) 04 Nov 2014 08:52:38

Generated On: 18 Jul 2016 22:07:14

Urine End Day	0
---------------	---

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day -1)

Form: Biomarker(Urine) (38)

Data signed: (Heart1) 04 Nov 2014 08:52:38

Generated On: 18 Jul 2016 22:07:14

Sample type	URINE
Sample Barcode	05112250001911
Analyte	4-ABP
Result	10.0
Result Unit	PG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	-1
Celerion Study Number	AA99127-09
Date of Collection	2014-JAN-23
Timepoint-minutes	
Urine Start Day	-1

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day -1)

Form: Biomarker(Urine) (38)

Data signed: (Heart1) 04 Nov 2014 08:52:38

Generated On: 18 Jul 2016 22:07:14

Urine End Day	0
---------------	---

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day -1)

Form: Biomarker(Urine) (39)

Data signed: (Heart1) 04 Nov 2014 08:52:38

Generated On: 18 Jul 2016 22:07:14

Sample type	URINE
Sample Barcode	05112250001911
Analyte	O-TOL
Result	178
Result Unit	PG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	-1
Celerion Study Number	AA99127-09
Date of Collection	2014-JAN-23
Timepoint-minutes	
Urine Start Day	-1

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day -1)

Form: Biomarker(Urine) (39)

Data signed: (Heart1) 04 Nov 2014 08:52:38

Generated On: 18 Jul 2016 22:07:14

Urine End Day	0
---------------	---

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day -1)

Form: Biomarker(Urine) (40)

Data signed: (Heart1) 04 Nov 2014 08:52:38

Generated On: 18 Jul 2016 22:07:14

Sample type	URINE
Sample Barcode	05113640001911
Analyte	1-OHP
Result	112
Result Unit	PG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	-1
Celerion Study Number	AA99599-03
Date of Collection	2014-JAN-23
Timepoint-minutes	
Urine Start Day	-1

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day -1)

Form: Biomarker(Urine) (40)

Data signed: (Heart1) 04 Nov 2014 08:52:38

Generated On: 18 Jul 2016 22:07:14

Urine End Day	0
---------------	---

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day -1)

Form: Biomarker(Urine) (41)

Data signed: (Heart1) 04 Nov 2014 08:52:38

Generated On: 18 Jul 2016 22:07:14

Sample type	URINE
Sample Barcode	05113620001911
Analyte	SBMA
Result	2.13
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	-1
Celerion Study Number	AA99599-01
Date of Collection	2014-JAN-23
Timepoint-minutes	
Urine Start Day	-1

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day -1)

Form: Biomarker(Urine) (41)

Data signed: (Heart1) 04 Nov 2014 08:52:38

Generated On: 18 Jul 2016 22:07:14

Urine End Day	0
---------------	---

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day -1)

Form: Biomarker(Urine) (42)

Data signed: (Heart1) 04 Nov 2014 08:52:38

Generated On: 18 Jul 2016 22:07:14

Sample type	URINE
Sample Barcode	05113620001911
Analyte	SPMA
Result	1.09
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	-1
Celerion Study Number	AA99599-01
Date of Collection	2014-JAN-23
Timepoint-minutes	
Urine Start Day	-1

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day -1)

Form: Biomarker(Urine) (42)

Data signed: (Heart1) 04 Nov 2014 08:52:38

Generated On: 18 Jul 2016 22:07:14

Urine End Day	0
---------------	---

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day -1)

Form: Biomarker(Urine) (43)

Data signed: (Heart1) 04 Nov 2014 08:52:38

Generated On: 18 Jul 2016 22:07:14

Sample type	URINE
Sample Barcode	05113630001911
Analyte	MHBMA
Result	0.573
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	-1
Celerion Study Number	AA99599-02
Date of Collection	2014-JAN-23
Timepoint-minutes	
Urine Start Day	-1

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day -1)

Form: Biomarker(Urine) (43)

Data signed: (Heart1) 04 Nov 2014 08:52:38

Generated On: 18 Jul 2016 22:07:14

Urine End Day	0
---------------	---

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day -1)

Form: Biomarker(Urine) (44)

Data signed: (Heart1) 04 Nov 2014 08:52:38

Generated On: 18 Jul 2016 22:07:14

Sample type	URINE
Sample Barcode	05113730002151
Analyte	CREATININE
Result	218
Result Unit	MG/DL
Lab Status	OK
Sample comment	
Detection method	SPECTROPHOTOMETRIC
Planned time point (Hour)	
Day of Visit	-1
Celerion Study Number	AA99127-14
Date of Collection	2014-JAN-23
Timepoint-minutes	
Urine Start Day	-1

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day -1)

Form: Biomarker(Urine) (44)

Data signed: (Heart1) 04 Nov 2014 08:52:38

Generated On: 18 Jul 2016 22:07:14

Urine End Day	0
---------------	---

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day -1)

Form: Lab-BU BIOMARKER(2014 JAN 23)

Data signed: (Heart1) 29 Oct 2014 09:21:44

Generated On: 18 Jul 2016 22:07:14

Test Category	BIOMARKER
---------------	-----------

Date of Sample Collection	2014 JAN 23
---------------------------	-------------

Date (BU)	2014/01/23
-----------	------------

Please document clinically relevant abnormalities in the AE form	
--	--

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day -1)

Form: Lab-BU BIOMARKER(2014 JAN 23)

Data signed: (Heart1) 29 Oct 2014 09:21:44

Generated On: 18 Jul 2016 22:07:14

Test Category	BIOMARKER
Date of Sample Collection	2014 JAN 23
Date (BU)	2014/01/23
Blood Sample time(BU)	2006
Urine Sample time(BU)	
Time of Blood Sample Collection	20:06
Time of Urine Sample Collection	
Test Name	COHB
Result	4.2
Text Result	
Unit	%
Lower limit	
Upper limit	
Flag	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day -1)

Form: Lab-BU BIOMARKER(2014 JAN 23)

Data signed: (Heart1) 29 Oct 2014 09:21:44

Generated On: 18 Jul 2016 22:07:14

Clinically Significant? _____

Comment _____

Result Category

N

Text Result Code _____

Reference Value Category _____

Timepoint(COHB)

20:00-21:30

Material Code

BLOOD

Chyle Comment Code _____

Chyle Comment English _____

Hemolysis Comment Code _____

Hemolysis Comment English _____

Specimen Comment Code 1 _____

Specimen English Comment 1 _____

Specimen Comment Code 2 _____

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day -1)

Form: Lab-BU BIOMARKER(2014 JAN 23)

Data signed: (Heart1) 29 Oct 2014 09:21:44

Generated On: 18 Jul 2016 22:07:14

Specimen English Comment 2

Result Supplementary Comment Code 1

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004672008

Please document clinically relevant abnormalities in the AE form

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Date of Visit

Data signed: (Heart1) 29 Oct 2014 09:21:46

Generated On: 18 Jul 2016 22:07:14

Date of Visit

24 JAN 2014
DD/MMM/YYYY

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Randomization

Data signed: (Heart1) 29 Oct 2014 09:21:46

Generated On: 18 Jul 2016 22:07:14

Randomization number (4 digits)	1054
---------------------------------	------

Allocation Arm	THS 2.2 menthol <input checked="" type="radio"/>
----------------	--

Cigarette Consumption	10 – 19 conventional menthol cigarettesper day <input checked="" type="radio"/>
-----------------------	--

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Vital Signs

Data signed: (Heart1) 29 Oct 2014 09:21:47

Generated On: 18 Jul 2016 22:07:14

Were Vitals Signs assessed?

Yes ☒

If No, please specify the reason: _____

Has the subject smoked within 15 minutes prior to assessment

No ☐

Time of assessment

10:22
hour:min 24-hour clock

Pulse rate

54
beats per minute

Respiratory rate

19
breaths per minute

Blood Pressure (systolic)

98
mmHg

Blood Pressure (diastolic)

55
mmHg

Vital Signs Position of Subject

Supine ☒

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Spirometry without a short-acting bronchodilator

Data signed: (Heart1) 29 Oct 2014 09:21:47

Generated On: 18 Jul 2016 22:07:14

Was the spirometry performed? Yes ☒

If No, please specify the reason: _____

Category Without short-acting bronchodilator ☒

Time of assessment 06:28
hour:min 24-hour clock

Predicted FVC value 4.65
L

Best measured FVC value 4.67
L

Percent of predicted FVC value 100.4
%

Best measured FEV1 value 3.66
L

Predicted FEV1 value 4.11
L

Percent of predicted FEV1 value 89.0
%

Interpretation Normal ☒

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Spirometry without a short-acting bronchodilator

Data signed: (Heart1) 29 Oct 2014 09:21:47

Generated On: 18 Jul 2016 22:07:14

If Abnormal, Clinical Significance _____

If Not Clinically Significant or Clinically Significant, Please
specify the finding(s) _____

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Haematology

Data signed: (Heart1) 29 Oct 2014 09:21:47

Generated On: 18 Jul 2016 22:07:14

Were samples collected?

Yes ☒

If No, please specify the reason: _____

Was the subject fasting for at least 10 hours at time of sample collection?

Yes ☒

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Clinical Chemistry

Data signed: (Heart1) 29 Oct 2014 09:21:47

Generated On: 18 Jul 2016 22:07:14

Were samples collected?

Yes ☒

If No, please specify the reason: _____

Was the subject fasting for at least 10 hours at time of
sample collection?

Yes ☒

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Urine analysis

Data signed: (Heart1) 29 Oct 2014 09:21:47

Generated On: 18 Jul 2016 22:07:14

Were samples collected?

Yes ☒

If No, please specify the reason:

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Plasma Nicotine Sample

Data signed: (Heart1) 29 Oct 2014 09:21:48

Generated On: 18 Jul 2016 22:07:14

Not Done

False

If Not Done, please specify the reason:

Date
DD/MMM/YYYY

Time
hour:min 24-hour clock

Record Number

24 JAN 2014

20:09

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Plasma Cotinine Sample

Data signed: (Heart1) 29 Oct 2014 09:21:48

Generated On: 18 Jul 2016 22:07:14

Not Done

False

If Not Done, please specify the reason:

Date
DD/MMM/YYYY

Time
hour:min 24-hour clock

Record number

24 JAN 2014

20:09

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: CoHb Blood Sample

Data signed: (Heart1) 29 Oct 2014 09:21:49

Generated On: 18 Jul 2016 22:07:14

Not Done

False

If Not Done, please specify the reason:

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: CO Breath Test (1)

Data signed: (Heart1) 29 Oct 2014 09:21:49

Generated On: 18 Jul 2016 22:07:14

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

If Not Done, please specify the reason: _____

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

Actual Time of Assessment hour:min 24-hour clock	06:36
---	-------

Result(ppm)	3
-------------	---

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: CO Breath Test (2)

Data signed: (Heart1) 29 Oct 2014 09:21:49

Generated On: 18 Jul 2016 22:07:14

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

If Not Done, please specify the reason: _____

Scheduled Time	12:00 - 13:30 <input checked="" type="radio"/>
----------------	--

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

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

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: CO Breath Test (3)

Data signed: (Heart1) 29 Oct 2014 09:21:49

Generated On: 18 Jul 2016 22:07:14

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

If Not Done, please specify the reason: _____

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

Actual Time of Assessment hour:min 24-hour clock	16:03
---	-------

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

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: CO Breath Test (4)

Data signed: (Heart1) 29 Oct 2014 09:21:49

Generated On: 18 Jul 2016 22:07:14

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

If Not Done, please specify the reason: _____

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

Actual Time of Assessment hour:min 24-hour clock	20:01
---	-------

Result(ppm)	8
-------------	---

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: CYP2A6 activity Sample

Data signed: (Heart1) 29 Oct 2014 09:21:49

Generated On: 18 Jul 2016 22:07:14

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

If Not Done, please specify the reason: _____

Date of sample collection
DD/MMM/YYYY

Time of sample collection
hour:min 24-hour clock

Parameter

24 JAN 2014

06:12

trans-3'-hydroxyc
otinine

24 JAN 2014

06:12

cotinine

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: CYP1A2 activity Sample

Data signed: (Heart1) 29 Oct 2014 09:21:49

Generated On: 18 Jul 2016 22:07:14

Time of caffeine tablet intake	10:07
	hour:min 24-hour clock

Sample collection Not Done	False
----------------------------	-------

If Not Done, please specify the reason: _____

Date of sample collection DD/MMM/YYYY	Time of sample collection hour:min 24-hour clock	Parameter
24 JAN 2014	16:07	Caffeine
24 JAN 2014	16:07	Paraxanthine

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230
Folder: Baseline (Day 0)
Form: Risk markers: hs-CRP, fibrinogen, homocysteine, LDL, HDL
Data signed: (Heart1) 29 Oct 2014 09:21:49
Generated On: 18 Jul 2016 22:07:14

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

If Not Done, please specify the reason: _____

Date
DD/MMM/YYYY

Time
hour:min 24-hour clock

24 JAN 2014

07:22

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Risk Marker: s-ICAM-1

Data signed: (Heart1) 29 Oct 2014 09:21:49

Generated On: 18 Jul 2016 22:07:14

Not Done

False

If Not Done, please specify the reason: _____

Date
DD/MMM/YYYY

Time
hour:min 24-hour clock

24 JAN 2014

07:22

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Risk Marker: HbA1c

Data signed: (Heart1) 29 Oct 2014 09:21:49

Generated On: 18 Jul 2016 22:07:14

Not Done

False

If Not Done, please specify the reason:

Date
DD/MMM/YYYY

Time
hour:min 24-hour clock

24 JAN 2014

07:22

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: 24 hour urine collections

Data signed: (Heart1) 29 Oct 2014 09:21:49

Generated On: 18 Jul 2016 22:07:14

Start Time	06:30
	hour:min 24-hour clock

End Date	25 JAN 2014
	DD/MMM/YYYY

End Time	06:29
	hour:min 24-hour clock

Volume	663
--------	-----

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Sample Urine Collection

Data signed: (Heart1) 29 Oct 2014 09:21:49

Generated On: 18 Jul 2016 22:07:14

Were samples 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-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Questionnaire on smoking urges (QSU)

Generated On: 18 Jul 2016 22:07:14

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

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

Date of assessment	2014 JAN 24
--------------------	-------------

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	Strongly 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	Strongly disagree <input type="radio"/>
---	---

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

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

7. A cigarette would taste good now	Somewhat agree <input type="radio"/>
-------------------------------------	--------------------------------------

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Questionnaire on smoking urges (QSU)

Generated On: 18 Jul 2016 22:07:14

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

9. Smoking would make me less depressed Strongly disagree ☐

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

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Generated On: 18 Jul 2016 22:07:14

Date of Birth

(b) (6)

Date of assessment
DD/MMM/YYYY

2014 JAN 24
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

How have you been feeling over the past 24 hours?

None ☐

5. Difficulty concentrating

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Generated On: 18 Jul 2016 22:07:14

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?

Slight ☐

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

How have you been feeling over the past 24 hours?

None ☐

13. Dreaming or nightmares

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Generated On: 18 Jul 2016 22:07:14

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-07-JP: Osaki Hospital Tokyo heart center: 0230
Folder: Baseline (Day 0)
Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)
Generated On: 18 Jul 2016 22:07:14

Date of Birth

(b) (6)

Date of assessment=
DD/MMM/YYYY

2014 JAN 24
DD/MMM/YYYY

Time of assessment

20:03
hour:min 24-hour clock

Assessment Status

Completed ☒

1. Was smoking satisfying?

Moderately ☒

2. Did cigarettes taste good?

Quite a lot ☒

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

A lot ☒

4. Did smoking calm you down?

Little ☒

5. Did smoking make you feel more awake?

Very little ☒

6. Did smoking make you feel less irritable?

Little ☒

7. Did smoking help you concentrate?

Very little ☒

8. Did smoking reduce your hunger for food?

Quite a lot ☒

9. Did smoking make you dizzy?

Not at all ☒

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230
Folder: Baseline (Day 0)
Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)
Generated On: 18 Jul 2016 22:07:14

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? Moderately ☐

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Cough Assessment

Generated On: 18 Jul 2016 22:07:14

Date of Birth

(b) (6)

Date of assessment
DD/MMM/YYYY

2014 JAN 24
DD/MMM/YYYY

Time of assessment

06:01
hour:min 24-hour clock

Assessment Status

Completed ☒

Have you experienced a regular need to cough e.g.
coughing several times in the last 24 hrs?

No ☒

If YES, please answer the following questions:

First Question: Cough Impact Scale
How much is your cough bothering you?

-9

Second Question: Cough Intensity Scale:
How intense is your cough?

Not Applicable ☒

Third Question: Cough Frequency Scale:
How frequently do you normally have to cough each
day?

Not Applicable ☒

Fourth Question: Sputum Production
To what extent do you produce sputum when coughing?

Not Applicable ☒

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Human Smoking Topography Questionnaire

Data signed: (Heart1) 29 Oct 2014 09:21:50

Generated On: 18 Jul 2016 22:07:14

Type	HUMAN SMOKING TOPOGRAPHY QUESTIONNAIRE
------	--

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

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

Date of assessment	24 JAN 2014 DD/MMM/YYYY
--------------------	----------------------------

Time of assessment	20:00 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 :	I SMOKE 1MM CIGARETTE USUALLY BUT I FEEL IT TASTES LITTLE STRONGLY.
---	---

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-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Human Smoking Topography Questionnaire

Data signed: (Heart1) 29 Oct 2014 09:21:50

Generated On: 18 Jul 2016 22:07:14

If you agree or strongly agree, please describe : SAME AS THE ANSWER FOR QUESTION 1

4. The device is easy to use. Disagree ☒

If you disagree or strongly disagree, please describe : IT IS COMPLICATED.

5. Your smoking is disturbed by the device. Strongly agree ☒

If you agree or strongly agree, please describe : SAME AS THE ANSWER FOR QUESTION 4.

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Bio-banking (Transcriptomics)

Data signed: (Heart1) 29 Oct 2014 09:21:50

Generated On: 18 Jul 2016 22:07:14

Was a Bio-banking sample for transcriptomics taken?

Yes ☒

Time of Sample Collection

07:22
hour:min 24-hour clock

Was the subject fasting for at least 10 hours at time of sample collection?

Yes ☒

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Bio-banking (Biomarkers of exposure and risk markers)

Data signed: (Heart1) 29 Oct 2014 09:21:50

Generated On: 18 Jul 2016 22:07:14

Was a Bio-banking sample for biomarkers of exposure
and risk markers taken?

Yes ☐

Date of Sample Collection

24 JAN 2014
DD/MMM/YYYY

Time of Sample Collection

07:22
hour:min 24-hour clock

Was the subject fasting for at least 10 hours at time of
sample collection?

Yes ☐

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Biomarker(Blood)

Data signed: (Heart1) 29 Oct 2014 09:22:38

Generated On: 18 Jul 2016 22:07:14

Sample type

PLASMA

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Biomarker(Blood) (1)

Data signed: (Heart1) 29 Oct 2014 09:22:38

Generated On: 18 Jul 2016 22:07:14

Sample type	PLASMA
Sample Barcode	05112170000609
Analyte	COT
Result	87.7
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	0
Celerion Study Number	AA99127-01
Date of Collection	2014-JAN-24
Timepoint-minutes	0
Urine Start Day	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Biomarker(Blood) (1)

Data signed: (Heart1) 29 Oct 2014 09:22:38

Generated On: 18 Jul 2016 22:07:14

Urine End Day	0
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ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Biomarker(Blood) (2)

Data signed: (Heart1) 29 Oct 2014 09:22:38

Generated On: 18 Jul 2016 22:07:14

Sample type	PLASMA
Sample Barcode	05112170000609
Analyte	NIC
Result	6.62
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	0
Celerion Study Number	AA99127-01
Date of Collection	2014-JAN-24
Timepoint-minutes	0
Urine Start Day	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Biomarker(Blood) (2)

Data signed: (Heart1) 29 Oct 2014 09:22:38

Generated On: 18 Jul 2016 22:07:14

Urine End Day	0
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ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Biomarker(Blood) (3)

Data signed: (Heart1) 29 Oct 2014 09:22:38

Generated On: 18 Jul 2016 22:07:14

Sample type	PLASMA
Sample Barcode	05112260000580
Analyte	COT
Result	84.7
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	0
Celerion Study Number	AA99127-10
Date of Collection	2014-JAN-24
Timepoint-minutes	
Urine Start Day	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Biomarker(Blood) (3)

Data signed: (Heart1) 29 Oct 2014 09:22:38

Generated On: 18 Jul 2016 22:07:14

Urine End Day	0
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ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Biomarker(Blood) (4)

Data signed: (Heart1) 29 Oct 2014 09:22:38

Generated On: 18 Jul 2016 22:07:14

Sample type	PLASMA
Sample Barcode	05112260000580
Analyte	THCOT
Result	17.9
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	0
Celerion Study Number	AA99127-10
Date of Collection	2014-JAN-24
Timepoint-minutes	
Urine Start Day	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Biomarker(Blood) (4)

Data signed: (Heart1) 29 Oct 2014 09:22:38

Generated On: 18 Jul 2016 22:07:14

Urine End Day	0
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ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Biomarker(Blood) (5)

Data signed: (Heart1) 29 Oct 2014 09:22:38

Generated On: 18 Jul 2016 22:07:14

Sample type	PLASMA
Sample Barcode	05112240000670
Analyte	CAFFEINE
Result	1820
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	6
Day of Visit	0
Celerion Study Number	AA99127-08
Date of Collection	2014-JAN-24
Timepoint-minutes	
Urine Start Day	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Biomarker(Blood) (5)

Data signed: (Heart1) 29 Oct 2014 09:22:38

Generated On: 18 Jul 2016 22:07:14

Urine End Day	0
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ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Biomarker(Blood) (6)

Data signed: (Heart1) 29 Oct 2014 09:22:38

Generated On: 18 Jul 2016 22:07:14

Sample type	PLASMA
Sample Barcode	05112240000670
Analyte	PARAXANTHINE
Result	1100
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	6
Day of Visit	0
Celerion Study Number	AA99127-08
Date of Collection	2014-JAN-24
Timepoint-minutes	
Urine Start Day	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Biomarker(Blood) (6)

Data signed: (Heart1) 29 Oct 2014 09:22:38

Generated On: 18 Jul 2016 22:07:14

Urine End Day	0
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ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Biomarker(Urine)

Data signed: (Heart1) 04 Nov 2014 08:55:01

Generated On: 18 Jul 2016 22:07:14

Sample type

URINE

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Biomarker(Urine) (26)

Data signed: (Heart1) 04 Nov 2014 08:55:01

Generated On: 18 Jul 2016 22:07:14

Sample type	URINE
Sample Barcode	05112190003262
Analyte	3-HPMA
Result	532
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	0
Celerion Study Number	AA99127-03
Date of Collection	2014-JAN-24
Timepoint-minutes	
Urine Start Day	0

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Biomarker(Urine) (26)

Data signed: (Heart1) 04 Nov 2014 08:55:01

Generated On: 18 Jul 2016 22:07:14

Urine End Day

1

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Biomarker(Urine) (27)

Data signed: (Heart1) 04 Nov 2014 08:55:01

Generated On: 18 Jul 2016 22:07:14

Sample type	URINE
Sample Barcode	05112190003262
Analyte	CEMA
Result	51.2
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	0
Celerion Study Number	AA99127-03
Date of Collection	2014-JAN-24
Timepoint-minutes	
Urine Start Day	0

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Biomarker(Urine) (27)

Data signed: (Heart1) 04 Nov 2014 08:55:01

Generated On: 18 Jul 2016 22:07:14

Urine End Day

1

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Biomarker(Urine) (28)

Data signed: (Heart1) 04 Nov 2014 08:55:01

Generated On: 18 Jul 2016 22:07:14

Sample type	URINE
Sample Barcode	05112190003262
Analyte	HBMA
Result	201
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	0
Celerion Study Number	AA99127-03
Date of Collection	2014-JAN-24
Timepoint-minutes	
Urine Start Day	0

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Biomarker(Urine) (28)

Data signed: (Heart1) 04 Nov 2014 08:55:01

Generated On: 18 Jul 2016 22:07:14

Urine End Day

1

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Biomarker(Urine) (29)

Data signed: (Heart1) 04 Nov 2014 08:55:01

Generated On: 18 Jul 2016 22:07:14

Sample type	URINE
Sample Barcode	05112200003832
Analyte	NNAL
Result	72.5
Result Unit	PG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	0
Celerion Study Number	AA99127-04
Date of Collection	2014-JAN-24
Timepoint-minutes	
Urine Start Day	0

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Biomarker(Urine) (29)

Data signed: (Heart1) 04 Nov 2014 08:55:01

Generated On: 18 Jul 2016 22:07:14

Urine End Day

1

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Biomarker(Urine) (30)

Data signed: (Heart1) 04 Nov 2014 08:55:01

Generated On: 18 Jul 2016 22:07:14

Sample type	URINE
Sample Barcode	05112200003832
Analyte	NNN
Result	3.35
Result Unit	PG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	0
Celerion Study Number	AA99127-04
Date of Collection	2014-JAN-24
Timepoint-minutes	
Urine Start Day	0

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Biomarker(Urine) (30)

Data signed: (Heart1) 04 Nov 2014 08:55:01

Generated On: 18 Jul 2016 22:07:14

Urine End Day

1

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Biomarker(Urine) (31)

Data signed: (Heart1) 04 Nov 2014 08:55:01

Generated On: 18 Jul 2016 22:07:14

Sample type	URINE
Sample Barcode	05112210001912
Analyte	HEMA
Result	1.46
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	0
Celerion Study Number	AA99127-05
Date of Collection	2014-JAN-24
Timepoint-minutes	
Urine Start Day	0

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Biomarker(Urine) (31)

Data signed: (Heart1) 04 Nov 2014 08:55:01

Generated On: 18 Jul 2016 22:07:14

Urine End Day

1

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Biomarker(Urine) (32)

Data signed: (Heart1) 04 Nov 2014 08:55:01

Generated On: 18 Jul 2016 22:07:14

Sample type	URINE
Sample Barcode	05112220001272
Analyte	COT
Result	709
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	0
Celerion Study Number	AA99127-06
Date of Collection	2014-JAN-24
Timepoint-minutes	
Urine Start Day	0

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Biomarker(Urine) (32)

Data signed: (Heart1) 04 Nov 2014 08:55:01

Generated On: 18 Jul 2016 22:07:14

Urine End Day

1

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Biomarker(Urine) (33)

Data signed: (Heart1) 04 Nov 2014 08:55:01

Generated On: 18 Jul 2016 22:07:14

Sample type	URINE
Sample Barcode	05112220001272
Analyte	NIC
Result	719
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	0
Celerion Study Number	AA99127-06
Date of Collection	2014-JAN-24
Timepoint-minutes	
Urine Start Day	0

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Biomarker(Urine) (33)

Data signed: (Heart1) 04 Nov 2014 08:55:01

Generated On: 18 Jul 2016 22:07:14

Urine End Day

1

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Biomarker(Urine) (34)

Data signed: (Heart1) 04 Nov 2014 08:55:01

Generated On: 18 Jul 2016 22:07:14

Sample type	URINE
Sample Barcode	05112220001272
Analyte	NIC-GLUC
Result	615
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	0
Celerion Study Number	AA99127-06
Date of Collection	2014-JAN-24
Timepoint-minutes	
Urine Start Day	0

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Biomarker(Urine) (34)

Data signed: (Heart1) 04 Nov 2014 08:55:01

Generated On: 18 Jul 2016 22:07:14

Urine End Day

1

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Biomarker(Urine) (35)

Data signed: (Heart1) 04 Nov 2014 08:55:01

Generated On: 18 Jul 2016 22:07:14

Sample type	URINE
Sample Barcode	05112220001272
Analyte	THCOT
Result	1100
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	0
Celerion Study Number	AA99127-06
Date of Collection	2014-JAN-24
Timepoint-minutes	
Urine Start Day	0

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Biomarker(Urine) (35)

Data signed: (Heart1) 04 Nov 2014 08:55:01

Generated On: 18 Jul 2016 22:07:14

Urine End Day

1

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Biomarker(Urine) (36)

Data signed: (Heart1) 04 Nov 2014 08:55:01

Generated On: 18 Jul 2016 22:07:14

Sample type	URINE
Sample Barcode	05112220001272
Analyte	COT-GLUC
Result	2700
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	0
Celerion Study Number	AA99127-06
Date of Collection	2014-JAN-24
Timepoint-minutes	
Urine Start Day	0

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Biomarker(Urine) (36)

Data signed: (Heart1) 04 Nov 2014 08:55:01

Generated On: 18 Jul 2016 22:07:14

Urine End Day

1

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Biomarker(Urine) (37)

Data signed: (Heart1) 04 Nov 2014 08:55:01

Generated On: 18 Jul 2016 22:07:14

Sample type	URINE
Sample Barcode	05112220001272
Analyte	THCOT-GLUC
Result	344
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	0
Celerion Study Number	AA99127-06
Date of Collection	2014-JAN-24
Timepoint-minutes	
Urine Start Day	0

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Biomarker(Urine) (37)

Data signed: (Heart1) 04 Nov 2014 08:55:01

Generated On: 18 Jul 2016 22:07:14

Urine End Day

1

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Biomarker(Urine) (38)

Data signed: (Heart1) 04 Nov 2014 08:55:01

Generated On: 18 Jul 2016 22:07:14

Sample type	URINE
Sample Barcode	05112230001912
Analyte	3-OH BAP
Result	25.3
Result Unit	FG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	0
Celerion Study Number	AA99127-07
Date of Collection	2014-JAN-24
Timepoint-minutes	
Urine Start Day	0

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Biomarker(Urine) (38)

Data signed: (Heart1) 04 Nov 2014 08:55:01

Generated On: 18 Jul 2016 22:07:14

Urine End Day

1

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Biomarker(Urine) (39)

Data signed: (Heart1) 04 Nov 2014 08:55:01

Generated On: 18 Jul 2016 22:07:14

Sample type	URINE
Sample Barcode	05112250001912
Analyte	1-NA
Result	75.0
Result Unit	PG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	0
Celerion Study Number	AA99127-09
Date of Collection	2014-JAN-24
Timepoint-minutes	
Urine Start Day	0

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Biomarker(Urine) (39)

Data signed: (Heart1) 04 Nov 2014 08:55:01

Generated On: 18 Jul 2016 22:07:14

Urine End Day

1

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Biomarker(Urine) (40)

Data signed: (Heart1) 04 Nov 2014 08:55:01

Generated On: 18 Jul 2016 22:07:14

Sample type	URINE
Sample Barcode	05112250001912
Analyte	2-NA
Result	16.1
Result Unit	PG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	0
Celerion Study Number	AA99127-09
Date of Collection	2014-JAN-24
Timepoint-minutes	
Urine Start Day	0

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Biomarker(Urine) (40)

Data signed: (Heart1) 04 Nov 2014 08:55:01

Generated On: 18 Jul 2016 22:07:14

Urine End Day

1

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Biomarker(Urine) (41)

Data signed: (Heart1) 04 Nov 2014 08:55:01

Generated On: 18 Jul 2016 22:07:14

Sample type	URINE
Sample Barcode	05112250001912
Analyte	4-ABP
Result	10.5
Result Unit	PG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	0
Celerion Study Number	AA99127-09
Date of Collection	2014-JAN-24
Timepoint-minutes	
Urine Start Day	0

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Biomarker(Urine) (41)

Data signed: (Heart1) 04 Nov 2014 08:55:01

Generated On: 18 Jul 2016 22:07:14

Urine End Day

1

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Biomarker(Urine) (42)

Data signed: (Heart1) 04 Nov 2014 08:55:01

Generated On: 18 Jul 2016 22:07:14

Sample type	URINE
Sample Barcode	05112250001912
Analyte	O-TOL
Result	160
Result Unit	PG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	0
Celerion Study Number	AA99127-09
Date of Collection	2014-JAN-24
Timepoint-minutes	
Urine Start Day	0

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Biomarker(Urine) (42)

Data signed: (Heart1) 04 Nov 2014 08:55:01

Generated On: 18 Jul 2016 22:07:14

Urine End Day

1

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Biomarker(Urine) (43)

Data signed: (Heart1) 04 Nov 2014 08:55:01

Generated On: 18 Jul 2016 22:07:14

Sample type	URINE
Sample Barcode	05112270000886
Analyte	11-DTXB2
Result	1110
Result Unit	PG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	0
Celerion Study Number	AA99127-11
Date of Collection	2014-JAN-24
Timepoint-minutes	
Urine Start Day	0

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Biomarker(Urine) (43)

Data signed: (Heart1) 04 Nov 2014 08:55:01

Generated On: 18 Jul 2016 22:07:14

Urine End Day

1

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Biomarker(Urine) (44)

Data signed: (Heart1) 04 Nov 2014 08:55:01

Generated On: 18 Jul 2016 22:07:14

Sample type	URINE
Sample Barcode	05112280000886
Analyte	IPF2A-III
Result	325
Result Unit	PG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	0
Celerion Study Number	AA99127-12
Date of Collection	2014-JAN-24
Timepoint-minutes	
Urine Start Day	0

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Biomarker(Urine) (44)

Data signed: (Heart1) 04 Nov 2014 08:55:01

Generated On: 18 Jul 2016 22:07:14

Urine End Day

1

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Biomarker(Urine) (45)

Data signed: (Heart1) 04 Nov 2014 08:55:01

Generated On: 18 Jul 2016 22:07:14

Sample type	URINE
Sample Barcode	05113640001912
Analyte	1-OHP
Result	101
Result Unit	PG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	0
Celerion Study Number	AA99599-03
Date of Collection	2014-JAN-24
Timepoint-minutes	
Urine Start Day	0

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Biomarker(Urine) (45)

Data signed: (Heart1) 04 Nov 2014 08:55:01

Generated On: 18 Jul 2016 22:07:14

Urine End Day

1

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Biomarker(Urine) (46)

Data signed: (Heart1) 04 Nov 2014 08:55:01

Generated On: 18 Jul 2016 22:07:14

Sample type	URINE
Sample Barcode	05113620001912
Analyte	SBMA
Result	1.56
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	0
Celerion Study Number	AA99599-01
Date of Collection	2014-JAN-24
Timepoint-minutes	
Urine Start Day	0

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Biomarker(Urine) (46)

Data signed: (Heart1) 04 Nov 2014 08:55:01

Generated On: 18 Jul 2016 22:07:14

Urine End Day

1

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Biomarker(Urine) (47)

Data signed: (Heart1) 04 Nov 2014 08:55:01

Generated On: 18 Jul 2016 22:07:14

Sample type	URINE
Sample Barcode	05113620001912
Analyte	SPMA
Result	0.858
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	0
Celerion Study Number	AA99599-01
Date of Collection	2014-JAN-24
Timepoint-minutes	
Urine Start Day	0

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Biomarker(Urine) (47)

Data signed: (Heart1) 04 Nov 2014 08:55:01

Generated On: 18 Jul 2016 22:07:14

Urine End Day

1

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Biomarker(Urine) (48)

Data signed: (Heart1) 04 Nov 2014 08:55:01

Generated On: 18 Jul 2016 22:07:14

Sample type	URINE
Sample Barcode	05113630001912
Analyte	MHBMA
Result	0.596
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	
Day of Visit	0
Celerion Study Number	AA99599-02
Date of Collection	2014-JAN-24
Timepoint-minutes	
Urine Start Day	0

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Biomarker(Urine) (48)

Data signed: (Heart1) 04 Nov 2014 08:55:01

Generated On: 18 Jul 2016 22:07:14

Urine End Day

1

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Biomarker(Urine) (49)

Data signed: (Heart1) 04 Nov 2014 08:55:01

Generated On: 18 Jul 2016 22:07:14

Sample type	URINE
Sample Barcode	05113310000154
Analyte	AMES
Result	4.08
Result Unit	REV/ML
Lab Status	OK
Sample comment	
Detection method	COUNT
Planned time point (Hour)	
Day of Visit	0
Celerion Study Number	AA99127-15
Date of Collection	2014-JAN-24
Timepoint-minutes	
Urine Start Day	0

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Biomarker(Urine) (49)

Data signed: (Heart1) 04 Nov 2014 08:55:01

Generated On: 18 Jul 2016 22:07:14

Urine End Day

1

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Biomarker(Urine) (50)

Data signed: (Heart1) 04 Nov 2014 08:55:01

Generated On: 18 Jul 2016 22:07:14

Sample type	URINE
Sample Barcode	05113730002152
Analyte	CREATININE
Result	164
Result Unit	MG/DL
Lab Status	OK
Sample comment	
Detection method	SPECTROPHOTOMETRIC
Planned time point (Hour)	
Day of Visit	0
Celerion Study Number	AA99127-14
Date of Collection	2014-JAN-24
Timepoint-minutes	
Urine Start Day	0

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Biomarker(Urine) (50)

Data signed: (Heart1) 04 Nov 2014 08:55:01

Generated On: 18 Jul 2016 22:07:14

Urine End Day

1

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Lab-BU BIOMARKER(2014 JAN 24)

Data signed: (Heart1) 29 Oct 2014 09:21:50

Generated On: 18 Jul 2016 22:07:14

Test Category	BIOMARKER
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Date of Sample Collection	2014 JAN 24
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Date (BU)	2014/01/24
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Please document clinically relevant abnormalities in the AE form	
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ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Lab-BU BIOMARKER(2014 JAN 24)

Data signed: (Heart1) 29 Oct 2014 09:21:50

Generated On: 18 Jul 2016 22:07:14

Test Category	BIOMARKER
Date of Sample Collection	2014 JAN 24
Date (BU)	2014/01/24
Blood Sample time(BU)	2009
Urine Sample time(BU)	
Time of Blood Sample Collection	20:09
Time of Urine Sample Collection	
Test Name	COHB
Result	4.3
Text Result	
Unit	%
Lower limit	
Upper limit	
Flag	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Lab-BU BIOMARKER(2014 JAN 24)

Data signed: (Heart1) 29 Oct 2014 09:21:50

Generated On: 18 Jul 2016 22:07:14

Clinically Significant? _____

Comment _____

Result Category

N

Text Result Code _____

Reference Value Category _____

Timepoint(COHB)

20:00-21:30

Material Code

BLOOD

Chyle Comment Code _____

Chyle Comment English _____

Hemolysis Comment Code _____

Hemolysis Comment English _____

Specimen Comment Code 1 _____

Specimen English Comment 1 _____

Specimen Comment Code 2 _____

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Lab-BU BIOMARKER(2014 JAN 24)

Data signed: (Heart1) 29 Oct 2014 09:21:50

Generated On: 18 Jul 2016 22:07:14

Specimen English Comment 2

Result Supplementary Comment Code 1

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004672126

Please document clinically relevant abnormalities in the AE form

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (1)

Data signed: (Heart1) 29 Oct 2014 09:21:51

Generated On: 18 Jul 2016 22:07:14

Transmission Type Cumulative ☐

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6) 

Visit Name DAY0

Visit Type Scheduled ☐

Accession ID B428104

Actual Collection Time 06:12

Specimen Condition _____

Battery ID HM1821

Battery Name HEMATOLOGY&DIFFERENTIAL
PANEL

Lab Test ID HMT10

Lab Test Name MONOCYTES


ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (1)

Data signed: (Heart1) 29 Oct 2014 09:21:51

Generated On: 18 Jul 2016 22:07:14

Test ID	
Test Status	Done 
Reported Text Result	0.13
Reported Numeric Result	0.13
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	
SI Numeric Result	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (1)

Data signed: (Heart1) 29 Oct 2014 09:21:51

Generated On: 18 Jul 2016 22:07:14

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (2)

Data signed: (Heart1) 29 Oct 2014 09:21:51

Generated On: 18 Jul 2016 22:07:14

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	M
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Subject Date of Birth	(b) (6)
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Visit Name	DAY0
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	B428104
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Actual Collection Time	06:12
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Specimen Condition	<hr/>
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Battery ID	HM1821
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Battery Name	HEMATOLOGY&DIFFERENTIAL PANEL
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Lab Test ID	HMT100
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Lab Test Name	MCH
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ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (2)

Data signed: (Heart1) 29 Oct 2014 09:21:51

Generated On: 18 Jul 2016 22:07:14

Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	33
Reported Numeric Result	33
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	
SI Numeric Result	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (2)

Data signed: (Heart1) 29 Oct 2014 09:21:51

Generated On: 18 Jul 2016 22:07:14

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (3)

Data signed: (Heart1) 29 Oct 2014 09:21:51

Generated On: 18 Jul 2016 22:07:14

Transmission Type Cumulative ☐

Subject ID or Number

Subject Sex M

Subject Date of Birth (b) (6)

Visit Name DAY0

Visit Type Scheduled ☐

Accession ID B428104

Actual Collection Time 06:12

Specimen Condition

Battery ID HM1821

Battery Name HEMATOLOGY&DIFFERENTIAL
PANEL

Lab Test ID HMT102

Lab Test Name MCHC

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (3)

Data signed: (Heart1) 29 Oct 2014 09:21:51

Generated On: 18 Jul 2016 22:07:14

Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	35
Reported Numeric Result	35
Reference Range low	31
Reference Range high	38
Range Units	G/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	
SI Numeric Result	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (3)

Data signed: (Heart1) 29 Oct 2014 09:21:51

Generated On: 18 Jul 2016 22:07:14

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (4)

Data signed: (Heart1) 29 Oct 2014 09:21:51

Generated On: 18 Jul 2016 22:07:14

Transmission Type Cumulative ☒

Subject ID or Number

Subject Sex M

Subject Date of Birth (b) (6)

Visit Name DAY0

Visit Type Scheduled ☒

Accession ID B428104

Actual Collection Time 06:12

Specimen Condition

Battery ID HM1821

Battery Name HEMATOLOGY&DIFFERENTIAL
PANEL

Lab Test ID HMT11

Lab Test Name EOSINOPHILS

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (4)

Data signed: (Heart1) 29 Oct 2014 09:21:51

Generated On: 18 Jul 2016 22:07:14

Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	0.07
Reported Numeric Result	0.07
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	
SI Numeric Result	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (4)

Data signed: (Heart1) 29 Oct 2014 09:21:51

Generated On: 18 Jul 2016 22:07:14

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (5)

Data signed: (Heart1) 29 Oct 2014 09:21:51

Generated On: 18 Jul 2016 22:07:14

Transmission Type Cumulative ☒

Subject ID or Number

Subject Sex M

Subject Date of Birth (b) (6)

Visit Name DAY0

Visit Type Scheduled ☒

Accession ID B428104

Actual Collection Time 06:12

Specimen Condition

Battery ID HM1821

Battery Name HEMATOLOGY&DIFFERENTIAL
PANEL

Lab Test ID HMT12

Lab Test Name BASOPHILS

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (5)

Data signed: (Heart1) 29 Oct 2014 09:21:51

Generated On: 18 Jul 2016 22:07:14

Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	0.05
Reported Numeric Result	0.05
Reference Range low	0.00
Reference Range high	0.20
Range Units	X10 ³ /UL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	
SI Numeric Result	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (5)

Data signed: (Heart1) 29 Oct 2014 09:21:51

Generated On: 18 Jul 2016 22:07:14

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (6)

Data signed: (Heart1) 29 Oct 2014 09:21:51

Generated On: 18 Jul 2016 22:07:14

Transmission Type Cumulative ☒

Subject ID or Number

Subject Sex M

Subject Date of Birth (b) (6)

Visit Name DAY0

Visit Type Scheduled ☒

Accession ID B428104

Actual Collection Time 06:12

Specimen Condition

Battery ID HM1821

Battery Name HEMATOLOGY&DIFFERENTIAL
PANEL

Lab Test ID HMT13

Lab Test Name PLATELETS


ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (6)

Data signed: (Heart1) 29 Oct 2014 09:21:51

Generated On: 18 Jul 2016 22:07:14

Test ID	
Test Status	Done 
Reported Text Result	196
Reported Numeric Result	196
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	
SI Numeric Result	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (6)

Data signed: (Heart1) 29 Oct 2014 09:21:51

Generated On: 18 Jul 2016 22:07:14

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (7)

Data signed: (Heart1) 29 Oct 2014 09:21:51

Generated On: 18 Jul 2016 22:07:14

Transmission Type Cumulative ☐

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6)

Visit Name DAY0

Visit Type Scheduled ☐

Accession ID B428104

Actual Collection Time 06:12

Specimen Condition _____

Battery ID HM1821

Battery Name HEMATOLOGY&DIFFERENTIAL
PANEL

Lab Test ID HMT2

Lab Test Name HEMATOCRIT

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (7)

Data signed: (Heart1) 29 Oct 2014 09:21:51

Generated On: 18 Jul 2016 22:07:14

Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	45
Reported Numeric Result	45
Reference Range low	39
Reference Range high	54
Range Units	%
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	
SI Numeric Result	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (7)

Data signed: (Heart1) 29 Oct 2014 09:21:51

Generated On: 18 Jul 2016 22:07:14

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (8)

Data signed: (Heart1) 29 Oct 2014 09:21:51

Generated On: 18 Jul 2016 22:07:14

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	M
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Subject Date of Birth	(b) (6) 
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Visit Name	DAY0
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	B428104
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Actual Collection Time	06:12
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Specimen Condition	<hr/>
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Battery ID	HM1821
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Battery Name	HEMATOLOGY&DIFFERENTIAL PANEL
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Lab Test ID	HMT3
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Lab Test Name	RBC
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ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (8)

Data signed: (Heart1) 29 Oct 2014 09:21:51

Generated On: 18 Jul 2016 22:07:14

Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	4.8
Reported Numeric Result	4.8
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	
SI Numeric Result	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (8)

Data signed: (Heart1) 29 Oct 2014 09:21:51

Generated On: 18 Jul 2016 22:07:14

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (9)

Data signed: (Heart1) 29 Oct 2014 09:21:51

Generated On: 18 Jul 2016 22:07:14

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	M
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Subject Date of Birth	(b) (6)
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Visit Name	DAY0
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	B428104
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Actual Collection Time	06:12
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Specimen Condition	<hr/>
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Battery ID	HM1821
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Battery Name	HEMATOLOGY&DIFFERENTIAL PANEL
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Lab Test ID	HMT4
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Lab Test Name	MCV
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ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (9)

Data signed: (Heart1) 29 Oct 2014 09:21:51

Generated On: 18 Jul 2016 22:07:14

Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	95
Reported Numeric Result	95
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	
SI Numeric Result	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (9)

Data signed: (Heart1) 29 Oct 2014 09:21:51

Generated On: 18 Jul 2016 22:07:14

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (10)

Data signed: (Heart1) 29 Oct 2014 09:21:51

Generated On: 18 Jul 2016 22:07:14

Transmission Type Cumulative ☐

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6)

Visit Name DAY0

Visit Type Scheduled ☐

Accession ID B428104

Actual Collection Time 06:12

Specimen Condition _____

Battery ID HM1821

Battery Name HEMATOLOGY&DIFFERENTIAL
PANEL

Lab Test ID HMT40

Lab Test Name HEMOGLOBIN

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (10)

Data signed: (Heart1) 29 Oct 2014 09:21:51

Generated On: 18 Jul 2016 22:07:14

Test ID	
Test Status	Done <input 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	
SI Numeric Result	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (10)

Data signed: (Heart1) 29 Oct 2014 09:21:51

Generated On: 18 Jul 2016 22:07:14

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (11)

Data signed: (Heart1) 29 Oct 2014 09:21:51

Generated On: 18 Jul 2016 22:07:14

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6)

Visit Name DAY0

Visit Type Scheduled ☒

Accession ID B428104

Actual Collection Time 06:12

Specimen Condition _____

Battery ID HM1821

Battery Name HEMATOLOGY&DIFFERENTIAL
PANEL

Lab Test ID HMT7

Lab Test Name WBC

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (11)

Data signed: (Heart1) 29 Oct 2014 09:21:51

Generated On: 18 Jul 2016 22:07:14

Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	6.16
Reported Numeric Result	6.16
Reference Range low	3.80
Reference Range high	10.70
Range Units	X10 ³ /UL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	
SI Numeric Result	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (11)

Data signed: (Heart1) 29 Oct 2014 09:21:51

Generated On: 18 Jul 2016 22:07:14

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (12)

Data signed: (Heart1) 29 Oct 2014 09:21:51

Generated On: 18 Jul 2016 22:07:14

Transmission Type Cumulative ☒

Subject ID or Number

Subject Sex M

Subject Date of Birth (b) (6)

Visit Name DAY0

Visit Type Scheduled ☒

Accession ID B428104

Actual Collection Time 06:12

Specimen Condition

Battery ID HM1821

Battery Name HEMATOLOGY&DIFFERENTIAL
PANEL

Lab Test ID HMT71

Lab Test Name RBC MORPHOLOGY 1

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)


Form: Lab_BU_CCLS (12)

Data signed: (Heart1) 29 Oct 2014 09:21:51

Generated On: 18 Jul 2016 22:07:14

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

SI Numeric Result

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (12)

Data signed: (Heart1) 29 Oct 2014 09:21:51

Generated On: 18 Jul 2016 22:07:14

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (13)

Data signed: (Heart1) 29 Oct 2014 09:21:51

Generated On: 18 Jul 2016 22:07:14

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	M
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Subject Date of Birth	(b) (6)
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Visit Name	DAY0
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	B428104
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Actual Collection Time	06:12
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Specimen Condition	<hr/>
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Battery ID	HM1821
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Battery Name	HEMATOLOGY&DIFFERENTIAL PANEL
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Lab Test ID	HMT8
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Lab Test Name	NEUTROPHILS
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ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (13)

Data signed: (Heart1) 29 Oct 2014 09:21:51

Generated On: 18 Jul 2016 22:07:14

Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	3.87
Reported Numeric Result	3.87
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	
SI Numeric Result	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (13)

Data signed: (Heart1) 29 Oct 2014 09:21:51

Generated On: 18 Jul 2016 22:07:14

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (14)

Data signed: (Heart1) 29 Oct 2014 09:21:51

Generated On: 18 Jul 2016 22:07:14

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	M
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Subject Date of Birth	(b) (6)
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Visit Name	DAY0
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Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	B428104
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Actual Collection Time	06:12
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Specimen Condition	<hr/>
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Battery ID	HM1821
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Battery Name	HEMATOLOGY&DIFFERENTIAL PANEL
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Lab Test ID	HMT9
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Lab Test Name	LYMPHOCYTES
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ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (14)

Data signed: (Heart1) 29 Oct 2014 09:21:51

Generated On: 18 Jul 2016 22:07:14

Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	2.02
Reported Numeric Result	2.02
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	
SI Numeric Result	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (14)

Data signed: (Heart1) 29 Oct 2014 09:21:51

Generated On: 18 Jul 2016 22:07:14

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (15)

Data signed: (Heart1) 29 Oct 2014 09:21:51

Generated On: 18 Jul 2016 22:07:14

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6)

Visit Name DAY0

Visit Type Scheduled ☒

Accession ID B428104

Actual Collection Time 06:12

Specimen Condition _____

Battery ID RC9255

Battery Name CHEMISTRY PANEL

Lab Test ID RCT1

Lab Test Name TOTAL BILIRUBIN

Test ID _____

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (15)

Data signed: (Heart1) 29 Oct 2014 09:21:51

Generated On: 18 Jul 2016 22:07:14

Test Status	Done <input type="radio"/>
Reported Text Result	1.5
Reported Numeric Result	1.5
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	
SI Numeric Result	
SI Reference Range Low	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (15)

Data signed: (Heart1) 29 Oct 2014 09:21:51

Generated On: 18 Jul 2016 22:07:14

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

High ☒

Clinically Significant?

No ☒

Comment

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (16)

Data signed: (Heart1) 29 Oct 2014 09:21:51

Generated On: 18 Jul 2016 22:07:14

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6)

Visit Name DAY0

Visit Type Scheduled ☒

Accession ID B428104

Actual Collection Time 06:12

Specimen Condition _____

Battery ID RC9255

Battery Name CHEMISTRY PANEL

Lab Test ID RCT12

Lab Test Name TOTAL PROTEIN

Test ID _____

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (16)

Data signed: (Heart1) 29 Oct 2014 09:21:51

Generated On: 18 Jul 2016 22:07:14

Test Status	Done <input type="radio"/>
Reported Text Result	6.7
Reported Numeric Result	6.7
Reference Range low	6.1
Reference Range high	8.4
Range Units	G/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	
SI Numeric Result	
SI Reference Range Low	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (16)

Data signed: (Heart1) 29 Oct 2014 09:21:51

Generated On: 18 Jul 2016 22:07:14

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (17)

Data signed: (Heart1) 29 Oct 2014 09:21:51

Generated On: 18 Jul 2016 22:07:14

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6)

Visit Name DAY0

Visit Type Scheduled ☒

Accession ID B428104

Actual Collection Time 06:12

Specimen Condition _____

Battery ID RC9255

Battery Name CHEMISTRY PANEL

Lab Test ID RCT13

Lab Test Name ALBUMIN

Test ID _____

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (17)

Data signed: (Heart1) 29 Oct 2014 09:21:51

Generated On: 18 Jul 2016 22:07:14

Test Status	Done <input 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	
SI Numeric Result	
SI Reference Range Low	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (17)

Data signed: (Heart1) 29 Oct 2014 09:21:51

Generated On: 18 Jul 2016 22:07:14

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (18)

Data signed: (Heart1) 29 Oct 2014 09:21:51

Generated On: 18 Jul 2016 22:07:14

Transmission Type Cumulative ☒

Subject ID or Number

Subject Sex M

Subject Date of Birth (b) (6)

Visit Name DAY0

Visit Type Scheduled ☒

Accession ID B428104

Actual Collection Time 06:12

Specimen Condition

Battery ID RC9255

Battery Name CHEMISTRY PANEL

Lab Test ID RCT1407

Lab Test Name ALKALINE PHOSPHATASE

Test ID

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (18)

Data signed: (Heart1) 29 Oct 2014 09:21:51

Generated On: 18 Jul 2016 22:07:14

Test Status	Done <input type="radio"/>
Reported Text Result	84
Reported Numeric Result	84
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	
SI Numeric Result	
SI Reference Range Low	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (18)

Data signed: (Heart1) 29 Oct 2014 09:21:51

Generated On: 18 Jul 2016 22:07:14

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (19)

Data signed: (Heart1) 29 Oct 2014 09:21:51

Generated On: 18 Jul 2016 22:07:14

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	M
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Subject Date of Birth	(b) (6)
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Visit Name	DAY0
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Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	B428104
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Actual Collection Time	06:12
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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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Lab Test Name	LDH
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Test ID	<hr/>
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ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230


Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (19)

Data signed: (Heart1) 29 Oct 2014 09:21:51

Generated On: 18 Jul 2016 22:07:14

Test Status

Done 

Reported Text Result 110

Reported Numeric Result 110

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

SI Numeric Result

SI Reference Range Low

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (19)

Data signed: (Heart1) 29 Oct 2014 09:21:51

Generated On: 18 Jul 2016 22:07:14

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (20)

Data signed: (Heart1) 29 Oct 2014 09:21:51

Generated On: 18 Jul 2016 22:07:14

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6)

Visit Name DAY0

Visit Type Scheduled ☒

Accession ID B428104

Actual Collection Time 06:12

Specimen Condition _____

Battery ID RC9255

Battery Name CHEMISTRY PANEL

Lab Test ID RCT15

Lab Test Name SERUM SODIUM

Test ID _____

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (20)

Data signed: (Heart1) 29 Oct 2014 09:21:51

Generated On: 18 Jul 2016 22:07:14

Test Status	Done <input type="radio"/>
Reported Text Result	140
Reported Numeric Result	140
Reference Range low	132
Reference Range high	147
Range Units	MEQ/L
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	
SI Numeric Result	
SI Reference Range Low	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (20)

Data signed: (Heart1) 29 Oct 2014 09:21:51

Generated On: 18 Jul 2016 22:07:14

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (21)

Data signed: (Heart1) 29 Oct 2014 09:21:51

Generated On: 18 Jul 2016 22:07:14

Transmission Type Cumulative ☒

Subject ID or Number

Subject Sex M

Subject Date of Birth (b) (6)

Visit Name DAY0

Visit Type Scheduled ☒

Accession ID B428104

Actual Collection Time 06:12

Specimen Condition

Battery ID RC9255

Battery Name CHEMISTRY PANEL

Lab Test ID RCT16

Lab Test Name SERUM POTASSIUM

Test ID


ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (21)

Data signed: (Heart1) 29 Oct 2014 09:21:51

Generated On: 18 Jul 2016 22:07:14

Test Status	Done 
Reported Text Result	4.1
Reported Numeric Result	4.1
Reference Range low	3.4
Reference Range high	5.4
Range Units	MEQ/L
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	
SI Numeric Result	
SI Reference Range Low	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (21)

Data signed: (Heart1) 29 Oct 2014 09:21:51

Generated On: 18 Jul 2016 22:07:14

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (22)

Data signed: (Heart1) 29 Oct 2014 09:21:51

Generated On: 18 Jul 2016 22:07:14

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	M
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Subject Date of Birth	(b) (6)
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Visit Name	DAY0
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	B428104
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Actual Collection Time	06:12
------------------------	-------

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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Lab Test Name	DIRECT BILIRUBIN
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Test ID	<hr/>
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ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (22)

Data signed: (Heart1) 29 Oct 2014 09:21:51

Generated On: 18 Jul 2016 22:07:14

Test Status	Done <input type="radio"/>
Reported Text Result	0.3
Reported Numeric Result	0.3
Reference Range low	0.0
Reference Range high	0.4
Range Units	MG/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	
SI Numeric Result	
SI Reference Range Low	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (22)

Data signed: (Heart1) 29 Oct 2014 09:21:51

Generated On: 18 Jul 2016 22:07:14

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (23)

Data signed: (Heart1) 29 Oct 2014 09:21:51

Generated On: 18 Jul 2016 22:07:14

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6)

Visit Name DAY0

Visit Type Scheduled ☒

Accession ID B428104

Actual Collection Time 06:12

Specimen Condition _____

Battery ID RC9255

Battery Name CHEMISTRY PANEL

Lab Test ID RCT3

Lab Test Name GGT

Test ID _____

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (23)

Data signed: (Heart1) 29 Oct 2014 09:21:51

Generated On: 18 Jul 2016 22:07:14

Test Status	Done <input type="radio"/>
Reported Text Result	38
Reported Numeric Result	38
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	
SI Numeric Result	
SI Reference Range Low	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (23)

Data signed: (Heart1) 29 Oct 2014 09:21:51

Generated On: 18 Jul 2016 22:07:14

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (24)

Data signed: (Heart1) 29 Oct 2014 09:21:51

Generated On: 18 Jul 2016 22:07:14

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6)

Visit Name DAY0

Visit Type Scheduled ☒

Accession ID B428104

Actual Collection Time 06:12

Specimen Condition _____

Battery ID RC9255

Battery Name CHEMISTRY PANEL

Lab Test ID RCT392

Lab Test Name CREATININE (RATE BLANKED)

Test ID _____

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (24)

Data signed: (Heart1) 29 Oct 2014 09:21:51

Generated On: 18 Jul 2016 22:07:14

Test Status	Done <input type="radio"/>
Reported Text Result	0.8
Reported Numeric Result	0.8
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	
SI Numeric Result	
SI Reference Range Low	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (24)

Data signed: (Heart1) 29 Oct 2014 09:21:51

Generated On: 18 Jul 2016 22:07:14

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (25)

Data signed: (Heart1) 29 Oct 2014 09:21:51

Generated On: 18 Jul 2016 22:07:14

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6)

Visit Name DAY0

Visit Type Scheduled ☒

Accession ID B428104

Actual Collection Time 06:12

Specimen Condition _____

Battery ID RC9255

Battery Name CHEMISTRY PANEL

Lab Test ID RCT4

Lab Test Name ALT (SGPT)

Test ID _____

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (25)

Data signed: (Heart1) 29 Oct 2014 09:21:51

Generated On: 18 Jul 2016 22:07:14

Test Status	Done <input type="radio"/>
Reported Text Result	50
Reported Numeric Result	50
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	
SI Numeric Result	
SI Reference Range Low	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (25)

Data signed: (Heart1) 29 Oct 2014 09:21:51

Generated On: 18 Jul 2016 22:07:14

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

High ☒

Clinically Significant?

No ☒

Comment

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (26)

Data signed: (Heart1) 29 Oct 2014 09:21:51

Generated On: 18 Jul 2016 22:07:14

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6)

Visit Name DAY0

Visit Type Scheduled ☒

Accession ID B428104

Actual Collection Time 06:12

Specimen Condition _____

Battery ID RC9255

Battery Name CHEMISTRY PANEL

Lab Test ID RCT5

Lab Test Name AST (SGOT)

Test ID _____

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (26)

Data signed: (Heart1) 29 Oct 2014 09:21:51

Generated On: 18 Jul 2016 22:07:14

Test Status	Done <input type="radio"/>
Reported Text Result	27
Reported Numeric Result	27
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	
SI Numeric Result	
SI Reference Range Low	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (26)

Data signed: (Heart1) 29 Oct 2014 09:21:51

Generated On: 18 Jul 2016 22:07:14

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (27)

Data signed: (Heart1) 29 Oct 2014 09:21:51

Generated On: 18 Jul 2016 22:07:14

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6)

Visit Name DAY0

Visit Type Scheduled ☒

Accession ID B428104

Actual Collection Time 06:12

Specimen Condition _____

Battery ID RC9255

Battery Name CHEMISTRY PANEL

Lab Test ID RCT6

Lab Test Name UREA NITROGEN

Test ID _____


ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (27)

Data signed: (Heart1) 29 Oct 2014 09:21:51

Generated On: 18 Jul 2016 22:07:14

Test Status	Done 
Reported Text Result	15
Reported Numeric Result	15
Reference Range low	4
Reference Range high	24
Range Units	MG/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	
SI Numeric Result	
SI Reference Range Low	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (27)

Data signed: (Heart1) 29 Oct 2014 09:21:51

Generated On: 18 Jul 2016 22:07:14

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (28)

Data signed: (Heart1) 29 Oct 2014 09:21:51

Generated On: 18 Jul 2016 22:07:14

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6)

Visit Name DAY0

Visit Type Scheduled ☒

Accession ID B428104

Actual Collection Time 06:12

Specimen Condition _____

Battery ID UA1538

Battery Name URINE MACRO PANEL

Lab Test ID UAT10

Lab Test Name UR NITRITE

Test ID _____

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230


Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (28)

Data signed: (Heart1) 29 Oct 2014 09:21:51

Generated On: 18 Jul 2016 22:07:14

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

SI Numeric Result

SI Reference Range Low

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (28)

Data signed: (Heart1) 29 Oct 2014 09:21:51

Generated On: 18 Jul 2016 22:07:14

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (29)

Data signed: (Heart1) 29 Oct 2014 09:21:51

Generated On: 18 Jul 2016 22:07:14

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6)

Visit Name DAY0

Visit Type Scheduled ☒

Accession ID B428104

Actual Collection Time 06:12

Specimen Condition _____

Battery ID UA1538

Battery Name URINE MACRO PANEL

Lab Test ID UAT2

Lab Test Name UR SPECIFIC GRAVITY

Test ID _____

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (29)

Data signed: (Heart1) 29 Oct 2014 09:21:51

Generated On: 18 Jul 2016 22:07:14

Test Status	Done <input type="radio"/>
Reported Text Result	1.023
Reported Numeric Result	1.023
Reference Range low	1.003
Reference Range high	1.035
Range Units	
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	
SI Numeric Result	
SI Reference Range Low	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (29)

Data signed: (Heart1) 29 Oct 2014 09:21:51

Generated On: 18 Jul 2016 22:07:14

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (30)

Data signed: (Heart1) 29 Oct 2014 09:21:51

Generated On: 18 Jul 2016 22:07:14

Transmission Type Cumulative ☒

Subject ID or Number

Subject Sex M

Subject Date of Birth (b) (6)

Visit Name DAY0

Visit Type Scheduled ☒

Accession ID B428104

Actual Collection Time 06:12

Specimen Condition

Battery ID UA1538

Battery Name URINE MACRO PANEL

Lab Test ID UAT3

Lab Test Name UR PH

Test ID

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (30)

Data signed: (Heart1) 29 Oct 2014 09:21:51

Generated On: 18 Jul 2016 22:07:14

Test Status	Done <input type="radio"/>
Reported Text Result	5.5
Reported Numeric Result	5.5
Reference Range low	5.0
Reference Range high	8.0
Range Units	
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	
SI Numeric Result	
SI Reference Range Low	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (30)

Data signed: (Heart1) 29 Oct 2014 09:21:51

Generated On: 18 Jul 2016 22:07:14

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (31)

Data signed: (Heart1) 29 Oct 2014 09:21:51

Generated On: 18 Jul 2016 22:07:14

Transmission Type Cumulative ☒

Subject ID or Number

Subject Sex M

Subject Date of Birth (b) (6)

Visit Name DAY0

Visit Type Scheduled ☒

Accession ID B428104

Actual Collection Time 06:12

Specimen Condition

Battery ID UA1538

Battery Name URINE MACRO PANEL

Lab Test ID UAT43

Lab Test Name UR BLOOD

Test ID

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230


Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (31)

Data signed: (Heart1) 29 Oct 2014 09:21:51

Generated On: 18 Jul 2016 22:07:14

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

SI Numeric Result

SI Reference Range Low

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (31)

Data signed: (Heart1) 29 Oct 2014 09:21:51

Generated On: 18 Jul 2016 22:07:14

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (32)

Data signed: (Heart1) 29 Oct 2014 09:21:51

Generated On: 18 Jul 2016 22:07:14

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	M
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Subject Date of Birth	(b) (6)
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Visit Name	DAY0
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	B428104
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Actual Collection Time	06:12
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Specimen Condition	<hr/>
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Battery ID	UA1538
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Battery Name	URINE MACRO PANEL
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Lab Test ID	UAT49
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Lab Test Name	UR PROTEIN
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Test ID	<hr/>
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ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230


Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (32)

Data signed: (Heart1) 29 Oct 2014 09:21:51

Generated On: 18 Jul 2016 22:07:14

Test Status

Done 

Reported Text Result

TRACE

Reported Numeric Result

Reference Range low

Reference Range high

Range Units

Conventional Text Result

Conventional Numeric Result

Conventional Reference Range Low

Conventional Reference Range High

Conventional Units

SI Text Result

SI Numeric Result

SI Reference Range Low

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (32)

Data signed: (Heart1) 29 Oct 2014 09:21:51

Generated On: 18 Jul 2016 22:07:14

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

High ☒

Clinically Significant?

No ☒

Comment

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (33)

Data signed: (Heart1) 29 Oct 2014 09:21:51

Generated On: 18 Jul 2016 22:07:14

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6)

Visit Name DAY0

Visit Type Scheduled ☒

Accession ID B428104

Actual Collection Time 06:12

Specimen Condition _____

Battery ID UA1538

Battery Name URINE MACRO PANEL

Lab Test ID UAT5

Lab Test Name UR GLUCOSE

Test ID _____

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230


Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (33)

Data signed: (Heart1) 29 Oct 2014 09:21:51

Generated On: 18 Jul 2016 22:07:14

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

SI Numeric Result

SI Reference Range Low

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (33)

Data signed: (Heart1) 29 Oct 2014 09:21:51

Generated On: 18 Jul 2016 22:07:14

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (34)

Data signed: (Heart1) 29 Oct 2014 09:21:51

Generated On: 18 Jul 2016 22:07:14

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6)

Visit Name DAY0

Visit Type Scheduled ☒

Accession ID B428104

Actual Collection Time 06:12

Specimen Condition _____

Battery ID UA1538

Battery Name URINE MACRO PANEL

Lab Test ID UAT7

Lab Test Name UR BILIRUBIN

Test ID _____

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230


Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (34)

Data signed: (Heart1) 29 Oct 2014 09:21:51

Generated On: 18 Jul 2016 22:07:14

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

SI Numeric Result

SI Reference Range Low

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (34)

Data signed: (Heart1) 29 Oct 2014 09:21:51

Generated On: 18 Jul 2016 22:07:14

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (35)

Data signed: (Heart1) 29 Oct 2014 09:21:51

Generated On: 18 Jul 2016 22:07:14

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6)

Visit Name DAY0

Visit Type Scheduled ☒

Accession ID B428104

Actual Collection Time 06:12

Specimen Condition _____

Battery ID RC1029

Battery Name TRIGLYCERIDES

Lab Test ID RCT19

Lab Test Name TRIGLYCERIDES (GPO)

Test ID _____

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (35)

Data signed: (Heart1) 29 Oct 2014 09:21:51

Generated On: 18 Jul 2016 22:07:14

Test Status	Done <input type="radio"/>
Reported Text Result	194
Reported Numeric Result	194
Reference Range low	50
Reference Range high	321
Range Units	MG/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	
SI Numeric Result	
SI Reference Range Low	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (35)

Data signed: (Heart1) 29 Oct 2014 09:21:51

Generated On: 18 Jul 2016 22:07:14

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (36)

Data signed: (Heart1) 29 Oct 2014 09:21:51

Generated On: 18 Jul 2016 22:07:14

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	M
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Subject Date of Birth	(b) (6)
-----------------------	---------

Visit Name	DAY0
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	B428104
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Actual Collection Time	06:12
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Specimen Condition	<hr/>
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Battery ID	RC1092
------------	--------

Battery Name	FASTING GLUCOSE
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Lab Test ID	RCT142
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Lab Test Name	FASTING GLUCOSE
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Test ID	<hr/>
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ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (36)

Data signed: (Heart1) 29 Oct 2014 09:21:51

Generated On: 18 Jul 2016 22:07:14

Test Status	Done <input type="radio"/>
Reported Text Result	90
Reported Numeric Result	90
Reference Range low	70
Reference Range high	100
Range Units	MG/DL
Conventional Text Result	<input type="text"/>
Conventional Numeric Result	<input type="text"/>
Conventional Reference Range Low	<input type="text"/>
Conventional Reference Range High	<input type="text"/>
Conventional Units	<input type="text"/>
SI Text Result	<input type="text"/>
SI Numeric Result	<input type="text"/>
SI Reference Range Low	<input type="text"/>

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (36)

Data signed: (Heart1) 29 Oct 2014 09:21:51

Generated On: 18 Jul 2016 22:07:14

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (37)

Data signed: (Heart1) 29 Oct 2014 09:21:51

Generated On: 18 Jul 2016 22:07:14

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	M
-------------	---

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

Visit Name	DAY0
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	B428104
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Actual Collection Time	06:12
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Specimen Condition	<hr/>
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Battery ID	RC272
------------	-------

Battery Name	TOTAL CHOLESTEROL
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Lab Test ID	RCT20
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Lab Test Name	CHOLESTEROL (HIGH PERFORMANCE)
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ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (37)

Data signed: (Heart1) 29 Oct 2014 09:21:51

Generated On: 18 Jul 2016 22:07:14

Test ID	
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	239
Reported Numeric Result	239
Reference Range low	150
Reference Range high	264
Range Units	MG/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	
SI Numeric Result	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Lab_BU_CCLS (37)

Data signed: (Heart1) 29 Oct 2014 09:21:51

Generated On: 18 Jul 2016 22:07:14

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Lab_BU Risk markers

Data signed: (Heart1) 29 Oct 2014 09:22:22

Generated On: 18 Jul 2016 22:07:14

Actual Collection Date	2014 01 24
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Battery Name	FIBRINOGEN
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ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Lab_BU Risk markers (1)

Data signed: (Heart1) 29 Oct 2014 09:22:22

Generated On: 18 Jul 2016 22:07:14

Actual Collection Date	2014 01 24
------------------------	------------

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	
----------------------	--

Subject Sex	M
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Subject Date of Birth	(b) (6)
-----------------------	---------

Visit ID or Number	DAY0
--------------------	------

Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	B428104
--------------	---------

Actual Collection Time	06:12
------------------------	-------

Specimen Condition	
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Battery ID	CG267
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Battery Name	FIBRINOGEN
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Lab Test ID	CGT285
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Test ID	
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ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Lab_BU Risk markers (1)

Data signed: (Heart1) 29 Oct 2014 09:22:22

Generated On: 18 Jul 2016 22:07:14

Lab Test Name	FIBRINOGEN
Test Status	Done 
Reported Text Result	287
Reported Numeric Result	287
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	
SI Reference Range Low	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Lab_BU Risk markers (1)

Data signed: (Heart1) 29 Oct 2014 09:22:22

Generated On: 18 Jul 2016 22:07:14

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

SI Numeric Result

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Lab_BU Risk markers

Data signed: (Heart1) 29 Oct 2014 09:22:24

Generated On: 18 Jul 2016 22:07:14

Actual Collection Date	2014 01 24
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Battery Name	HOMOCYSTEINE
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ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Lab_BU Risk markers (1)

Data signed: (Heart1) 29 Oct 2014 09:22:24

Generated On: 18 Jul 2016 22:07:14

Actual Collection Date	2014 01 24
------------------------	------------

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	
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Subject Sex	M
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Subject Date of Birth	(b) (6)
-----------------------	---------

Visit ID or Number	DAY0
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	B428104
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Actual Collection Time	06:12
------------------------	-------

Specimen Condition	
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Battery ID	CN236
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Battery Name	HOMOCYSTEINE
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Lab Test ID	CNT145
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Test ID	
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ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Lab_BU Risk markers (1)

Data signed: (Heart1) 29 Oct 2014 09:22:24

Generated On: 18 Jul 2016 22:07:14

Lab Test Name	HOMOCYSTEINE, EDTAPL
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	48.27
Reported Numeric Result	48.27
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	
SI Reference Range Low	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Lab_BU Risk markers (1)

Data signed: (Heart1) 29 Oct 2014 09:22:24

Generated On: 18 Jul 2016 22:07:14

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

High ☒

SI Numeric Result

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Lab_BU Risk markers

Data signed: (Heart1) 29 Oct 2014 09:22:26

Generated On: 18 Jul 2016 22:07:14

Actual Collection Date	2014 01 24
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Battery Name	SICAM-1
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ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Lab_BU Risk markers (1)

Data signed: (Heart1) 29 Oct 2014 09:22:26

Generated On: 18 Jul 2016 22:07:14

Actual Collection Date	2014 01 24
------------------------	------------

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	
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Subject Sex	M
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Subject Date of Birth	(b) (6)
-----------------------	---------

Visit ID or Number	DAY0
--------------------	------

Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	B428104
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Actual Collection Time	06:12
------------------------	-------

Specimen Condition	
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Battery ID	IM2293
------------	--------

Battery Name	SICAM-1
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Lab Test ID	IMT1768
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Test ID	
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ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Lab_BU Risk markers (1)

Data signed: (Heart1) 29 Oct 2014 09:22:26

Generated On: 18 Jul 2016 22:07:14

Lab Test Name	SICAM-1-RUO
Test Status	Done <input type="radio"/>
Reported Text Result	285.6
Reported Numeric Result	285.6
Reference Range low	98.8
Reference Range high	320.0
Range Units	NG/ML
Conventional Text Result	<input type="text"/>
Conventional Numeric Result	<input type="text"/>
Conventional Reference Range Low	<input type="text"/>
Conventional Reference Range High	<input type="text"/>
Conventional Units	<input type="text"/>
SI Text Result	<input type="text"/>
SI Reference Range Low	<input type="text"/>

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Lab_BU Risk markers (1)

Data signed: (Heart1) 29 Oct 2014 09:22:26

Generated On: 18 Jul 2016 22:07:14

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

SI Numeric Result

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Lab_BU Risk markers

Data signed: (Heart1) 29 Oct 2014 09:22:28

Generated On: 18 Jul 2016 22:07:14

Actual Collection Date	2014 01 24
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Battery Name	HBA1C
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ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Lab_BU Risk markers (1)

Data signed: (Heart1) 29 Oct 2014 09:22:28

Generated On: 18 Jul 2016 22:07:14

Actual Collection Date	2014 01 24
------------------------	------------

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	
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Subject Sex	M
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Subject Date of Birth	(b) (6)
-----------------------	---------

Visit ID or Number	DAY0
--------------------	------

Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	B428104
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Actual Collection Time	06:12
------------------------	-------

Specimen Condition	
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Battery ID	HM1072
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Battery Name	HBA1C
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Lab Test ID	HMT370
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Test ID	
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ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Lab_BU Risk markers (1)

Data signed: (Heart1) 29 Oct 2014 09:22:28

Generated On: 18 Jul 2016 22:07:14

Lab Test Name	HEMOGLOBIN A1C,VARIANT(-70)
Test Status	Done <input type="radio"/>
Reported Text Result	4.8
Reported Numeric Result	4.8
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	
SI Text Result	
SI Reference Range Low	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Lab_BU Risk markers (1)

Data signed: (Heart1) 29 Oct 2014 09:22:28

Generated On: 18 Jul 2016 22:07:14

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

SI Numeric Result

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Lab_BU Risk markers

Data signed: (Heart1) 29 Oct 2014 09:22:30

Generated On: 18 Jul 2016 22:07:14

Actual Collection Date	2014 01 24
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Battery Name	HDL
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ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Lab_BU Risk markers (1)

Data signed: (Heart1) 29 Oct 2014 09:22:30

Generated On: 18 Jul 2016 22:07:14

Actual Collection Date	2014 01 24
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Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	
----------------------	--

Subject Sex	M
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Subject Date of Birth	(b) (6)
-----------------------	---------

Visit ID or Number	DAY0
--------------------	------

Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	B428104
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Actual Collection Time	06:12
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Specimen Condition	
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Battery ID	RC6871
------------	--------

Battery Name	HDL
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Lab Test ID	RCT1684
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Test ID	
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ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Lab_BU Risk markers (1)

Data signed: (Heart1) 29 Oct 2014 09:22:30

Generated On: 18 Jul 2016 22:07:14

Lab Test Name	DIRECT HDL-C 3RD GENERATION
Test Status	Done <input type="radio"/>
Reported Text Result	36
Reported Numeric Result	36
Reference Range low	28
Reference Range high	63
Range Units	MG/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	
SI Reference Range Low	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Lab_BU Risk markers (1)

Data signed: (Heart1) 29 Oct 2014 09:22:30

Generated On: 18 Jul 2016 22:07:14

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

SI Numeric Result

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Lab_BU Risk markers

Data signed: (Heart1) 29 Oct 2014 09:22:32

Generated On: 18 Jul 2016 22:07:14

Actual Collection Date	2014 01 24
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Battery Name	LDL
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ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Lab_BU Risk markers (1)

Data signed: (Heart1) 29 Oct 2014 09:22:32

Generated On: 18 Jul 2016 22:07:14

Actual Collection Date	2014 01 24
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Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	
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Subject Sex	M
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Subject Date of Birth	(b) (6)
-----------------------	---------

Visit ID or Number	DAY0
--------------------	------

Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	B428104
--------------	---------

Actual Collection Time	06:12
------------------------	-------

Specimen Condition	
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Battery ID	RC9267
------------	--------

Battery Name	LDL
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Lab Test ID	RCT2394
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Test ID	
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ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Lab_BU Risk markers (1)

Data signed: (Heart1) 29 Oct 2014 09:22:32

Generated On: 18 Jul 2016 22:07:14

Lab Test Name	DIRECT LDL-C 2ND GEN (-70)
Test Status	Done <input checked="" type="radio"/>
Reported Text Result	174
Reported Numeric Result	174
Reference Range low	78
Reference Range high	185
Range Units	MG/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	
SI Reference Range Low	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Lab_BU Risk markers (1)

Data signed: (Heart1) 29 Oct 2014 09:22:32

Generated On: 18 Jul 2016 22:07:14

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

SI Numeric Result

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Lab_BU Risk markers

Data signed: (Heart1) 29 Oct 2014 09:22:34

Generated On: 18 Jul 2016 22:07:14

Actual Collection Date	2014 01 24
------------------------	------------

Battery Name	CRP
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ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Lab_BU Risk markers (2)

Data signed: (Heart1) 29 Oct 2014 09:22:34

Generated On: 18 Jul 2016 22:07:14

Actual Collection Date	2014 01 24
------------------------	------------

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	
----------------------	--

Subject Sex	M
-------------	---

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

Visit ID or Number	DAY0
--------------------	------

Visit Type	Scheduled <input checked="" type="radio"/>
------------	--

Accession ID	B428104
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Actual Collection Time	06:12
------------------------	-------

Specimen Condition	
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Battery ID	SC1088
------------	--------

Battery Name	CRP
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Lab Test ID	SCT1528
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Test ID	
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ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Lab_BU Risk markers (2)

Data signed: (Heart1) 29 Oct 2014 09:22:34

Generated On: 18 Jul 2016 22:07:14

Lab Test Name	C-REACTIVE PROTEIN (NHS)-QT
Test Status	Done <input type="radio"/>
Reported Text Result	0.036
Reported Numeric Result	0.036
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	
SI Text Result	
SI Reference Range Low	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Baseline (Day 0)

Form: Lab_BU Risk markers (2)

Data signed: (Heart1) 29 Oct 2014 09:22:34

Generated On: 18 Jul 2016 22:07:14

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

SI Numeric Result

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Day 1

Form: Date of Visit

Data signed: (Heart1) 29 Oct 2014 09:22:39

Generated On: 18 Jul 2016 22:07:14

Date of Visit

25 JAN 2014
DD/MMM/YYYY

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Day 1

Form: Vital Signs

Data signed: (Heart1) 29 Oct 2014 09:22:39

Generated On: 18 Jul 2016 22:07:14

Were Vitals Signs assessed?

Yes ☒

If No, please specify the reason: _____

Has the subject smoked within 15 minutes prior to assessment

No ☒

Time of assessment

10:22
hour:min 24-hour clock

Pulse rate

62
beats per minute

Respiratory rate

15
breaths per minute

Blood Pressure (systolic)

111
mmHg

Blood Pressure (diastolic)

65
mmHg

Vital Signs Position of Subject

Supine ☒

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Day 1

Form: Plasma Nicotine Sample

Data signed: (Heart1) 29 Oct 2014 09:22:39

Generated On: 18 Jul 2016 22:07:14

Not Done

False

If Not Done, please specify the reason:

Date
DD/MMM/YYYY

Time
hour:min 24-hour clock

Record Number

25 JAN 2014

20:18

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Day 1

Form: Plasma Cotinine Sample

Data signed: (Heart1) 29 Oct 2014 09:22:40

Generated On: 18 Jul 2016 22:07:14

Not Done

False

If Not Done, please specify the reason:

Date
DD/MMM/YYYY

Time
hour:min 24-hour clock

Record number

25 JAN 2014

20:18

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Day 1

Form: CoHb Blood Sample

Data signed: (Heart1) 29 Oct 2014 09:22:40

Generated On: 18 Jul 2016 22:07:14

Not Done

False

If Not Done, please specify the reason:

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Day 1

Form: CO Breath Test (1)

Data signed: (Heart1) 29 Oct 2014 09:22:40

Generated On: 18 Jul 2016 22:07:14

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

If Not Done, please specify the reason: _____

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

Actual Time of Assessment hour:min 24-hour clock	06:37
---	-------

Result(ppm)	4
-------------	---

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Day 1

Form: CO Breath Test (2)

Data signed: (Heart1) 29 Oct 2014 09:22:40

Generated On: 18 Jul 2016 22:07:14

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

If Not Done, please specify the reason: _____

Scheduled Time	12:00 - 13:30 <input checked="" type="radio"/>
----------------	--

Actual Time of Assessment hour:min 24-hour clock	12:09
---	-------

Result(ppm)	4
-------------	---

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Day 1

Form: CO Breath Test (3)

Data signed: (Heart1) 29 Oct 2014 09:22:40

Generated On: 18 Jul 2016 22:07:14

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

If Not Done, please specify the reason: _____

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

Actual Time of Assessment hour:min 24-hour clock	16:03
---	-------

Result(ppm)	5
-------------	---

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Day 1

Form: CO Breath Test (4)

Data signed: (Heart1) 29 Oct 2014 09:22:40

Generated On: 18 Jul 2016 22:07:14

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

If Not Done, please specify the reason: _____

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

Actual Time of Assessment hour:min 24-hour clock	20:18
---	-------

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

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Day 1

Form: 24 hour urine collections

Data signed: (Heart1) 29 Oct 2014 09:22:40

Generated On: 18 Jul 2016 22:07:14

Start Time	06:30
	hour:min 24-hour clock

End Date	<hr/>
----------	-------

End Time	<hr/>
----------	-------

Volume	<hr/>
--------	-------

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Day 1

Form: Sample Urine Collection

Data signed: (Heart1) 29 Oct 2014 09:22:40

Generated On: 18 Jul 2016 22:07:14

Were samples collected?

No ☒

If No, please specify the reason:

DUE TO DISCONTINUE FROM
STUDY

How many primary tubes were collected? _____

How many back up tubes were collected? _____

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Day 1

Form: Questionnaire on smoking urges (QSU)

Generated On: 18 Jul 2016 22:07:14

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

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

Date of assessment	2014 JAN 25
--------------------	-------------

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	Strongly disagree <input type="radio"/>
---	---

3. If it were possible I would probably smoke now	Strongly disagree <input type="radio"/>
---	---

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

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

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

7. A cigarette would taste good now	Somewhat disagree <input type="radio"/>
-------------------------------------	---

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Day 1

Form: Questionnaire on smoking urges (QSU)

Generated On: 18 Jul 2016 22:07:14

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

9. Smoking would make me less depressed Agree ☐

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

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Day 1

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Generated On: 18 Jul 2016 22:07:14

Date of Birth

(b) (6)

Date of assessment
DD/MMM/YYYY

2014 JAN 25
DD/MMM/YYYY

Time of assessment

06:28
hour:min 24-hour clock

Assessment Status

Completed ☒

Please indicate for each of the items below, how you have been feeling over the past 24 hours

How have you been feeling over the past 24 hours?

Slight ☒

1. Angry, irritable, frustrated

How have you been feeling over the past 24 hours?

None ☒

2. Anxious, nervous

How have you been feeling over the past 24 hours?

None ☒

3. Depressed Mood, sad

How have you been feeling over the past 24 hours?

Slight ☒

4. Desire or craving to smoke

How have you been feeling over the past 24 hours?

Mild ☒

5. Difficulty concentrating

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Day 1

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Generated On: 18 Jul 2016 22:07:14

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?

Moderate ☒

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?

Mild ☒

9. Impatient

How have you been feeling over the past 24 hours?

None ☒

10. Constipation

How have you been feeling over the past 24 hours?

Mild ☒

11. Dizziness

How have you been feeling over the past 24 hours?

None ☒

12. Coughing

How have you been feeling over the past 24 hours?

None ☒

13. Dreaming or nightmares

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Day 1

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Generated On: 18 Jul 2016 22:07:14

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-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Day 1

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)

Generated On: 18 Jul 2016 22:07:14

Date of Birth

(b) (6)

Date of assessment=
DD/MMM/YYYY

2014 JAN 25
DD/MMM/YYYY

Time of assessment

20:02
hour:min 24-hour clock

Assessment Status

Completed ☒

1. Was smoking satisfying?

Moderately ☒

2. Did cigarettes taste good?

A lot ☒

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

Little ☒

4. Did smoking calm you down?

Quite a lot ☒

5. Did smoking make you feel more awake?

Quite a lot ☒

6. Did smoking make you feel less irritable?

Little ☒

7. Did smoking help you concentrate?

Moderately ☒

8. Did smoking reduce your hunger for food?

Extremely ☒

9. Did smoking make you dizzy?

Not at all ☒

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Day 1

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)

Generated On: 18 Jul 2016 22:07:14

10. Did smoking make you nauseous? A lot ☐

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

12. Did you enjoy smoking? Moderately ☐

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Day 1

Form: Cough Assessment

Generated On: 18 Jul 2016 22:07:14

Date of Birth

(b) (6)

Date of assessment
DD/MMM/YYYY

2014 JAN 25
DD/MMM/YYYY

Time of assessment

06:26
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-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Day 1

Form: Biomarker(Blood)

Data signed: (Heart1) 29 Oct 2014 09:22:42

Generated On: 18 Jul 2016 22:07:14

Sample type

PLASMA

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Day 1

Form: Biomarker(Blood) (1)

Data signed: (Heart1) 29 Oct 2014 09:22:42

Generated On: 18 Jul 2016 22:07:14

Sample type	PLASMA
Sample Barcode	05112170000610
Analyte	COT
Result	88.6
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	1
Celerion Study Number	AA99127-01
Date of Collection	2014-JAN-25
Timepoint-minutes	0
Urine Start Day	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Day 1

Form: Biomarker(Blood) (1)

Data signed: (Heart1) 29 Oct 2014 09:22:42

Generated On: 18 Jul 2016 22:07:14

Urine End Day

1

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Day 1

Form: Biomarker(Blood) (2)

Data signed: (Heart1) 29 Oct 2014 09:22:42

Generated On: 18 Jul 2016 22:07:14

Sample type	PLASMA
Sample Barcode	05112170000610
Analyte	NIC
Result	6.12
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	0
Day of Visit	1
Celerion Study Number	AA99127-01
Date of Collection	2014-JAN-25
Timepoint-minutes	0
Urine Start Day	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Day 1

Form: Biomarker(Blood) (2)

Data signed: (Heart1) 29 Oct 2014 09:22:42

Generated On: 18 Jul 2016 22:07:14

Urine End Day

1

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Day 1

Form: Lab-BU BIOMARKER(2014 JAN 25)

Data signed: (Heart1) 29 Oct 2014 09:22:41

Generated On: 18 Jul 2016 22:07:14

Test Category	BIOMARKER
---------------	-----------

Date of Sample Collection	2014 JAN 25
---------------------------	-------------

Date (BU)	2014/01/25
-----------	------------

Please document clinically relevant abnormalities in the AE form	
--	--

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Day 1

Form: Lab-BU BIOMARKER(2014 JAN 25)

Data signed: (Heart1) 29 Oct 2014 09:22:41

Generated On: 18 Jul 2016 22:07:14

Test Category	BIOMARKER
Date of Sample Collection	2014 JAN 25
Date (BU)	2014/01/25
Blood Sample time(BU)	2018
Urine Sample time(BU)	
Time of Blood Sample Collection	20:18
Time of Urine Sample Collection	
Test Name	COHB
Result	2.8
Text Result	
Unit	%
Lower limit	
Upper limit	
Flag	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Day 1

Form: Lab-BU BIOMARKER(2014 JAN 25)

Data signed: (Heart1) 29 Oct 2014 09:22:41

Generated On: 18 Jul 2016 22:07:14

Clinically Significant? _____

Comment _____

Result Category

N

Text Result Code _____

Reference Value Category _____

Timepoint(COHB)

20:00-21:30

Material Code

BLOOD

Chyle Comment Code _____

Chyle Comment English _____

Hemolysis Comment Code _____

Hemolysis Comment English _____

Specimen Comment Code 1 _____

Specimen English Comment 1 _____

Specimen Comment Code 2 _____

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Day 1

Form: Lab-BU BIOMARKER(2014 JAN 25)

Data signed: (Heart1) 29 Oct 2014 09:22:41

Generated On: 18 Jul 2016 22:07:14

Specimen English Comment 2

Result Supplementary Comment Code 1

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004672246

Please document clinically relevant abnormalities in the AE form

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Discharge (Confinement)

Form: Date of Discharge

Data signed: (Heart1) 29 Oct 2014 09:22:43

Generated On: 18 Jul 2016 22:07:14

Date of Visit

25 JAN 2014
DD/MMM/YYYY

Discharge Time

21:19
hour:min 24-hour clock

Is the subject continuing in the ambulatory period?

No ☐

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Discharge (Confinement)

Form: Vital Signs

Data signed: (Heart1) 29 Oct 2014 09:22:43

Generated On: 18 Jul 2016 22:07:14

Were Vitals Signs assessed?

Yes ☒

If No, please specify the reason: _____

Has the subject smoked within 15 minutes prior to
assessment

No ☒

Time of assessment

20:59
hour:min 24-hour clock

Pulse rate

71
beats per minute

Respiratory rate

16
breaths per minute

Blood Pressure (systolic)

119
mmHg

Blood Pressure (diastolic)

77
mmHg

Vital Signs Position of Subject

Supine ☒

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Discharge (Confinement)

Form: Advice on the risk of smoking and debriefing

Data signed: (Heart1) 29 Oct 2014 09:22:43

Generated On: 18 Jul 2016 22:07:14

Has the subject received advices on the risks of
smoking?

Yes ☒

Has a debriefing been performed about THS 2.2?

Yes ☒

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Discharge (Confinement)

Form: Physical Examination

Data signed: (Heart1) 29 Oct 2014 09:22:44

Generated On: 18 Jul 2016 22:07:14

Was the physical examination performed?

Yes ☒

If No, please specify the reason:

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Discharge (Confinement)

Form: Physical Examination (1)

Data signed: (Heart1) 29 Oct 2014 09:22:44

Generated On: 18 Jul 2016 22:07:14

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

System

General Appearance ☒

Outcome

Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done

False

Not Done; please specify the reason: _____

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Discharge (Confinement)

Form: Physical Examination (2)

Data signed: (Heart1) 29 Oct 2014 09:22:44

Generated On: 18 Jul 2016 22:07:14

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

System

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

Outcome

Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done

False

Not Done; please specify the reason: _____

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Discharge (Confinement)

Form: Physical Examination (3)

Data signed: (Heart1) 29 Oct 2014 09:22:44

Generated On: 18 Jul 2016 22:07:14

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

System

Thyroid Gland ☒

Outcome

Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done

False

Not Done; please specify the reason: _____

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Discharge (Confinement)

Form: Physical Examination (4)

Data signed: (Heart1) 29 Oct 2014 09:22:44

Generated On: 18 Jul 2016 22:07:14

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

System

Heart ☒

Outcome

Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done

False

Not Done; please specify the reason: _____

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Discharge (Confinement)

Form: Physical Examination (5)

Data signed: (Heart1) 29 Oct 2014 09:22:44

Generated On: 18 Jul 2016 22:07:14

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

System

Chest ☒

Outcome

Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done

False

Not Done; please specify the reason: _____

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Discharge (Confinement)

Form: Physical Examination (6)

Data signed: (Heart1) 29 Oct 2014 09:22:44

Generated On: 18 Jul 2016 22:07:14

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

System

Lungs ☒

Outcome

Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done

False

Not Done; please specify the reason: _____

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Discharge (Confinement)

Form: Physical Examination (7)

Data signed: (Heart1) 29 Oct 2014 09:22:44

Generated On: 18 Jul 2016 22:07:14

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

System

Gastrointestinal ☒

Outcome

Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done

False

Not Done; please specify the reason: _____

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Discharge (Confinement)

Form: Physical Examination (8)

Data signed: (Heart1) 29 Oct 2014 09:22:44

Generated On: 18 Jul 2016 22:07:14

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

System

Cardiovascular System ☒

Outcome

Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done

False

Not Done; please specify the reason: _____

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Discharge (Confinement)

Form: Physical Examination (9)

Data signed: (Heart1) 29 Oct 2014 09:22:44

Generated On: 18 Jul 2016 22:07:14

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

System

Neurologic ☒

Outcome

Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done

False

Not Done; please specify the reason: _____

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Discharge (Confinement)

Form: Physical Examination (10)

Data signed: (Heart1) 29 Oct 2014 09:22:44

Generated On: 18 Jul 2016 22:07:14

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

System

Skin ☒

Outcome

Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done

False

Not Done; please specify the reason: _____

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Discharge (Confinement)

Form: Physical Examination (11)

Data signed: (Heart1) 29 Oct 2014 09:22:44

Generated On: 18 Jul 2016 22:07:14

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

System

Back ☒

Outcome

Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done

False

Not Done; please specify the reason: _____

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Discharge (Confinement)

Form: Physical Examination (12)

Data signed: (Heart1) 29 Oct 2014 09:22:44

Generated On: 18 Jul 2016 22:07:14

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

System

Musculoskeletal ☒

Outcome

Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done

False

Not Done; please specify the reason: _____

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Discharge (Confinement)

Form: Physical Examination (13)

Data signed: (Heart1) 29 Oct 2014 09:22:44

Generated On: 18 Jul 2016 22:07:14

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

System

Abdomen ☒

Outcome

Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done

False

Not Done; please specify the reason: _____

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Discharge (Confinement)

Form: Physical Examination (14)

Data signed: (Heart1) 29 Oct 2014 09:22:44

Generated On: 18 Jul 2016 22:07:14

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

System

Dentition ☒

Outcome

Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done

False

Not Done; please specify the reason: _____

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Discharge (Confinement)

Form: Physical Examination (15)

Data signed: (Heart1) 29 Oct 2014 09:22:44

Generated On: 18 Jul 2016 22:07:14

Was the physical examination performed?

Yes ☒

If No, please specify the reason:

System

Other ☒

Other, Specify

Outcome

Abnormal, please specify

Clinically significant

Not Done

True

Not Done; please specify the reason:

THERE IS NO SPECIFIC.

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Discharge (Confinement)

Form: Physical Examination (16)

Data signed: (Heart1) 29 Oct 2014 09:22:44

Generated On: 18 Jul 2016 22:07:14

Was the physical examination performed?

Yes ☒

If No, please specify the reason:

System

Other ☒

Other, Specify

Outcome

Abnormal, please specify

Clinically significant

Not Done

True

Not Done; please specify the reason:

THERE IS NO SPECIFIC.

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Discharge (Confinement)

Form: Physical Examination (17)

Data signed: (Heart1) 29 Oct 2014 09:22:44

Generated On: 18 Jul 2016 22:07:14

Was the physical examination performed?

Yes ☒

If No, please specify the reason:

System

Other ☒

Other, Specify

Outcome

Abnormal, please specify

Clinically significant

Not Done

True

Not Done; please specify the reason:

THERE IS NO SPECIFIC.

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Discharge (Confinement)

Form: Physical Examination (18)

Data signed: (Heart1) 29 Oct 2014 09:22:44

Generated On: 18 Jul 2016 22:07:14

Was the physical examination performed?

Yes ☒

If No, please specify the reason:

System

Other ☒

Other, Specify

Outcome

Abnormal, please specify

Clinically significant

Not Done

True

Not Done; please specify the reason:

THERE IS NO SPECIFIC.

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Discharge (Confinement)

Form: Physical Examination (19)

Data signed: (Heart1) 29 Oct 2014 09:22:44

Generated On: 18 Jul 2016 22:07:14

Was the physical examination performed?

Yes ☒

If No, please specify the reason:

System

Other ☒

Other, Specify

Outcome

Abnormal, please specify

Clinically significant

Not Done

True

Not Done; please specify the reason:

THERE IS NO SPECIFIC.

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Discharge (Confinement)

Form: Weight

Data signed: (Heart1) 29 Oct 2014 09:22:47

Generated On: 18 Jul 2016 22:07:14

Measurement(s) assessed?

Yes ☒

If No, please specify the reason: _____

Date of Assessment

25 JAN 2014
DD/MMM/YYYY

Time of assessment

21:09
hour:min 24-hour clock

Weight

83.5
kg

BMI

28.6

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Discharge (Confinement)

Form: ECG (12-Lead Standard)

Data signed: (Heart1) 29 Oct 2014 09:22:48

Generated On: 18 Jul 2016 22:07:14

Was the ECG performed? Yes ☒

If No, please specify the reason: _____

Position Supine ☒

Heart Rate 66
beats per minute

QRS Interval 90
msec

QT Interval 382
msec

QTcB Interval 403
msec

PR Interval 158
msec

Interpretation Normal ☒

If Abnormal, Clinical Significance _____

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

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Discharge (Confinement)

Form: Spirometry without a short-acting bronchodilator

Data signed: (Heart1) 29 Oct 2014 09:22:48

Generated On: 18 Jul 2016 22:07:14

Was the spirometry performed? Yes ☒

If No, please specify the reason: _____

Category Without short-acting bronchodilator ☒

Time of assessment 21:11
hour:min 24-hour clock

Predicted FVC value 4.65
L

Best measured FVC value 4.66
L

Percent of predicted FVC value 100.2
%

Best measured FEV1 value 3.78
L

Predicted FEV1 value 4.11
L

Percent of predicted FEV1 value 91.9
%

Interpretation Normal ☒

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Discharge (Confinement)

Form: Spirometry without a short-acting bronchodilator

Data signed: (Heart1) 29 Oct 2014 09:22:48

Generated On: 18 Jul 2016 22:07:14

If Abnormal, Clinical Significance

If Not Clinically Significant or Clinically Significant, Please
specify the finding(s)

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Discharge (Confinement)

Form: Haematology

Data signed: (Heart1) 29 Oct 2014 09:22:48

Generated On: 18 Jul 2016 22:07:14

Were samples collected?

Yes ☒

If No, please specify the reason: _____

Was the subject fasting for at least 10 hours at time of
sample collection?

Yes ☒

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Discharge (Confinement)

Form: Clinical Chemistry

Data signed: (Heart1) 29 Oct 2014 09:22:48

Generated On: 18 Jul 2016 22:07:14

Were samples collected?

Yes ☒

If No, please specify the reason: _____

Was the subject fasting for at least 10 hours at time of
sample collection?

Yes ☒

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Discharge (Confinement)

Form: Urine analysis

Data signed: (Heart1) 29 Oct 2014 09:22:48

Generated On: 18 Jul 2016 22:07:14

Were samples collected?

Yes ☒

If No, please specify the reason:

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Discharge (Confinement)

Form: CO Breath Test

Data signed: (Heart1) 29 Oct 2014 09:22:48

Generated On: 18 Jul 2016 22:07:14

Assessment not done	False
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If Not Done, please specify the reason: _____

Actual Time of Assessment	21:13
	hour:min 24-hour clock

Result	3
	ppm

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (1)

Data signed: (Heart1) 29 Oct 2014 09:22:49

Generated On: 18 Jul 2016 22:07:14

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	M
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Subject Date of Birth	(b) (6)
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Visit Name	DISCHARGE
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	A369987
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Actual Collection Time	20:53
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Specimen Condition	<hr/>
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Battery ID	HM1821
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Battery Name	HEMATOLOGY&DIFFERENTIAL PANEL
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Lab Test ID	HMT10
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Lab Test Name	MONOCYTES
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ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (1)

Data signed: (Heart1) 29 Oct 2014 09:22:49

Generated On: 18 Jul 2016 22:07:14

Test ID	
Test Status	Done 
Reported Text Result	0.23
Reported Numeric Result	0.23
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	
SI Numeric Result	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (1)

Data signed: (Heart1) 29 Oct 2014 09:22:49

Generated On: 18 Jul 2016 22:07:14

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (2)

Data signed: (Heart1) 29 Oct 2014 09:22:49

Generated On: 18 Jul 2016 22:07:14

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6)

Visit Name DISCHARGE

Visit Type Scheduled ☒

Accession ID A369987

Actual Collection Time 20:53

Specimen Condition _____

Battery ID HM1821

Battery Name HEMATOLOGY&DIFFERENTIAL
PANEL

Lab Test ID HMT100

Lab Test Name MCH

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (2)

Data signed: (Heart1) 29 Oct 2014 09:22:49

Generated On: 18 Jul 2016 22:07:14

Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	32
Reported Numeric Result	32
Reference Range low	26
Reference Range high	34
Range Units	PG
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	
SI Numeric Result	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (2)

Data signed: (Heart1) 29 Oct 2014 09:22:49

Generated On: 18 Jul 2016 22:07:14

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (3)

Data signed: (Heart1) 29 Oct 2014 09:22:49

Generated On: 18 Jul 2016 22:07:14

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6)

Visit Name DISCHARGE

Visit Type Scheduled ☒

Accession ID A369987

Actual Collection Time 20:53

Specimen Condition _____

Battery ID HM1821

Battery Name HEMATOLOGY&DIFFERENTIAL
PANEL

Lab Test ID HMT102

Lab Test Name MCHC

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (3)

Data signed: (Heart1) 29 Oct 2014 09:22:49

Generated On: 18 Jul 2016 22:07:14

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	
SI Numeric Result	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (3)

Data signed: (Heart1) 29 Oct 2014 09:22:49

Generated On: 18 Jul 2016 22:07:14

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (4)

Data signed: (Heart1) 29 Oct 2014 09:22:49

Generated On: 18 Jul 2016 22:07:14

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6)

Visit Name DISCHARGE

Visit Type Scheduled ☒

Accession ID A369987

Actual Collection Time 20:53

Specimen Condition _____

Battery ID HM1821

Battery Name HEMATOLOGY&DIFFERENTIAL
PANEL

Lab Test ID HMT11

Lab Test Name EOSINOPHILS


ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (4)

Data signed: (Heart1) 29 Oct 2014 09:22:49

Generated On: 18 Jul 2016 22:07:14

Test ID	
Test Status	Done 
Reported Text Result	0.08
Reported Numeric Result	0.08
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	
SI Numeric Result	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (4)

Data signed: (Heart1) 29 Oct 2014 09:22:49

Generated On: 18 Jul 2016 22:07:14

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (5)

Data signed: (Heart1) 29 Oct 2014 09:22:49

Generated On: 18 Jul 2016 22:07:14

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6)

Visit Name DISCHARGE

Visit Type Scheduled ☒

Accession ID A369987

Actual Collection Time 20:53

Specimen Condition _____

Battery ID HM1821

Battery Name HEMATOLOGY&DIFFERENTIAL
PANEL

Lab Test ID HMT12

Lab Test Name BASOPHILS

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (5)

Data signed: (Heart1) 29 Oct 2014 09:22:49

Generated On: 18 Jul 2016 22:07:14

Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	0.05
Reported Numeric Result	0.05
Reference Range low	0.00
Reference Range high	0.20
Range Units	X10 ³ /UL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	
SI Numeric Result	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (5)

Data signed: (Heart1) 29 Oct 2014 09:22:49

Generated On: 18 Jul 2016 22:07:14

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (6)

Data signed: (Heart1) 29 Oct 2014 09:22:49

Generated On: 18 Jul 2016 22:07:14

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6)

Visit Name DISCHARGE

Visit Type Scheduled ☒

Accession ID A369987

Actual Collection Time 20:53

Specimen Condition _____

Battery ID HM1821

Battery Name HEMATOLOGY&DIFFERENTIAL
PANEL

Lab Test ID HMT13

Lab Test Name PLATELETS


ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (6)

Data signed: (Heart1) 29 Oct 2014 09:22:49

Generated On: 18 Jul 2016 22:07:14

Test ID	
Test Status	Done 
Reported Text Result	219
Reported Numeric Result	219
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	
SI Numeric Result	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (6)

Data signed: (Heart1) 29 Oct 2014 09:22:49

Generated On: 18 Jul 2016 22:07:14

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (7)

Data signed: (Heart1) 29 Oct 2014 09:22:49

Generated On: 18 Jul 2016 22:07:14

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6)

Visit Name DISCHARGE

Visit Type Scheduled ☒

Accession ID A369987

Actual Collection Time 20:53

Specimen Condition _____

Battery ID HM1821

Battery Name HEMATOLOGY&DIFFERENTIAL
PANEL

Lab Test ID HMT2

Lab Test Name HEMATOCRIT

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (7)

Data signed: (Heart1) 29 Oct 2014 09:22:49

Generated On: 18 Jul 2016 22:07:14

Test ID	<hr/>
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Test Status	Done 
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Reported Text Result	46
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Reported Numeric Result	46
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Reference Range low	39
---------------------	----

Reference Range high	54
----------------------	----

Range Units	%
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Conventional Text Result	<hr/>
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Conventional Numeric Result	<hr/>
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Conventional Reference Range Low	<hr/>
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Conventional Reference Range High	<hr/>
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Conventional Units	<hr/>
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SI Text Result	<hr/>
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SI Numeric Result	<hr/>
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ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (7)

Data signed: (Heart1) 29 Oct 2014 09:22:49

Generated On: 18 Jul 2016 22:07:14

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (8)

Data signed: (Heart1) 29 Oct 2014 09:22:49

Generated On: 18 Jul 2016 22:07:14

Transmission Type Cumulative ☒

Subject ID or Number

Subject Sex M

Subject Date of Birth (b) (6)

Visit Name DISCHARGE

Visit Type Scheduled ☒

Accession ID A369987

Actual Collection Time 20:53

Specimen Condition

Battery ID HM1821

Battery Name HEMATOLOGY&DIFFERENTIAL
PANEL

Lab Test ID HMT3

Lab Test Name RBC


ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (8)

Data signed: (Heart1) 29 Oct 2014 09:22:49

Generated On: 18 Jul 2016 22:07:14

Test ID	
Test Status	Done 
Reported Text Result	4.9
Reported Numeric Result	4.9
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	
SI Numeric Result	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (8)

Data signed: (Heart1) 29 Oct 2014 09:22:49

Generated On: 18 Jul 2016 22:07:14

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (9)

Data signed: (Heart1) 29 Oct 2014 09:22:49

Generated On: 18 Jul 2016 22:07:14

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6)

Visit Name DISCHARGE

Visit Type Scheduled ☒

Accession ID A369987

Actual Collection Time 20:53

Specimen Condition _____

Battery ID HM1821

Battery Name HEMATOLOGY&DIFFERENTIAL
PANEL

Lab Test ID HMT4

Lab Test Name MCV


ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (9)

Data signed: (Heart1) 29 Oct 2014 09:22:49

Generated On: 18 Jul 2016 22:07:14

Test ID	
Test Status	Done 
Reported Text Result	95
Reported Numeric Result	95
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	
SI Numeric Result	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (9)

Data signed: (Heart1) 29 Oct 2014 09:22:49

Generated On: 18 Jul 2016 22:07:14

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (10)

Data signed: (Heart1) 29 Oct 2014 09:22:49

Generated On: 18 Jul 2016 22:07:14

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	M
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Subject Date of Birth	(b) (6)
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Visit Name	DISCHARGE
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	A369987
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Actual Collection Time	20:53
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Specimen Condition	<hr/>
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Battery ID	HM1821
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Battery Name	HEMATOLOGY&DIFFERENTIAL PANEL
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Lab Test ID	HMT40
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Lab Test Name	HEMOGLOBIN
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ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (10)

Data signed: (Heart1) 29 Oct 2014 09:22:49

Generated On: 18 Jul 2016 22:07:14

Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	15.8
Reported Numeric Result	15.8
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	
SI Numeric Result	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (10)

Data signed: (Heart1) 29 Oct 2014 09:22:49

Generated On: 18 Jul 2016 22:07:14

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (11)

Data signed: (Heart1) 29 Oct 2014 09:22:49

Generated On: 18 Jul 2016 22:07:14

Transmission Type Cumulative ☒

Subject ID or Number

Subject Sex M

Subject Date of Birth (b) (6)

Visit Name DISCHARGE

Visit Type Scheduled ☒

Accession ID A369987

Actual Collection Time 20:53

Specimen Condition

Battery ID HM1821

Battery Name HEMATOLOGY&DIFFERENTIAL
PANEL

Lab Test ID HMT7

Lab Test Name WBC

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (11)

Data signed: (Heart1) 29 Oct 2014 09:22:49

Generated On: 18 Jul 2016 22:07:14

Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	6.96
Reported Numeric Result	6.96
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	
SI Numeric Result	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (11)

Data signed: (Heart1) 29 Oct 2014 09:22:49

Generated On: 18 Jul 2016 22:07:14

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (12)

Data signed: (Heart1) 29 Oct 2014 09:22:49

Generated On: 18 Jul 2016 22:07:14

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6)

Visit Name DISCHARGE

Visit Type Scheduled ☒

Accession ID A369987

Actual Collection Time 20:53

Specimen Condition _____

Battery ID HM1821

Battery Name HEMATOLOGY&DIFFERENTIAL
PANEL

Lab Test ID HMT71

Lab Test Name RBC MORPHOLOGY 1

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Discharge (Confinement)


Form: Lab_BU_CCLS (12)

Data signed: (Heart1) 29 Oct 2014 09:22:49

Generated On: 18 Jul 2016 22:07:14

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

SI Numeric Result

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (12)

Data signed: (Heart1) 29 Oct 2014 09:22:49

Generated On: 18 Jul 2016 22:07:14

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (13)

Data signed: (Heart1) 29 Oct 2014 09:22:49

Generated On: 18 Jul 2016 22:07:14

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6)

Visit Name DISCHARGE

Visit Type Scheduled ☒

Accession ID A369987

Actual Collection Time 20:53

Specimen Condition _____

Battery ID HM1821

Battery Name HEMATOLOGY&DIFFERENTIAL
PANEL

Lab Test ID HMT8

Lab Test Name NEUTROPHILS

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (13)

Data signed: (Heart1) 29 Oct 2014 09:22:49

Generated On: 18 Jul 2016 22:07:14

Test ID	
Test Status	Done <input type="radio"/>
Reported Text Result	4.03
Reported Numeric Result	4.03
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	
SI Numeric Result	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (13)

Data signed: (Heart1) 29 Oct 2014 09:22:49

Generated On: 18 Jul 2016 22:07:14

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (14)

Data signed: (Heart1) 29 Oct 2014 09:22:49

Generated On: 18 Jul 2016 22:07:14

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	M
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Subject Date of Birth	(b) (6)
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Visit Name	DISCHARGE
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	A369987
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Actual Collection Time	20:53
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Specimen Condition	<hr/>
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Battery ID	HM1821
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Battery Name	HEMATOLOGY&DIFFERENTIAL PANEL
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Lab Test ID	HMT9
-------------	------

Lab Test Name	LYMPHOCYTES
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ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (14)

Data signed: (Heart1) 29 Oct 2014 09:22:49

Generated On: 18 Jul 2016 22:07:14

Test ID	
Test Status	Done <input 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	
SI Numeric Result	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (14)

Data signed: (Heart1) 29 Oct 2014 09:22:49

Generated On: 18 Jul 2016 22:07:14

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (15)

Data signed: (Heart1) 29 Oct 2014 09:22:49

Generated On: 18 Jul 2016 22:07:14

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6)

Visit Name DISCHARGE

Visit Type Scheduled ☒

Accession ID A369987

Actual Collection Time 20:53

Specimen Condition _____

Battery ID RC9255

Battery Name CHEMISTRY PANEL

Lab Test ID RCT1

Lab Test Name TOTAL BILIRUBIN

Test ID _____

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (15)

Data signed: (Heart1) 29 Oct 2014 09:22:49

Generated On: 18 Jul 2016 22:07:14

Test Status	Done <input type="radio"/>
Reported Text Result	0.7
Reported Numeric Result	0.7
Reference Range low	0.2
Reference Range high	1.2
Range Units	MG/DL
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	
SI Numeric Result	
SI Reference Range Low	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (15)

Data signed: (Heart1) 29 Oct 2014 09:22:49

Generated On: 18 Jul 2016 22:07:14

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (16)

Data signed: (Heart1) 29 Oct 2014 09:22:49

Generated On: 18 Jul 2016 22:07:14

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6)

Visit Name DISCHARGE

Visit Type Scheduled ☒

Accession ID A369987

Actual Collection Time 20:53

Specimen Condition _____

Battery ID RC9255

Battery Name CHEMISTRY PANEL

Lab Test ID RCT12

Lab Test Name TOTAL PROTEIN

Test ID _____

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (16)

Data signed: (Heart1) 29 Oct 2014 09:22:49

Generated On: 18 Jul 2016 22:07:14

Test Status	Done <input type="radio"/>
Reported Text Result	6.9
Reported Numeric Result	6.9
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	
SI Numeric Result	
SI Reference Range Low	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (16)

Data signed: (Heart1) 29 Oct 2014 09:22:49

Generated On: 18 Jul 2016 22:07:14

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (17)

Data signed: (Heart1) 29 Oct 2014 09:22:49

Generated On: 18 Jul 2016 22:07:14

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6)

Visit Name DISCHARGE

Visit Type Scheduled ☒

Accession ID A369987

Actual Collection Time 20:53

Specimen Condition _____

Battery ID RC9255

Battery Name CHEMISTRY PANEL

Lab Test ID RCT13

Lab Test Name ALBUMIN

Test ID _____

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (17)

Data signed: (Heart1) 29 Oct 2014 09:22:49

Generated On: 18 Jul 2016 22:07:14

Test Status	Done <input type="radio"/>
Reported Text Result	4.7
Reported Numeric Result	4.7
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	
SI Numeric Result	
SI Reference Range Low	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (17)

Data signed: (Heart1) 29 Oct 2014 09:22:49

Generated On: 18 Jul 2016 22:07:14

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (18)

Data signed: (Heart1) 29 Oct 2014 09:22:49

Generated On: 18 Jul 2016 22:07:14

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6)

Visit Name DISCHARGE

Visit Type Scheduled ☒

Accession ID A369987

Actual Collection Time 20:53

Specimen Condition _____

Battery ID RC9255

Battery Name CHEMISTRY PANEL

Lab Test ID RCT1407

Lab Test Name ALKALINE PHOSPHATASE

Test ID _____

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (18)

Data signed: (Heart1) 29 Oct 2014 09:22:49

Generated On: 18 Jul 2016 22:07:14

Test Status	Done <input type="radio"/>
Reported Text Result	86
Reported Numeric Result	86
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	
SI Numeric Result	
SI Reference Range Low	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (18)

Data signed: (Heart1) 29 Oct 2014 09:22:49

Generated On: 18 Jul 2016 22:07:14

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (19)

Data signed: (Heart1) 29 Oct 2014 09:22:49

Generated On: 18 Jul 2016 22:07:14

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6)

Visit Name DISCHARGE

Visit Type Scheduled ☒

Accession ID A369987

Actual Collection Time 20:53

Specimen Condition _____

Battery ID RC9255

Battery Name CHEMISTRY PANEL

Lab Test ID RCT1408

Lab Test Name LDH

Test ID _____


ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (19)

Data signed: (Heart1) 29 Oct 2014 09:22:49

Generated On: 18 Jul 2016 22:07:14

Test Status	Done 
Reported Text Result	120
Reported Numeric Result	120
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	
SI Numeric Result	
SI Reference Range Low	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (19)

Data signed: (Heart1) 29 Oct 2014 09:22:49

Generated On: 18 Jul 2016 22:07:14

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (20)

Data signed: (Heart1) 29 Oct 2014 09:22:49

Generated On: 18 Jul 2016 22:07:14

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6)

Visit Name DISCHARGE

Visit Type Scheduled ☒

Accession ID A369987

Actual Collection Time 20:53

Specimen Condition _____

Battery ID RC9255

Battery Name CHEMISTRY PANEL

Lab Test ID RCT15

Lab Test Name SERUM SODIUM

Test ID _____

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (20)

Data signed: (Heart1) 29 Oct 2014 09:22:49

Generated On: 18 Jul 2016 22:07:14

Test Status	Done <input type="radio"/>
Reported Text Result	140
Reported Numeric Result	140
Reference Range low	132
Reference Range high	147
Range Units	MEQ/L
Conventional Text Result	<input type="text"/>
Conventional Numeric Result	<input type="text"/>
Conventional Reference Range Low	<input type="text"/>
Conventional Reference Range High	<input type="text"/>
Conventional Units	<input type="text"/>
SI Text Result	<input type="text"/>
SI Numeric Result	<input type="text"/>
SI Reference Range Low	<input type="text"/>

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (20)

Data signed: (Heart1) 29 Oct 2014 09:22:49

Generated On: 18 Jul 2016 22:07:14

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (21)

Data signed: (Heart1) 29 Oct 2014 09:22:49

Generated On: 18 Jul 2016 22:07:14

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6)

Visit Name DISCHARGE

Visit Type Scheduled ☒

Accession ID A369987

Actual Collection Time 20:53

Specimen Condition _____

Battery ID RC9255

Battery Name CHEMISTRY PANEL

Lab Test ID RCT16

Lab Test Name SERUM POTASSIUM

Test ID _____

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (21)

Data signed: (Heart1) 29 Oct 2014 09:22:49

Generated On: 18 Jul 2016 22:07:14

Test Status	Done <input type="radio"/>
Reported Text Result	4.1
Reported Numeric Result	4.1
Reference Range low	3.4
Reference Range high	5.4
Range Units	MEQ/L
Conventional Text Result	
Conventional Numeric Result	
Conventional Reference Range Low	
Conventional Reference Range High	
Conventional Units	
SI Text Result	
SI Numeric Result	
SI Reference Range Low	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (21)

Data signed: (Heart1) 29 Oct 2014 09:22:49

Generated On: 18 Jul 2016 22:07:14

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (22)

Data signed: (Heart1) 29 Oct 2014 09:22:49

Generated On: 18 Jul 2016 22:07:14

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	M
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Subject Date of Birth	(b) (6)
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Visit Name	DISCHARGE
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	A369987
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Actual Collection Time	20:53
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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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Lab Test Name	DIRECT BILIRUBIN
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Test ID	<hr/>
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ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (22)

Data signed: (Heart1) 29 Oct 2014 09:22:49

Generated On: 18 Jul 2016 22:07:14

Test Status	Done <input type="radio"/>
Reported Text Result	0.2
Reported Numeric Result	0.2
Reference Range low	0.0
Reference Range high	0.4
Range Units	MG/DL
Conventional Text Result	<input type="text"/>
Conventional Numeric Result	<input type="text"/>
Conventional Reference Range Low	<input type="text"/>
Conventional Reference Range High	<input type="text"/>
Conventional Units	<input type="text"/>
SI Text Result	<input type="text"/>
SI Numeric Result	<input type="text"/>
SI Reference Range Low	<input type="text"/>

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (22)

Data signed: (Heart1) 29 Oct 2014 09:22:49

Generated On: 18 Jul 2016 22:07:14

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (23)

Data signed: (Heart1) 29 Oct 2014 09:22:49

Generated On: 18 Jul 2016 22:07:14

Transmission Type Cumulative ☒

Subject ID or Number

Subject Sex M

Subject Date of Birth (b) (6)

Visit Name DISCHARGE

Visit Type Scheduled ☒

Accession ID A369987

Actual Collection Time 20:53

Specimen Condition

Battery ID RC9255

Battery Name CHEMISTRY PANEL

Lab Test ID RCT3

Lab Test Name GGT

Test ID

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (23)

Data signed: (Heart1) 29 Oct 2014 09:22:49

Generated On: 18 Jul 2016 22:07:14

Test Status	Done <input type="radio"/>
Reported Text Result	37
Reported Numeric Result	37
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	
SI Numeric Result	
SI Reference Range Low	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (23)

Data signed: (Heart1) 29 Oct 2014 09:22:49

Generated On: 18 Jul 2016 22:07:14

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (24)

Data signed: (Heart1) 29 Oct 2014 09:22:49

Generated On: 18 Jul 2016 22:07:14

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	M
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Subject Date of Birth	(b) (6)
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Visit Name	DISCHARGE
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	A369987
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Actual Collection Time	20:53
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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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Lab Test Name	CREATININE (RATE BLANKED)
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Test ID	<hr/>
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ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (24)

Data signed: (Heart1) 29 Oct 2014 09:22:49

Generated On: 18 Jul 2016 22:07:14

Test Status	Done <input type="radio"/>
Reported Text Result	1.0
Reported Numeric Result	1.0
Reference Range low	0.5
Reference Range high	1.2
Range Units	MG/DL
Conventional Text Result	<input type="text"/>
Conventional Numeric Result	<input type="text"/>
Conventional Reference Range Low	<input type="text"/>
Conventional Reference Range High	<input type="text"/>
Conventional Units	<input type="text"/>
SI Text Result	<input type="text"/>
SI Numeric Result	<input type="text"/>
SI Reference Range Low	<input type="text"/>

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (24)

Data signed: (Heart1) 29 Oct 2014 09:22:49

Generated On: 18 Jul 2016 22:07:14

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (25)

Data signed: (Heart1) 29 Oct 2014 09:22:49

Generated On: 18 Jul 2016 22:07:14

Transmission Type Cumulative ☐

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6) 

Visit Name DISCHARGE

Visit Type Scheduled ☐

Accession ID A369987

Actual Collection Time 20:53

Specimen Condition _____

Battery ID RC9255

Battery Name CHEMISTRY PANEL

Lab Test ID RCT4

Lab Test Name ALT (SGPT)

Test ID _____

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (25)

Data signed: (Heart1) 29 Oct 2014 09:22:49

Generated On: 18 Jul 2016 22:07:14

Test Status	Done <input type="radio"/>
Reported Text Result	46
Reported Numeric Result	46
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	
SI Numeric Result	
SI Reference Range Low	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (25)

Data signed: (Heart1) 29 Oct 2014 09:22:49

Generated On: 18 Jul 2016 22:07:14

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

High ☒

Clinically Significant?

No ☒

Comment

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (26)

Data signed: (Heart1) 29 Oct 2014 09:22:49

Generated On: 18 Jul 2016 22:07:14

Transmission Type Cumulative ☐

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6)

Visit Name DISCHARGE

Visit Type Scheduled ☐

Accession ID A369987

Actual Collection Time 20:53

Specimen Condition _____

Battery ID RC9255

Battery Name CHEMISTRY PANEL

Lab Test ID RCT5

Lab Test Name AST (SGOT)

Test ID _____


ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (26)

Data signed: (Heart1) 29 Oct 2014 09:22:49

Generated On: 18 Jul 2016 22:07:14

Test Status	Done 
Reported Text Result	26
Reported Numeric Result	26
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	
SI Numeric Result	
SI Reference Range Low	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (26)

Data signed: (Heart1) 29 Oct 2014 09:22:49

Generated On: 18 Jul 2016 22:07:14

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (27)

Data signed: (Heart1) 29 Oct 2014 09:22:49

Generated On: 18 Jul 2016 22:07:14

Transmission Type Cumulative ☐

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6)

Visit Name DISCHARGE

Visit Type Scheduled ☐

Accession ID A369987

Actual Collection Time 20:53

Specimen Condition _____

Battery ID RC9255

Battery Name CHEMISTRY PANEL

Lab Test ID RCT6

Lab Test Name UREA NITROGEN

Test ID _____


ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (27)

Data signed: (Heart1) 29 Oct 2014 09:22:49

Generated On: 18 Jul 2016 22:07:14

Test Status	Done 
Reported Text Result	18
Reported Numeric Result	18
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	
SI Numeric Result	
SI Reference Range Low	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (27)

Data signed: (Heart1) 29 Oct 2014 09:22:49

Generated On: 18 Jul 2016 22:07:14

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (28)

Data signed: (Heart1) 29 Oct 2014 09:22:49

Generated On: 18 Jul 2016 22:07:14

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	M
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Subject Date of Birth	(b) (6)
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Visit Name	DISCHARGE
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	A369987
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Actual Collection Time	20:53
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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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Lab Test Name	UR NITRITE
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Test ID	<hr/>
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ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230


Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (28)

Data signed: (Heart1) 29 Oct 2014 09:22:49

Generated On: 18 Jul 2016 22:07:14

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

SI Numeric Result

SI Reference Range Low

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (28)

Data signed: (Heart1) 29 Oct 2014 09:22:49

Generated On: 18 Jul 2016 22:07:14

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (29)

Data signed: (Heart1) 29 Oct 2014 09:22:49

Generated On: 18 Jul 2016 22:07:14

Transmission Type	Cumulative <input checked="" type="radio"/>
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Subject ID or Number	<hr/>
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Subject Sex	M
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Subject Date of Birth	(b) (6) <div></div>
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Visit Name	DISCHARGE
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Visit Type	Scheduled <input checked="" type="radio"/>
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Accession ID	A369987
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Actual Collection Time	20:53
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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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Lab Test Name	UR SPECIFIC GRAVITY
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Test ID	<hr/>
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ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230


Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (29)

Data signed: (Heart1) 29 Oct 2014 09:22:49

Generated On: 18 Jul 2016 22:07:14

Test Status

Done 

Reported Text Result

1.026

Reported Numeric Result

1.026

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

SI Numeric Result

SI Reference Range Low

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (29)

Data signed: (Heart1) 29 Oct 2014 09:22:49

Generated On: 18 Jul 2016 22:07:14

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (30)

Data signed: (Heart1) 29 Oct 2014 09:22:49

Generated On: 18 Jul 2016 22:07:14

Transmission Type Cumulative ☐

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6) 

Visit Name DISCHARGE

Visit Type Scheduled ☐

Accession ID A369987

Actual Collection Time 20:53

Specimen Condition _____

Battery ID UA1538

Battery Name URINE MACRO PANEL

Lab Test ID UAT3

Lab Test Name UR PH

Test ID _____

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230


Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (30)

Data signed: (Heart1) 29 Oct 2014 09:22:49

Generated On: 18 Jul 2016 22:07:14

Test Status

Done 

Reported Text Result

5.5

Reported Numeric Result

5.5

Reference Range low

5.0

Reference Range high

8.0

Range Units

Conventional Text Result

Conventional Numeric Result

Conventional Reference Range Low

Conventional Reference Range High

Conventional Units

SI Text Result

SI Numeric Result

SI Reference Range Low

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (30)

Data signed: (Heart1) 29 Oct 2014 09:22:49

Generated On: 18 Jul 2016 22:07:14

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (31)

Data signed: (Heart1) 29 Oct 2014 09:22:49

Generated On: 18 Jul 2016 22:07:14

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6) _____

Visit Name DISCHARGE

Visit Type Scheduled ☒

Accession ID A369987

Actual Collection Time 20:53

Specimen Condition _____

Battery ID UA1538

Battery Name URINE MACRO PANEL

Lab Test ID UAT43

Lab Test Name UR BLOOD

Test ID _____

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230


Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (31)

Data signed: (Heart1) 29 Oct 2014 09:22:49

Generated On: 18 Jul 2016 22:07:14

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

SI Numeric Result

SI Reference Range Low

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (31)

Data signed: (Heart1) 29 Oct 2014 09:22:49

Generated On: 18 Jul 2016 22:07:14

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (32)

Data signed: (Heart1) 29 Oct 2014 09:22:49

Generated On: 18 Jul 2016 22:07:14

Transmission Type Cumulative ☐

Subject ID or Number

Subject Sex M

Subject Date of Birth (b) (6) 

Visit Name DISCHARGE

Visit Type Scheduled ☐

Accession ID A369987

Actual Collection Time 20:53

Specimen Condition

Battery ID UA1538

Battery Name URINE MACRO PANEL

Lab Test ID UAT49

Lab Test Name UR PROTEIN

Test ID

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230


Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (32)

Data signed: (Heart1) 29 Oct 2014 09:22:49

Generated On: 18 Jul 2016 22:07:14

Test Status

Done 

Reported Text Result

TRACE

Reported Numeric Result

Reference Range low

Reference Range high

Range Units

Conventional Text Result

Conventional Numeric Result

Conventional Reference Range Low

Conventional Reference Range High

Conventional Units

SI Text Result

SI Numeric Result

SI Reference Range Low

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (32)

Data signed: (Heart1) 29 Oct 2014 09:22:49

Generated On: 18 Jul 2016 22:07:14

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

High ☒

Clinically Significant?

No ☒

Comment

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (33)

Data signed: (Heart1) 29 Oct 2014 09:22:49

Generated On: 18 Jul 2016 22:07:14

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6)

Visit Name DISCHARGE

Visit Type Scheduled ☒

Accession ID A369987

Actual Collection Time 20:53

Specimen Condition _____

Battery ID UA1538

Battery Name URINE MACRO PANEL

Lab Test ID UAT5

Lab Test Name UR GLUCOSE

Test ID _____

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230


Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (33)

Data signed: (Heart1) 29 Oct 2014 09:22:49

Generated On: 18 Jul 2016 22:07:14

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

SI Numeric Result

SI Reference Range Low

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (33)

Data signed: (Heart1) 29 Oct 2014 09:22:49

Generated On: 18 Jul 2016 22:07:14

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (34)

Data signed: (Heart1) 29 Oct 2014 09:22:49

Generated On: 18 Jul 2016 22:07:14

Transmission Type Cumulative ☒

Subject ID or Number _____

Subject Sex M

Subject Date of Birth (b) (6) _____

Visit Name DISCHARGE

Visit Type Scheduled ☒

Accession ID A369987

Actual Collection Time 20:53

Specimen Condition _____

Battery ID UA1538

Battery Name URINE MACRO PANEL

Lab Test ID UAT7

Lab Test Name UR BILIRUBIN

Test ID _____

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230


Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (34)

Data signed: (Heart1) 29 Oct 2014 09:22:49

Generated On: 18 Jul 2016 22:07:14

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

SI Numeric Result

SI Reference Range Low

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Discharge (Confinement)

Form: Lab_BU_CCLS (34)

Data signed: (Heart1) 29 Oct 2014 09:22:49

Generated On: 18 Jul 2016 22:07:14

SI Reference Range High

SI Units

Reported Result Type

Alert Flag

Clinically Significant?

Comment

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Product Use

Form: Product administration-mCC

Data signed: (Heart1) 29 Oct 2014 09:23:07

Generated On: 18 Jul 2016 22:07:14

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Product Use

Form: Product administration-mCC (1)

Data signed: (Heart1) 29 Oct 2014 09:23:07

Generated On: 18 Jul 2016 22:07:14

Date of product use DD/MMM/YYYY	23 JAN 2014
------------------------------------	-------------

Visit	Day -1 <input checked="" type="radio"/>
-------	---

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	06:38
----------------------	-------

Time of butt return	06:42
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Product Use

Form: Product administration-mCC (1)

Data signed: (Heart1) 29 Oct 2014 09:23:07

Generated On: 18 Jul 2016 22:07:14

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Product Use

Form: Product administration-mCC (2)

Data signed: (Heart1) 29 Oct 2014 09:23:07

Generated On: 18 Jul 2016 22:07:14

Date of product use DD/MMM/YYYY	23 JAN 2014
------------------------------------	-------------

Visit	Day -1 <input checked="" type="radio"/>
-------	---

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	09:11
----------------------	-------

Time of butt return	09:15
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Product Use

Form: Product administration-mCC (2)

Data signed: (Heart1) 29 Oct 2014 09:23:07

Generated On: 18 Jul 2016 22:07:14

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Product Use

Form: Product administration-mCC (3)

Data signed: (Heart1) 29 Oct 2014 09:23:07

Generated On: 18 Jul 2016 22:07:14

Date of product use DD/MMM/YYYY	23 JAN 2014
------------------------------------	-------------

Visit	Day -1 <input checked="" type="radio"/>
-------	---

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	12:35
----------------------	-------

Time of butt return	12:39
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Product Use

Form: Product administration-mCC (3)

Data signed: (Heart1) 29 Oct 2014 09:23:07

Generated On: 18 Jul 2016 22:07:14

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Product Use

Form: Product administration-mCC (4)

Data signed: (Heart1) 29 Oct 2014 09:23:07

Generated On: 18 Jul 2016 22:07:14

Date of product use DD/MMM/YYYY	23 JAN 2014
------------------------------------	-------------

Visit	Day -1 <input checked="" type="radio"/>
-------	---

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	15:17
----------------------	-------

Time of butt return	15:21
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Product Use

Form: Product administration-mCC (4)

Data signed: (Heart1) 29 Oct 2014 09:23:07

Generated On: 18 Jul 2016 22:07:14

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Product Use

Form: Product administration-mCC (5)

Data signed: (Heart1) 29 Oct 2014 09:23:07

Generated On: 18 Jul 2016 22:07:14

Date of product use DD/MMM/YYYY	23 JAN 2014
------------------------------------	-------------

Visit	Day -1 <input checked="" type="radio"/>
-------	---

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	19:04
----------------------	-------

Time of butt return	19:08
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Product Use

Form: Product administration-mCC (5)

Data signed: (Heart1) 29 Oct 2014 09:23:07

Generated On: 18 Jul 2016 22:07:14

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Product Use

Form: Product administration-mCC (6)

Data signed: (Heart1) 29 Oct 2014 09:23:07

Generated On: 18 Jul 2016 22:07:14

Date of product use DD/MMM/YYYY	23 JAN 2014
------------------------------------	-------------

Visit	Day -1 <input checked="" type="radio"/>
-------	---

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	19:55
----------------------	-------

Time of butt return	19:59
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	_____
---------------------	-------

SODIM sample holder number	_____
----------------------------	-------

SODIM file number	_____
-------------------	-------

Comment	_____
---------	-------

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Product Use

Form: Product administration-mCC (6)

Data signed: (Heart1) 29 Oct 2014 09:23:07

Generated On: 18 Jul 2016 22:07:14

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Product Use

Form: Product administration-mCC (7)

Data signed: (Heart1) 29 Oct 2014 09:23:07

Generated On: 18 Jul 2016 22:07:14

Date of product use DD/MMM/YYYY	24 JAN 2014
------------------------------------	-------------

Visit	Day 0 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain

Time of distribution	06:37
----------------------	-------

Time of butt return	06:42
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	143
---------------------	-----

SODIM sample holder number	534
----------------------------	-----

SODIM file number	07TC0143OWN050534001
-------------------	----------------------

Comment	
---------	--

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Product Use

Form: Product administration-mCC (7)

Data signed: (Heart1) 29 Oct 2014 09:23:07

Generated On: 18 Jul 2016 22:07:14

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Product Use

Form: Product administration-mCC (8)

Data signed: (Heart1) 29 Oct 2014 09:23:07

Generated On: 18 Jul 2016 22:07:14

Date of product use DD/MMM/YYYY	24 JAN 2014
------------------------------------	-------------

Visit	Day 0 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	09:10
----------------------	-------

Time of butt return	09:15
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	143
---------------------	-----

SODIM sample holder number	534
----------------------------	-----

SODIM file number	07TC0143OWN050534003
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Product Use

Form: Product administration-mCC (8)

Data signed: (Heart1) 29 Oct 2014 09:23:07

Generated On: 18 Jul 2016 22:07:14

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Product Use

Form: Product administration-mCC (9)

Data signed: (Heart1) 29 Oct 2014 09:23:07

Generated On: 18 Jul 2016 22:07:14

Date of product use DD/MMM/YYYY	24 JAN 2014
------------------------------------	-------------

Visit	Day 0 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	10:39
----------------------	-------

Time of butt return	10:42
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	143
---------------------	-----

SODIM sample holder number	534
----------------------------	-----

SODIM file number	07TC0143OWN050534004
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Product Use

Form: Product administration-mCC (9)

Data signed: (Heart1) 29 Oct 2014 09:23:07

Generated On: 18 Jul 2016 22:07:14

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Product Use

Form: Product administration-mCC (10)

Data signed: (Heart1) 29 Oct 2014 09:23:07

Generated On: 18 Jul 2016 22:07:14

Date of product use DD/MMM/YYYY	24 JAN 2014
------------------------------------	-------------

Visit	Day 0 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	12:37
----------------------	-------

Time of butt return	12:43
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	143
---------------------	-----

SODIM sample holder number	534
----------------------------	-----

SODIM file number	07TC0143OWN050534005
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Product Use

Form: Product administration-mCC (10)

Data signed: (Heart1) 29 Oct 2014 09:23:07

Generated On: 18 Jul 2016 22:07:14

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Product Use

Form: Product administration-mCC (11)

Data signed: (Heart1) 29 Oct 2014 09:23:07

Generated On: 18 Jul 2016 22:07:14

Date of product use DD/MMM/YYYY	24 JAN 2014
------------------------------------	-------------

Visit	Day 0 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain

Time of distribution	13:58
----------------------	-------

Time of butt return	14:04
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	143
---------------------	-----

SODIM sample holder number	534
----------------------------	-----

SODIM file number	07TC0143OWN050534007
-------------------	----------------------

Comment	
---------	--

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Product Use

Form: Product administration-mCC (11)

Data signed: (Heart1) 29 Oct 2014 09:23:07

Generated On: 18 Jul 2016 22:07:14

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Product Use

Form: Product administration-mCC (12)

Data signed: (Heart1) 29 Oct 2014 09:23:07

Generated On: 18 Jul 2016 22:07:14

Date of product use DD/MMM/YYYY	24 JAN 2014
------------------------------------	-------------

Visit	Day 0 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	15:44
----------------------	-------

Time of butt return	15:50
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	143
---------------------	-----

SODIM sample holder number	534
----------------------------	-----

SODIM file number	07TC0143OWN050534008
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Product Use

Form: Product administration-mCC (12)

Data signed: (Heart1) 29 Oct 2014 09:23:07

Generated On: 18 Jul 2016 22:07:14

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Product Use

Form: Product administration-mCC (13)

Data signed: (Heart1) 29 Oct 2014 09:23:07

Generated On: 18 Jul 2016 22:07:14

Date of product use DD/MMM/YYYY	24 JAN 2014
------------------------------------	-------------

Visit	Day 0 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	18:13
----------------------	-------

Time of butt return	18:19
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	143
---------------------	-----

SODIM sample holder number	534
----------------------------	-----

SODIM file number	07TC0143OWN050534009
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Product Use

Form: Product administration-mCC (13)

Data signed: (Heart1) 29 Oct 2014 09:23:07

Generated On: 18 Jul 2016 22:07:14

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Product Use

Form: Product administration-mCC (14)

Data signed: (Heart1) 29 Oct 2014 09:23:07

Generated On: 18 Jul 2016 22:07:14

Date of product use DD/MMM/YYYY	24 JAN 2014
------------------------------------	-------------

Visit	Day 0 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	19:05
----------------------	-------

Time of butt return	19:11
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	143
---------------------	-----

SODIM sample holder number	534
----------------------------	-----

SODIM file number	07TC0143OWN050534010
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Product Use

Form: Product administration-mCC (14)

Data signed: (Heart1) 29 Oct 2014 09:23:07

Generated On: 18 Jul 2016 22:07:14

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Product Use

Form: Product administration-mCC (15)

Data signed: (Heart1) 29 Oct 2014 09:23:07

Generated On: 18 Jul 2016 22:07:14

Date of product use DD/MMM/YYYY	24 JAN 2014
------------------------------------	-------------

Visit	Day 0 <input checked="" type="radio"/>
-------	--

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If type of Product Use different from the randomization
please explain _____

Time of distribution	20:51
----------------------	-------

Time of butt return	20:57
---------------------	-------

CC with SODIM?	True
----------------	------

CC not compatible?	False
--------------------	-------

SODIM device number	143
---------------------	-----

SODIM sample holder number	534
----------------------------	-----

SODIM file number	07TC0143OWN050534011
-------------------	----------------------

Comment	_____
---------	-------

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Product Use

Form: Product administration-mCC (15)

Data signed: (Heart1) 29 Oct 2014 09:23:07

Generated On: 18 Jul 2016 22:07:14

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Product Use

Form: Product administration-THS menthol

Data signed: (Heart1) 29 Oct 2014 09:23:10

Generated On: 18 Jul 2016 22:07:14

At Day 0, Day 1 and Day 4 complete all SODIM related questions

At Day 30, Day 60, Day 90 complete the Time in 'HST' Form.

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Product Use

Form: Product administration-THS menthol (1)

Data signed: (Heart1) 29 Oct 2014 09:23:10

Generated On: 18 Jul 2016 22:07:14

Date of product use DD/MMM/YYYY	25 JAN 2014
------------------------------------	-------------

Visit	Day 1 <input checked="" type="radio"/>
-------	--

Type of Product Use	THS 2.2 Menthol <input checked="" type="radio"/>
---------------------	--

If type of Product Use different from the randomization
please explain

Time of distribution	06:37
----------------------	-------

Time of product return	06:44
------------------------	-------

SODIM device number	143
---------------------	-----

SODIM sample holder number	1089
----------------------------	------

Filter kit number	F0811
-------------------	-------

Filter vial number	1
--------------------	---

Tobacco plug kit number	T1350
-------------------------	-------

Tobacco plug vial number	01
--------------------------	----

SODIM file number	07TC0143THM051089001
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ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Product Use

Form: Product administration-THS menthol (1)

Data signed: (Heart1) 29 Oct 2014 09:23:10

Generated On: 18 Jul 2016 22:07:14

Comment

Batch Number

B-08544

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-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Product Use

Form: Product administration-THS menthol (2)

Data signed: (Heart1) 29 Oct 2014 09:23:10

Generated On: 18 Jul 2016 22:07:14

Date of product use DD/MMM/YYYY	25 JAN 2014
------------------------------------	-------------

Visit	Day 1 <input checked="" type="radio"/>
-------	--

Type of Product Use	THS 2.2 Menthol <input checked="" type="radio"/>
---------------------	--

If type of Product Use different from the randomization
please explain

Time of distribution	09:02
----------------------	-------

Time of product return	09:09
------------------------	-------

SODIM device number	143
---------------------	-----

SODIM sample holder number	1089
----------------------------	------

Filter kit number	F0811
-------------------	-------

Filter vial number	2
--------------------	---

Tobacco plug kit number	T1350
-------------------------	-------

Tobacco plug vial number	02
--------------------------	----

SODIM file number	07TC0143THM051089001
-------------------	----------------------

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Product Use

Form: Product administration-THS menthol (2)

Data signed: (Heart1) 29 Oct 2014 09:23:10

Generated On: 18 Jul 2016 22:07:14

Comment

Batch Number

B-08544

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-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Product Use

Form: Product administration-THS menthol (3)

Data signed: (Heart1) 29 Oct 2014 09:23:10

Generated On: 18 Jul 2016 22:07:14

Date of product use DD/MMM/YYYY	25 JAN 2014
------------------------------------	-------------

Visit	Day 1 <input checked="" type="radio"/>
-------	--

Type of Product Use	THS 2.2 Menthol <input checked="" type="radio"/>
---------------------	--

If type of Product Use different from the randomization
please explain

Time of distribution	11:16
----------------------	-------

Time of product return	11:21
------------------------	-------

SODIM device number	143
---------------------	-----

SODIM sample holder number	1089
----------------------------	------

Filter kit number	F0811
-------------------	-------

Filter vial number	3
--------------------	---

Tobacco plug kit number	T1350
-------------------------	-------

Tobacco plug vial number	03
--------------------------	----

SODIM file number	07TC0143THM051089002
-------------------	----------------------

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Product Use

Form: Product administration-THS menthol (3)

Data signed: (Heart1) 29 Oct 2014 09:23:10

Generated On: 18 Jul 2016 22:07:14

Comment

Batch Number

B-08544

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-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Product Use

Form: Product administration-THS menthol (4)

Data signed: (Heart1) 29 Oct 2014 09:23:10

Generated On: 18 Jul 2016 22:07:14

Date of product use DD/MMM/YYYY	25 JAN 2014
------------------------------------	-------------

Visit	Day 1 <input checked="" type="radio"/>
-------	--

Type of Product Use	THS 2.2 Menthol <input checked="" type="radio"/>
---------------------	--

If type of Product Use different from the randomization
please explain

Time of distribution	13:08
----------------------	-------

Time of product return	13:17
------------------------	-------

SODIM device number	143
---------------------	-----

SODIM sample holder number	1089
----------------------------	------

Filter kit number	F0811
-------------------	-------

Filter vial number	4
--------------------	---

Tobacco plug kit number	T1350
-------------------------	-------

Tobacco plug vial number	04
--------------------------	----

SODIM file number	07TC0143THM051089002
-------------------	----------------------

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Product Use

Form: Product administration-THS menthol (4)

Data signed: (Heart1) 29 Oct 2014 09:23:10

Generated On: 18 Jul 2016 22:07:14

Comment

Batch Number

B-08544

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-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Product Use

Form: Product administration-THS menthol (5)

Data signed: (Heart1) 29 Oct 2014 09:23:10

Generated On: 18 Jul 2016 22:07:14

Date of product use DD/MMM/YYYY	25 JAN 2014
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Visit	Day 1 <input checked="" type="radio"/>
-------	--

Type of Product Use	THS 2.2 Menthol <input checked="" type="radio"/>
---------------------	--

If type of Product Use different from the randomization
please explain

Time of distribution	16:10
----------------------	-------

Time of product return	16:15
------------------------	-------

SODIM device number	143
---------------------	-----

SODIM sample holder number	1089
----------------------------	------

Filter kit number	F0811
-------------------	-------

Filter vial number	5
--------------------	---

Tobacco plug kit number	T1350
-------------------------	-------

Tobacco plug vial number	05
--------------------------	----

SODIM file number	07TC0143THM051089003
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ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Product Use

Form: Product administration-THS menthol (5)

Data signed: (Heart1) 29 Oct 2014 09:23:10

Generated On: 18 Jul 2016 22:07:14

Comment

Batch Number

B-08544

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-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Product Use

Form: Product administration-THS menthol (6)

Data signed: (Heart1) 29 Oct 2014 09:23:10

Generated On: 18 Jul 2016 22:07:14

Date of product use DD/MMM/YYYY	25 JAN 2014
------------------------------------	-------------

Visit	Day 1 <input checked="" type="radio"/>
-------	--

Type of Product Use	THS 2.2 Menthol <input checked="" type="radio"/>
---------------------	--

If type of Product Use different from the randomization
please explain

Time of distribution	19:09
----------------------	-------

Time of product return	19:14
------------------------	-------

SODIM device number	143
---------------------	-----

SODIM sample holder number	1089
----------------------------	------

Filter kit number	F0811
-------------------	-------

Filter vial number	6
--------------------	---

Tobacco plug kit number	T1350
-------------------------	-------

Tobacco plug vial number	06
--------------------------	----

SODIM file number	07TC0143THM051089004
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ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Product Use

Form: Product administration-THS menthol (6)

Data signed: (Heart1) 29 Oct 2014 09:23:10

Generated On: 18 Jul 2016 22:07:14

Comment

Batch Number

B-08544

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-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Product Use

Form: Product administration-THS menthol (7)

Data signed: (Heart1) 29 Oct 2014 09:23:10

Generated On: 18 Jul 2016 22:07:14

Date of product use DD/MMM/YYYY	22 JAN 2014
------------------------------------	-------------

Visit	Day -2 <input type="radio"/>
-------	------------------------------

Type of Product Use	THS 2.2 Menthol <input type="radio"/>
---------------------	---------------------------------------

If type of Product Use different from the randomization
please explain

Time of distribution	<hr/>
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Time of product return	<hr/>
------------------------	-------

SODIM device number	<hr/>
---------------------	-------

SODIM sample holder number	<hr/>
----------------------------	-------

Filter kit number	<hr/>
-------------------	-------

Filter vial number	<hr/>
--------------------	-------

Tobacco plug kit number	<hr/>
-------------------------	-------

Tobacco plug vial number	<hr/>
--------------------------	-------

SODIM file number	<hr/>
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ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Product Use

Form: Product administration-THS menthol (7)

Data signed: (Heart1) 29 Oct 2014 09:23:10

Generated On: 18 Jul 2016 22:07:14

Comment

Batch Number

B-08544

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-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Product Use

Form: Topography files status for mCC (1)

Data signed: (Heart1) 29 Oct 2014 09:23:12

Generated On: 18 Jul 2016 22:07:14

SODIM file number

File Status

Rejection / Error reason

Date of analysis
DD/MMM/YYYY

Operator

Comment

Modified File Number

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Product Use

Form: Topography files status for mCC (2)

Data signed: (Heart1) 29 Oct 2014 09:23:12

Generated On: 18 Jul 2016 22:07:14

SODIM file number

File Status

Rejection / Error reason

Date of analysis
DD/MMM/YYYY

Operator

Comment

Modified File Number

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Product Use

Form: Topography files status for mCC (3)

Data signed: (Heart1) 29 Oct 2014 09:23:12

Generated On: 18 Jul 2016 22:07:14

SODIM file number

File Status

Rejection / Error reason

Date of analysis
DD/MMM/YYYY

Operator

Comment

Modified File Number

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Product Use

Form: Topography files status for mCC (4)

Data signed: (Heart1) 29 Oct 2014 09:23:12

Generated On: 18 Jul 2016 22:07:14

SODIM file number

File Status

Rejection / Error reason

Date of analysis
DD/MMM/YYYY

Operator

Comment

Modified File Number

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Product Use

Form: Topography files status for mCC (5)

Data signed: (Heart1) 29 Oct 2014 09:23:12

Generated On: 18 Jul 2016 22:07:14

SODIM file number

File Status

Rejection / Error reason

Date of analysis
DD/MMM/YYYY

Operator

Comment

Modified File Number

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Product Use

Form: Topography files status for mCC (6)

Data signed: (Heart1) 29 Oct 2014 09:23:12

Generated On: 18 Jul 2016 22:07:14

SODIM file number

File Status

Rejection / Error reason

Date of analysis
DD/MMM/YYYY

Operator

Comment

Modified File Number

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Product Use

Form: Topography files status for mCC (7)

Data signed: (Heart1) 29 Oct 2014 09:23:12

Generated On: 18 Jul 2016 22:07:14

SODIM file number	07TC0143OWN050534001
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File Status	Accepted 
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Rejection / Error reason	
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Date of analysis DD/MMM/YYYY	27 MAY 2014
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Operator	Valerie Poux 
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Comment	
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Modified File Number	
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ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Product Use

Form: Topography files status for mCC (8)

Data signed: (Heart1) 29 Oct 2014 09:23:12


Generated On: 18 Jul 2016 22:07:14

SODIM file number	07TC0143OWN050534003
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File Status	Accepted 
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Rejection / Error reason	BASELINE DEVIATION
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Date of analysis DD/MMM/YYYY	27 MAY 2014
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Operator	Valerie Poux 
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Comment	<hr/>
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Modified File Number	<hr/>
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ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Product Use

Form: Topography files status for mCC (9)

Data signed: (Heart1) 29 Oct 2014 09:23:12

Generated On: 18 Jul 2016 22:07:14

SODIM file number	07TC0143OWN050534004
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File Status	Accepted 
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Rejection / Error reason	
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Date of analysis DD/MMM/YYYY	27 MAY 2014
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Operator	Valerie Poux 
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Comment	
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Modified File Number	
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ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Product Use

Form: Topography files status for mCC (10)

Data signed: (Heart1) 29 Oct 2014 09:23:12

Generated On: 18 Jul 2016 22:07:14

SODIM file number	07TC0143OWN050534005
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File Status	Error 
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Rejection / Error reason	DATA INCOMPATIBLE
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Date of analysis DD/MMM/YYYY	27 MAY 2014
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Operator	Valerie Poux 
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Comment	<hr/>
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Modified File Number	<hr/>
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ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Product Use

Form: Topography files status for mCC (11)

Data signed: (Heart1) 29 Oct 2014 09:23:12

Generated On: 18 Jul 2016 22:07:14

SODIM file number	07TC0143OWN050534007
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File Status	Accepted 
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Rejection / Error reason	
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Date of analysis DD/MMM/YYYY	27 MAY 2014
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Operator	Valerie Poux 
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Comment	
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Modified File Number	
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ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Product Use

Form: Topography files status for mCC (12)

Data signed: (Heart1) 29 Oct 2014 09:23:12

Generated On: 18 Jul 2016 22:07:14

SODIM file number	07TC0143OWN050534008
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File Status	Accepted 
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Rejection / Error reason	
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Date of analysis DD/MMM/YYYY	27 MAY 2014
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Operator	Valerie Poux 
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Comment	
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Modified File Number	
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ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Product Use

Form: Topography files status for mCC (13)

Data signed: (Heart1) 29 Oct 2014 09:23:12

Generated On: 18 Jul 2016 22:07:14

SODIM file number	07TC0143OWN050534009
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File Status	Accepted 
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Rejection / Error reason	
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Date of analysis DD/MMM/YYYY	27 MAY 2014
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Operator	Valerie Poux 
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Comment	
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Modified File Number	
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ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Product Use

Form: Topography files status for mCC (14)

Data signed: (Heart1) 29 Oct 2014 09:23:12

Generated On: 18 Jul 2016 22:07:14

SODIM file number	07TC0143OWN050534010
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File Status	Accepted 
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Rejection / Error reason	
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Date of analysis DD/MMM/YYYY	27 MAY 2014
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Operator	Valerie Poux 
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Comment	
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Modified File Number	
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ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Product Use

Form: Topography files status for mCC (15)

Data signed: (Heart1) 29 Oct 2014 09:23:12

Generated On: 18 Jul 2016 22:07:14

SODIM file number	07TC0143OWN050534011
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File Status	Accepted 
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Rejection / Error reason	
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Date of analysis DD/MMM/YYYY	27 MAY 2014
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Operator	Valerie Poux 
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Comment	
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Modified File Number	
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ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Product Use

Form: Topography files status for THS menthol (1)

Data signed: (Heart1) 29 Oct 2014 09:23:15


Generated On: 18 Jul 2016 22:07:14

SODIM file number	07TC0143THM051089001
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File Status	Accepted 
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Rejection / Error reason	
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Date of analysis DD/MMM/YYYY	27 MAY 2014
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Operator	Valerie Poux 
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Comment	
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Modified File Number	
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ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Product Use

Form: Topography files status for THS menthol (3)

Data signed: (Heart1) 29 Oct 2014 09:23:15

Generated On: 18 Jul 2016 22:07:14

SODIM file number	07TC0143THM051089002
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File Status	Accepted 
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Rejection / Error reason	
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Date of analysis DD/MMM/YYYY	27 MAY 2014
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Operator	Valerie Poux 
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Comment	
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Modified File Number	
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ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Product Use

Form: Topography files status for THS menthol (5)

Data signed: (Heart1) 29 Oct 2014 09:23:15

Generated On: 18 Jul 2016 22:07:14

SODIM file number	07TC0143THM051089003
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File Status	Accepted 
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Rejection / Error reason	
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Date of analysis DD/MMM/YYYY	27 MAY 2014
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Operator	Valerie Poux 
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Comment	
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Modified File Number	
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ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Product Use

Form: Topography files status for THS menthol (6)

Data signed: (Heart1) 29 Oct 2014 09:23:15

Generated On: 18 Jul 2016 22:07:14

SODIM file number	07TC0143THM051089004
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File Status	Accepted 
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Rejection / Error reason	
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Date of analysis DD/MMM/YYYY	27 MAY 2014
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Operator	Valerie Poux 
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Comment	
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Modified File Number	
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ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Product Use

Form: Topography files status for THS menthol (7)

Data signed: (Heart1) 29 Oct 2014 09:23:15

Generated On: 18 Jul 2016 22:07:14

SODIM file number

File Status

Rejection / Error reason

Date of analysis
DD/MMM/YYYY

Operator

Comment

Modified File Number

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (1)

Data signed: (Heart1) 29 Oct 2014 09:23:17

Generated On: 18 Jul 2016 22:07:14

Tobacco plug kit number	T1350
-------------------------	-------

Tobacco plug vial number	01
--------------------------	----

Level	0 <input checked="" type="radio"/>
-------	------------------------------------

Observation	
-------------	--

Picture File Name	T1350_01_FZ3C.JPG
-------------------	-------------------

Date of analysis DD/MMM/YYYY	07 APR 2014
---------------------------------	-------------

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (2)

Data signed: (Heart1) 29 Oct 2014 09:23:17

Generated On: 18 Jul 2016 22:07:14

Tobacco plug kit number	T1350
-------------------------	-------

Tobacco plug vial number	02
--------------------------	----

Level	0 <input type="radio"/>
-------	-------------------------

Observation	<hr/>
-------------	-------

Picture File Name	T1350_02_NV8V.JPG
-------------------	-------------------

Date of analysis DD/MMM/YYYY	07 APR 2014
---------------------------------	-------------

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (3)

Data signed: (Heart1) 29 Oct 2014 09:23:17

Generated On: 18 Jul 2016 22:07:14

Tobacco plug kit number	T1350
-------------------------	-------

Tobacco plug vial number	03
--------------------------	----

Level	NA <input type="radio"/>
-------	--------------------------

Observation	Not enough tobacco in the plug to perform the analysis <input type="radio"/>
-------------	--

Picture File Name	T1350_03_SXUZ.JPG
-------------------	-------------------

Date of analysis DD/MMM/YYYY	07 APR 2014
---------------------------------	-------------

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (4)

Data signed: (Heart1) 29 Oct 2014 09:23:17

Generated On: 18 Jul 2016 22:07:14

Tobacco plug kit number	T1350
-------------------------	-------

Tobacco plug vial number	04
--------------------------	----

Level	0 
-------	---

Observation	<hr/>
-------------	-------

Picture File Name	T1350_04_L70M.JPG
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Date of analysis DD/MMM/YYYY	07 APR 2014
---------------------------------	-------------

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (5)

Data signed: (Heart1) 29 Oct 2014 09:23:17

Generated On: 18 Jul 2016 22:07:14

Tobacco plug kit number	T1350
-------------------------	-------

Tobacco plug vial number	05
--------------------------	----

Level	0 
-------	---

Observation	<hr/>
-------------	-------

Picture File Name	T1350_05_PZIS.JPG
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Date of analysis DD/MMM/YYYY	07 APR 2014
---------------------------------	-------------

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Product Use

Form: Visual Inspection of the Tobacco Plugs Results for THS (6)

Data signed: (Heart1) 29 Oct 2014 09:23:17

Generated On: 18 Jul 2016 22:07:14

Tobacco plug kit number	T1350
-------------------------	-------

Tobacco plug vial number	06
--------------------------	----

Level	0 
-------	---

Observation	<hr/>
-------------	-------

Picture File Name	T1350_06_09CN.JPG
-------------------	-------------------

Date of analysis DD/MMM/YYYY	07 APR 2014
---------------------------------	-------------

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Adverse Events

Form: Adverse Events Y/N

Data signed: (Heart1) 29 Oct 2014 09:23:19

Generated On: 18 Jul 2016 22:07:14

Was there any Adverse Event for this subject?

No ☒

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Previous and Concomitant Medication

Form: Previous and Concomitant Medication Y/N

Data signed: (Heart1) 29 Oct 2014 09:23:20

Generated On: 18 Jul 2016 22:07:14

Has the subject taken previous or concomitant
medication?

No ☒

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Device Events

Form: Device report - THS 2.2 menthol Cigarette Holder

Data signed: (Heart1) 29 Oct 2014 09:23:20

Generated On: 18 Jul 2016 22:07:14

Were there any events with the device?

No ☒

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Device Events

Form: Device report - THS 2.2 menthol Cigarette Holder (1)

Data signed: (Heart1) 29 Oct 2014 09:23:20

Generated On: 18 Jul 2016 22:07:14

Were there any events with the device?

No ☒

Event Log Number

Date of Device Event
DD/MMM/YYYY

Time of
Device Event
hour:min 24-hour clock

Event Relates to Device Type:

THS 2.2 CIGARETTE HOLDER

Unique Device Identifier Serial Number

Event Description

Other Describe

Severity of Event

Adverse Event
Relationship

If Related to AE, AE Number

Solution Proposed:

If the device was replaced, New Device Serial Number:

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Device Events

Form: Device report - THS 2.2 menthol Cigarette Holder (1)

Data signed: (Heart1) 29 Oct 2014 09:23:20

Generated On: 18 Jul 2016 22:07:14

Date of Device Event Closure
DD/MMM/YYYY

Time of Device Event Closure
hour:min 24-hour clock

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Device Events

Form: Device report - THS 2.2 menthol Charging Unit

Data signed: (Heart1) 29 Oct 2014 09:23:21

Generated On: 18 Jul 2016 22:07:14

Were there any events with the device?

Yes ☐

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Device Events

Form: Device report - THS 2.2 menthol Charging Unit (1)

Data signed: (Heart1) 29 Oct 2014 09:23:21

Generated On: 18 Jul 2016 22:07:14

Were there any events with the device? Yes ☒

Event Log Number 101

Date of Device Event 25 JAN 2014
DD/MMM/YYYY

Time of Device Event 14:40
hour:min 24-hour clock

Event Relates to Device Type: THS 2.2 CHARGING UNIT

Unique Device Identifier Serial Number 1316758

Event Description Other ☒

Other Describe THE COVER OF CHARGER
DOESN'T CLOSE.

Severity of Event Major (cannot be resolved. Device needs to be exchanged) ☒

Adverse Event Relationship Is not related to AE ☒

Solution Proposed: Device Replaced ☒

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Device Events

Form: Device report - THS 2.2 menthol Charging Unit (1)

Data signed: (Heart1) 29 Oct 2014 09:23:21

Generated On: 18 Jul 2016 22:07:14

If the device was replaced, New Device Serial Number:	1318003
---	---------

Date of Device Event Closure DD/MMM/YYYY	25 JAN 2014
---	-------------

Time of Device Event Closure hour:min 24-hour clock	14:40
--	-------

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Device Inventory

Form: Device Inventory - THS 2.2 menthol Cigarette Holder (1)

Data signed: (Heart1) 29 Oct 2014 09:23:22

Generated On: 18 Jul 2016 22:07:14

Device Inventory	1
Log Number	

Date of Device Distribution	22 JAN 2014
DD/MMM/YYYY	

Time of	17:30
Device Distribution	
hour:min 24-hour clock	

Device Type	THS 2.2 CIGARETTE HOLDER
-------------	--------------------------

Device Serial Number	1245810
----------------------	---------

Date of Device Collection	25 JAN 2014
DD/MMM/YYYY	

Time of	21:20
Device Collection	
hour:min 24-hour clock	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Device Inventory

Form: Device Inventory - THS 2.2 menthol Cigarette Holder (2)

Data signed: (Heart1) 29 Oct 2014 09:23:22

Generated On: 18 Jul 2016 22:07:14

Device Inventory	2
Log Number	

Date of Device Distribution	25 JAN 2014
DD/MMM/YYYY	

Time of	06:30
Device Distribution	
hour:min 24-hour clock	

Device Type	THS 2.2 CIGARETTE HOLDER
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Device Serial Number	1245807
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Date of Device Collection	25 JAN 2014
DD/MMM/YYYY	

Time of	21:20
Device Collection	
hour:min 24-hour clock	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Device Inventory

Form: Device Inventory - THS 2.2 menthol Charging Unit (1)

Data signed: (Heart1) 29 Oct 2014 09:23:23

Generated On: 18 Jul 2016 22:07:14

Device Inventory	1
Log Number	

Date of Device Distribution	22 JAN 2014
DD/MMM/YYYY	

Time of	17:30
Device Distribution	
hour:min 24-hour clock	

Device Type	THS 2.2 CHARGING UNIT
-------------	-----------------------

Device Serial Number	1318045
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Date of Device Collection	22 JAN 2014
DD/MMM/YYYY	

Time of	17:40
Device Collection	
hour:min 24-hour clock	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Device Inventory

Form: Device Inventory - THS 2.2 menthol Charging Unit (2)

Data signed: (Heart1) 29 Oct 2014 09:23:23

Generated On: 18 Jul 2016 22:07:14

Device Inventory	2
Log Number	

Date of Device Distribution	25 JAN 2014
DD/MMM/YYYY	

Time of	06:30
Device Distribution	
hour:min 24-hour clock	

Device Type	THS 2.2 CHARGING UNIT
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Device Serial Number	1316758
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Date of Device Collection	25 JAN 2014
DD/MMM/YYYY	

Time of	14:40
Device Collection	
hour:min 24-hour clock	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Folder: Device Inventory

Form: Device Inventory - THS 2.2 menthol Charging Unit (3)

Data signed: (Heart1) 29 Oct 2014 09:23:23

Generated On: 18 Jul 2016 22:07:14

Device Inventory	3
Log Number	

Date of Device Distribution	25 JAN 2014
DD/MMM/YYYY	

Time of	14:40
Device Distribution	
hour:min 24-hour clock	

Device Type	THS 2.2 CHARGING UNIT
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Device Serial Number	1318003
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Date of Device Collection	25 JAN 2014
DD/MMM/YYYY	

Time of	21:20
Device Collection	
hour:min 24-hour clock	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Form: End of study

Data signed: (Heart1) 29 Oct 2014 09:21:05

Generated On: 18 Jul 2016 22:07:14

End of study date

22 FEB 2014
DD/MMM/YYYY

Has the subject completed the study ?

No ☒

If No, please specify the reason:

Withdrawal by Subject ☒

Details:

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Form: LABSTAT results (1)

Generated On: 18 Jul 2016 22:07:14

Cohort Number	05
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Kit Number	F0811
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Vial Number	01
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Day Number	01
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Sample Collection Date	25 JAN 2014
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Group No.	01
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Run No.	02
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Port No.	14
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Sample ID	1401455
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Number of Filters	3
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Extraction Volume (ml)	30
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Date of Extraction	21 FEB 2014
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Sample Volume (ml)	02.00
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Dilution Volume (ml)	10.00
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Total Volume (ml)	12.00
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ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230**Form: LABSTAT results (1)****Generated On: 18 Jul 2016 22:07:14**

Date of analysis (UV)	21 FEB 2014
Absolute UV Absorbance Mouthpiece part of the Filter	0.0709
Absolute UV Absorbance 'PLA + HAT' part of the Filter	NA
Absolute UV Absorbance Full Filter	NA
Normalized UV Absorbance Mouthpiece part of the Filter	0.4254
Normalized UV Absorbance 'PLA + HAT' part of the Filter	NA
Normalized UV Absorbance Full Filter	NA
Date of analysis (Nicotine)	22 FEB 2014
Nicotine Amount Mouthpiece part of the Filter (mg/ml)	0.0271
Nicotine Amount 'PLA + HAT' part of the Filter (mg/ml)	NA
Nicotine Amount Full Filter (mg/ml)	NA
Nicotine Amount Mouthpiece part of the Filter (mg/filter)	0.2707
Nicotine Amount 'PLA + HAT' part of the Filter (mg/filter)	NA
Nicotine Amount Full Filter (mg/filter)	NA
Comments	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Form: LABSTAT results (2)

Generated On: 18 Jul 2016 22:07:14

Cohort Number	05
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Kit Number	F0811
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Vial Number	02
-------------	----

Day Number	01
------------	----

Sample Collection Date	25 JAN 2014
------------------------	-------------

Group No.	01
-----------	----

Run No.	02
---------	----

Port No.	14
----------	----

Sample ID	1401455
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Number of Filters	3
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Extraction Volume (ml)	30
------------------------	----

Date of Extraction	21 FEB 2014
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Sample Volume (ml)	02.00
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Dilution Volume (ml)	10.00
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Total Volume (ml)	12.00
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ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230
Form: LABSTAT results (2)
Generated On: 18 Jul 2016 22:07:14

Date of analysis (UV)	21 FEB 2014
Absolute UV Absorbance Mouthpiece part of the Filter	0.0709
Absolute UV Absorbance 'PLA + HAT' part of the Filter	NA
Absolute UV Absorbance Full Filter	NA
Normalized UV Absorbance Mouthpiece part of the Filter	0.4254
Normalized UV Absorbance 'PLA + HAT' part of the Filter	NA
Normalized UV Absorbance Full Filter	NA
Date of analysis (Nicotine)	22 FEB 2014
Nicotine Amount Mouthpiece part of the Filter (mg/ml)	0.0271
Nicotine Amount 'PLA + HAT' part of the Filter (mg/ml)	NA
Nicotine Amount Full Filter (mg/ml)	NA
Nicotine Amount Mouthpiece part of the Filter (mg/filter)	0.2707
Nicotine Amount 'PLA + HAT' part of the Filter (mg/filter)	NA
Nicotine Amount Full Filter (mg/filter)	NA
Comments	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Form: LABSTAT results (3)

Generated On: 18 Jul 2016 22:07:14

Cohort Number	05
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Kit Number	F0811
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Vial Number	03
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Day Number	01
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Sample Collection Date	25 JAN 2014
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Group No.	01
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Run No.	02
---------	----

Port No.	14
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Sample ID	1401455
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Number of Filters	3
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Extraction Volume (ml)	30
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Date of Extraction	21 FEB 2014
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Sample Volume (ml)	02.00
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Dilution Volume (ml)	10.00
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Total Volume (ml)	12.00
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ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230
Form: LABSTAT results (3)
Generated On: 18 Jul 2016 22:07:14

Date of analysis (UV)	21 FEB 2014
Absolute UV Absorbance Mouthpiece part of the Filter	0.0709
Absolute UV Absorbance 'PLA + HAT' part of the Filter	NA
Absolute UV Absorbance Full Filter	NA
Normalized UV Absorbance Mouthpiece part of the Filter	0.4254
Normalized UV Absorbance 'PLA + HAT' part of the Filter	NA
Normalized UV Absorbance Full Filter	NA
Date of analysis (Nicotine)	22 FEB 2014
Nicotine Amount Mouthpiece part of the Filter (mg/ml)	0.0271
Nicotine Amount 'PLA + HAT' part of the Filter (mg/ml)	NA
Nicotine Amount Full Filter (mg/ml)	NA
Nicotine Amount Mouthpiece part of the Filter (mg/filter)	0.2707
Nicotine Amount 'PLA + HAT' part of the Filter (mg/filter)	NA
Nicotine Amount Full Filter (mg/filter)	NA
Comments	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Form: LABSTAT results (4)

Generated On: 18 Jul 2016 22:07:14

Cohort Number	05
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Kit Number	F0811
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Vial Number	04
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Day Number	01
------------	----

Sample Collection Date	25 JAN 2014
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Group No.	02
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Run No.	02
---------	----

Port No.	15
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Sample ID	1401455
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Number of Filters	3
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Extraction Volume (ml)	30
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Date of Extraction	21 FEB 2014
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Sample Volume (ml)	02.00
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Dilution Volume (ml)	10.00
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Total Volume (ml)	12.00
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ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230
Form: LABSTAT results (4)
Generated On: 18 Jul 2016 22:07:14

Date of analysis (UV)	21 FEB 2014
Absolute UV Absorbance Mouthpiece part of the Filter	0.0773
Absolute UV Absorbance 'PLA + HAT' part of the Filter	NA
Absolute UV Absorbance Full Filter	NA
Normalized UV Absorbance Mouthpiece part of the Filter	0.4638
Normalized UV Absorbance 'PLA + HAT' part of the Filter	NA
Normalized UV Absorbance Full Filter	NA
Date of analysis (Nicotine)	22 FEB 2014
Nicotine Amount Mouthpiece part of the Filter (mg/ml)	0.0325
Nicotine Amount 'PLA + HAT' part of the Filter (mg/ml)	NA
Nicotine Amount Full Filter (mg/ml)	NA
Nicotine Amount Mouthpiece part of the Filter (mg/filter)	0.3249
Nicotine Amount 'PLA + HAT' part of the Filter (mg/filter)	NA
Nicotine Amount Full Filter (mg/filter)	NA
Comments	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Form: LABSTAT results (5)

Generated On: 18 Jul 2016 22:07:14

Cohort Number	05
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Kit Number	F0811
------------	-------

Vial Number	05
-------------	----

Day Number	01
------------	----

Sample Collection Date	25 JAN 2014
------------------------	-------------

Group No.	02
-----------	----

Run No.	02
---------	----

Port No.	15
----------	----

Sample ID	1401455
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Number of Filters	3
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Extraction Volume (ml)	30
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Date of Extraction	21 FEB 2014
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Sample Volume (ml)	02.00
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Dilution Volume (ml)	10.00
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Total Volume (ml)	12.00
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ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230
Form: LABSTAT results (5)
Generated On: 18 Jul 2016 22:07:14

Date of analysis (UV)	21 FEB 2014
Absolute UV Absorbance Mouthpiece part of the Filter	0.0773
Absolute UV Absorbance 'PLA + HAT' part of the Filter	NA
Absolute UV Absorbance Full Filter	NA
Normalized UV Absorbance Mouthpiece part of the Filter	0.4638
Normalized UV Absorbance 'PLA + HAT' part of the Filter	NA
Normalized UV Absorbance Full Filter	NA
Date of analysis (Nicotine)	22 FEB 2014
Nicotine Amount Mouthpiece part of the Filter (mg/ml)	0.0325
Nicotine Amount 'PLA + HAT' part of the Filter (mg/ml)	NA
Nicotine Amount Full Filter (mg/ml)	NA
Nicotine Amount Mouthpiece part of the Filter (mg/filter)	0.3249
Nicotine Amount 'PLA + HAT' part of the Filter (mg/filter)	NA
Nicotine Amount Full Filter (mg/filter)	NA
Comments	

ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230

Form: LABSTAT results (6)

Generated On: 18 Jul 2016 22:07:14

Cohort Number	05
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Kit Number	F0811
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Vial Number	06
-------------	----

Day Number	01
------------	----

Sample Collection Date	25 JAN 2014
------------------------	-------------

Group No.	02
-----------	----

Run No.	02
---------	----

Port No.	15
----------	----

Sample ID	1401455
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Number of Filters	3
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Extraction Volume (ml)	30
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Date of Extraction	21 FEB 2014
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Sample Volume (ml)	02.00
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Dilution Volume (ml)	10.00
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Total Volume (ml)	12.00
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ZRHM-REXA-07-JP: Osaki Hospital Tokyo heart center: 0230
Form: LABSTAT results (6)
Generated On: 18 Jul 2016 22:07:14

Date of analysis (UV)	21 FEB 2014
Absolute UV Absorbance Mouthpiece part of the Filter	0.0773
Absolute UV Absorbance 'PLA + HAT' part of the Filter	NA
Absolute UV Absorbance Full Filter	NA
Normalized UV Absorbance Mouthpiece part of the Filter	0.4638
Normalized UV Absorbance 'PLA + HAT' part of the Filter	NA
Normalized UV Absorbance Full Filter	NA
Date of analysis (Nicotine)	22 FEB 2014
Nicotine Amount Mouthpiece part of the Filter (mg/ml)	0.0325
Nicotine Amount 'PLA + HAT' part of the Filter (mg/ml)	NA
Nicotine Amount Full Filter (mg/ml)	NA
Nicotine Amount Mouthpiece part of the Filter (mg/filter)	0.3249
Nicotine Amount 'PLA + HAT' part of the Filter (mg/filter)	NA
Nicotine Amount Full Filter (mg/filter)	NA
Comments	