

Subject Case Report Forms

0107 (Prod: Ageo Medical Clinic)

Generated On: 23 Jun 2014 15:19:04

All time stamps listed in this document are displayed in GMT

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Form: Subject

Data signed: (FumimasaNobuoka) 14 May 2014 06:16:57

Generated On: 23 Jun 2014 15:19:04

Screening number	0107
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Site number	AGE
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ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Subject Status

Form: Subject Status

Data signed: (FumimasaNobuoka) 14 May 2014 06:16:57

Generated On: 23 Jun 2014 15:19:04

Date of 'Screen Failed' Event

Date of 'Discontinued From
Enrollment' Event

Randomization Date

12 OCT 2013
DD/MMM/YYYY

Randomization Time

10:37
hour:min 24-hour clock

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Date of Visit

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:27

Generated On: 23 Jun 2014 15:19:04

Date of Visit

30 SEP 2013
DD/MMM/YYYY

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Inclusion Criteria

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:28

Generated On: 23 Jun 2014 15:19:04

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

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Inclusion Criteria (1)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:28

Generated On: 23 Jun 2014 15:19:04

Inclusion/Exclusion Criterion Number	1
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Inclusion/Exclusion 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-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Inclusion Criteria (2)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:28

Generated On: 23 Jun 2014 15:19:04

Inclusion/Exclusion Criterion Number	2
--------------------------------------	---

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

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

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Inclusion Criteria (3)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:28

Generated On: 23 Jun 2014 15:19:04

Inclusion/Exclusion Criterion Number	3
--------------------------------------	---

Inclusion/Exclusion Criterion	Subject is Japanese.	<input checked="" type="radio"/>
-------------------------------	----------------------	----------------------------------

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

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

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Inclusion Criteria (4)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:28

Generated On: 23 Jun 2014 15:19:04

Inclusion/Exclusion Criterion Number

4

Inclusion/Exclusion Criterion

Smoking, healthy subject
as judged by the
Investigator based on all
available assessments in
the Screening period/day
of Admission (e.g., safety
laboratory, spirometry*
[forced expiratory volume
in 1 second {FEV1}/forced
vital capacity {FVC} >0.7
at post bronchodilator
basal spirometry, post
bronchodilator FEV1 >80%
predicted value, and post
bronchodilator FVC >0.8],
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-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Inclusion Criteria (5)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:28

Generated On: 23 Jun 2014 15:19:04

Inclusion/Exclusion Criterion Number

5

Inclusion/Exclusion Criterion

Subject smokes at least 10 commercially available menthol CCs 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 3 consecutive years. The smoking status will be verified based on a urinary cotinine test (cotinine ≥ 200 ng/mL).

Result

Yes

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

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Inclusion Criteria (6)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:28

Generated On: 23 Jun 2014 15:19:04

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

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

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

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Inclusion Criteria (7)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:28

Generated On: 23 Jun 2014 15:19:04

Inclusion/Exclusion Criterion Number	7
--------------------------------------	---

Inclusion/Exclusion Criterion	The subject is ready to accept interruptions of smoking for up to 4 days.
-------------------------------	---

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

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

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Inclusion Criteria (8)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:28

Generated On: 23 Jun 2014 15:19:04

Inclusion/Exclusion Criterion Number

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Inclusion Criteria (8)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:28

Generated On: 23 Jun 2014 15:19:04

Inclusion/Exclusion Criterion

Subject has signed the ICF ☐
and is able to understand
the information provided in
the Subject Information
Sheet and ICF.
Subject is aged from 23 to ☐
65 years (inclusive).
Subject is Japanese. ☐
Smoking, healthy subject ☐
as judged by the
Investigator based on all
available assessments in
the Screening period/day
of Admission (e.g., safety
laboratory, spirometry*
[forced expiratory volume
in 1 second {FEV1}/forced
vital capacity {FVC} >0.7
at post bronchodilator
basal spirometry, post
bronchodilator FEV1 >80%
predicted value, and post
bronchodilator FVC >0.8],
vital signs, physical
examination, ECG, chest
X-ray and medical history). ☐

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Inclusion Criteria (8)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:28

Generated On: 23 Jun 2014 15:19:04

Subject smokes at least 10 commercially available menthol CCs 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 3 consecutive years. The smoking status will be verified based on a urinary cotinine test (cotinine ≥ 200 ng/mL).

The subject does not plan to quit smoking in the next 3 months. ☐

The subject is ready to accept interruptions of smoking for up to 4 days. ☐

The subject is ready to accept using both the THS 2.2 Menthol and NRT gum products. ☐

Result

No ☐

Yes ☐

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

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Inclusion Criteria (9)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:28

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Inclusion/Exclusion Criterion Number

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Inclusion Criteria (9)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:28

Generated On: 23 Jun 2014 15:19:04

Inclusion/Exclusion Criterion

Subject has signed the ICF ☐
and is able to understand
the information provided in
the Subject Information
Sheet and ICF.
Subject is aged from 23 to ☐
65 years (inclusive).
Subject is Japanese. ☐
Smoking, healthy subject ☐
as judged by the
Investigator based on all
available assessments in
the Screening period/day
of Admission (e.g., safety
laboratory, spirometry*
[forced expiratory volume
in 1 second {FEV1}/forced
vital capacity {FVC} >0.7
at post bronchodilator
basal spirometry, post
bronchodilator FEV1 >80%
predicted value, and post
bronchodilator FVC >0.8],
vital signs, physical
examination, ECG, chest
X-ray and medical history). ☐

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Inclusion Criteria (9)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:28

Generated On: 23 Jun 2014 15:19:04

Subject smokes at least 10 commercially available menthol CCs 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 3 consecutive years. The smoking status will be verified based on a urinary cotinine test (cotinine ≥ 200 ng/mL).

The subject does not plan to quit smoking in the next 3 months. ☐

The subject is ready to accept interruptions of smoking for up to 4 days. ☐

The subject is ready to accept using both the THS 2.2 Menthol and NRT gum products. ☐

Result

No ☐

Yes ☐

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

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Inclusion Criteria (10)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:28

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Inclusion/Exclusion Criterion Number

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Inclusion Criteria (10)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:28

Generated On: 23 Jun 2014 15:19:04

Inclusion/Exclusion Criterion

Subject has signed the ICF ☐
and is able to understand
the information provided in
the Subject Information
Sheet and ICF.
Subject is aged from 23 to ☐
65 years (inclusive).
Subject is Japanese. ☐
Smoking, healthy subject ☐
as judged by the
Investigator based on all
available assessments in
the Screening period/day
of Admission (e.g., safety
laboratory, spirometry*
[forced expiratory volume
in 1 second {FEV1}/forced
vital capacity {FVC} >0.7
at post bronchodilator
basal spirometry, post
bronchodilator FEV1 >80%
predicted value, and post
bronchodilator FVC >0.8],
vital signs, physical
examination, ECG, chest
X-ray and medical history). ☐

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Inclusion Criteria (10)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:28

Generated On: 23 Jun 2014 15:19:04

Subject smokes at least 10 commercially available menthol CCs 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 3 consecutive years. The smoking status will be verified based on a urinary cotinine test (cotinine \geq 200 ng/mL).

The subject does not plan to quit smoking in the next 3 months. ☐

The subject is ready to accept interruptions of smoking for up to 4 days. ☐

The subject is ready to accept using both the THS 2.2 Menthol and NRT gum products. ☐

Result

No ☐

Yes ☐

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ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Inclusion Criteria (11)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:28

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Inclusion/Exclusion Criterion Number

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Inclusion Criteria (11)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:28

Generated On: 23 Jun 2014 15:19:04

Inclusion/Exclusion Criterion

Subject has signed the ICF ☐
and is able to understand
the information provided in
the Subject Information
Sheet and ICF.
Subject is aged from 23 to ☐
65 years (inclusive).
Subject is Japanese. ☐
Smoking, healthy subject ☐
as judged by the
Investigator based on all
available assessments in
the Screening period/day
of Admission (e.g., safety
laboratory, spirometry*
[forced expiratory volume
in 1 second {FEV1}/forced
vital capacity {FVC} >0.7
at post bronchodilator
basal spirometry, post
bronchodilator FEV1 >80%
predicted value, and post
bronchodilator FVC >0.8],
vital signs, physical
examination, ECG, chest
X-ray and medical history). ☐

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Inclusion Criteria (11)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:28

Generated On: 23 Jun 2014 15:19:04

Subject smokes at least 10 commercially available menthol CCs 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 3 consecutive years. The smoking status will be verified based on a urinary cotinine test (cotinine ≥ 200 ng/mL).

The subject does not plan to quit smoking in the next 3 months. ☐

The subject is ready to accept interruptions of smoking for up to 4 days. ☐

The subject is ready to accept using both the THS 2.2 Menthol and NRT gum products. ☐

Result

No ☐

Yes ☐

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

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Inclusion Criteria (12)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:28

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Inclusion/Exclusion Criterion Number

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Inclusion Criteria (12)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:28

Generated On: 23 Jun 2014 15:19:04

Inclusion/Exclusion Criterion

Subject has signed the ICF ☐
and is able to understand
the information provided in
the Subject Information
Sheet and ICF.
Subject is aged from 23 to ☐
65 years (inclusive).
Subject is Japanese. ☐
Smoking, healthy subject ☐
as judged by the
Investigator based on all
available assessments in
the Screening period/day
of Admission (e.g., safety
laboratory, spirometry*
[forced expiratory volume
in 1 second {FEV1}/forced
vital capacity {FVC} >0.7
at post bronchodilator
basal spirometry, post
bronchodilator FEV1 >80%
predicted value, and post
bronchodilator FVC >0.8],
vital signs, physical
examination, ECG, chest
X-ray and medical history). ☐

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Inclusion Criteria (12)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:28

Generated On: 23 Jun 2014 15:19:04

Subject smokes at least 10 commercially available menthol CCs 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 3 consecutive years. The smoking status will be verified based on a urinary cotinine test (cotinine \geq 200 ng/mL).

The subject does not plan to quit smoking in the next 3 months. ☐

The subject is ready to accept interruptions of smoking for up to 4 days. ☐

The subject is ready to accept using both the THS 2.2 Menthol and NRT gum products. ☐

Result

No ☐

Yes ☐

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

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Inclusion Criteria (13)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:28

Generated On: 23 Jun 2014 15:19:04

Inclusion/Exclusion Criterion Number

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Inclusion Criteria (13)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:28

Generated On: 23 Jun 2014 15:19:04

Inclusion/Exclusion Criterion

Subject has signed the ICF ☐
and is able to understand
the information provided in
the Subject Information
Sheet and ICF.
Subject is aged from 23 to ☐
65 years (inclusive).
Subject is Japanese. ☐
Smoking, healthy subject ☐
as judged by the
Investigator based on all
available assessments in
the Screening period/day
of Admission (e.g., safety
laboratory, spirometry*
[forced expiratory volume
in 1 second {FEV1}/forced
vital capacity {FVC} >0.7
at post bronchodilator
basal spirometry, post
bronchodilator FEV1 >80%
predicted value, and post
bronchodilator FVC >0.8],
vital signs, physical
examination, ECG, chest
X-ray and medical history). ☐

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Inclusion Criteria (13)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:28

Generated On: 23 Jun 2014 15:19:04

Subject smokes at least 10 commercially available menthol CCs 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 3 consecutive years. The smoking status will be verified based on a urinary cotinine test (cotinine ≥ 200 ng/mL).

The subject does not plan to quit smoking in the next 3 months. ☐

The subject is ready to accept interruptions of smoking for up to 4 days. ☐

The subject is ready to accept using both the THS 2.2 Menthol and NRT gum products. ☐

Result

No ☐

Yes ☐

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

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Inclusion Criteria (14)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:28

Generated On: 23 Jun 2014 15:19:04

Inclusion/Exclusion Criterion Number

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Inclusion Criteria (14)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:28

Generated On: 23 Jun 2014 15:19:04

Inclusion/Exclusion Criterion

Subject has signed the ICF ☐
and is able to understand
the information provided in
the Subject Information
Sheet and ICF.
Subject is aged from 23 to ☐
65 years (inclusive).
Subject is Japanese. ☐
Smoking, healthy subject ☐
as judged by the
Investigator based on all
available assessments in
the Screening period/day
of Admission (e.g., safety
laboratory, spirometry*
[forced expiratory volume
in 1 second {FEV1}/forced
vital capacity {FVC} >0.7
at post bronchodilator
basal spirometry, post
bronchodilator FEV1 >80%
predicted value, and post
bronchodilator FVC >0.8],
vital signs, physical
examination, ECG, chest
X-ray and medical history). ☐

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Inclusion Criteria (14)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:28

Generated On: 23 Jun 2014 15:19:04

Subject smokes at least 10 commercially available menthol CCs 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 3 consecutive years. The smoking status will be verified based on a urinary cotinine test (cotinine ≥ 200 ng/mL).

The subject does not plan to quit smoking in the next 3 months. ☐

The subject is ready to accept interruptions of smoking for up to 4 days. ☐

The subject is ready to accept using both the THS 2.2 Menthol and NRT gum products. ☐

Result

No ☐

Yes ☐

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

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Inclusion Criteria (15)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:28

Generated On: 23 Jun 2014 15:19:04

Inclusion/Exclusion Criterion Number

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Inclusion Criteria (15)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:28

Generated On: 23 Jun 2014 15:19:04

Inclusion/Exclusion Criterion

Subject has signed the ICF ☐
and is able to understand
the information provided in
the Subject Information
Sheet and ICF.
Subject is aged from 23 to ☐
65 years (inclusive).
Subject is Japanese. ☐
Smoking, healthy subject ☐
as judged by the
Investigator based on all
available assessments in
the Screening period/day
of Admission (e.g., safety
laboratory, spirometry*
[forced expiratory volume
in 1 second {FEV1}/forced
vital capacity {FVC} >0.7
at post bronchodilator
basal spirometry, post
bronchodilator FEV1 >80%
predicted value, and post
bronchodilator FVC >0.8],
vital signs, physical
examination, ECG, chest
X-ray and medical history). ☐

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Inclusion Criteria (15)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:28

Generated On: 23 Jun 2014 15:19:04

Subject smokes at least 10 commercially available menthol CCs 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 3 consecutive years. The smoking status will be verified based on a urinary cotinine test (cotinine ≥ 200 ng/mL).

The subject does not plan to quit smoking in the next 3 months. ☐

The subject is ready to accept interruptions of smoking for up to 4 days. ☐

The subject is ready to accept using both the THS 2.2 Menthol and NRT gum products. ☐

Result

No ☐

Yes ☐

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

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Inclusion Criteria (16)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:28

Generated On: 23 Jun 2014 15:19:04

Inclusion/Exclusion Criterion Number

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Inclusion Criteria (16)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:28

Generated On: 23 Jun 2014 15:19:04

Inclusion/Exclusion Criterion

Subject has signed the ICF ☐
and is able to understand
the information provided in
the Subject Information
Sheet and ICF.
Subject is aged from 23 to ☐
65 years (inclusive).
Subject is Japanese. ☐
Smoking, healthy subject ☐
as judged by the
Investigator based on all
available assessments in
the Screening period/day
of Admission (e.g., safety
laboratory, spirometry*
[forced expiratory volume
in 1 second {FEV1}/forced
vital capacity {FVC} >0.7
at post bronchodilator
basal spirometry, post
bronchodilator FEV1 >80%
predicted value, and post
bronchodilator FVC >0.8],
vital signs, physical
examination, ECG, chest
X-ray and medical history). ☐

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Inclusion Criteria (16)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:28

Generated On: 23 Jun 2014 15:19:04

Subject smokes at least 10 commercially available menthol CCs 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 3 consecutive years. The smoking status will be verified based on a urinary cotinine test (cotinine ≥ 200 ng/mL).

The subject does not plan to quit smoking in the next 3 months. ☐

The subject is ready to accept interruptions of smoking for up to 4 days. ☐

The subject is ready to accept using both the THS 2.2 Menthol and NRT gum products. ☐

Result

No ☐

Yes ☐

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

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Inclusion Criteria (17)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:28

Generated On: 23 Jun 2014 15:19:04

Inclusion/Exclusion Criterion Number

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Inclusion Criteria (17)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:28

Generated On: 23 Jun 2014 15:19:04

Inclusion/Exclusion Criterion

Subject has signed the ICF ☐
and is able to understand
the information provided in
the Subject Information
Sheet and ICF.
Subject is aged from 23 to ☐
65 years (inclusive).
Subject is Japanese. ☐
Smoking, healthy subject ☐
as judged by the
Investigator based on all
available assessments in
the Screening period/day
of Admission (e.g., safety
laboratory, spirometry*
[forced expiratory volume
in 1 second {FEV1}/forced
vital capacity {FVC} >0.7
at post bronchodilator
basal spirometry, post
bronchodilator FEV1 >80%
predicted value, and post
bronchodilator FVC >0.8],
vital signs, physical
examination, ECG, chest
X-ray and medical history). ☐

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Inclusion Criteria (17)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:28

Generated On: 23 Jun 2014 15:19:04

Subject smokes at least 10 commercially available menthol CCs 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 3 consecutive years. The smoking status will be verified based on a urinary cotinine test (cotinine ≥ 200 ng/mL).

The subject does not plan to quit smoking in the next 3 months. ☐

The subject is ready to accept interruptions of smoking for up to 4 days. ☐

The subject is ready to accept using both the THS 2.2 Menthol and NRT gum products. ☐

Result

No ☐

Yes ☐

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

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Exclusion Criteria

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:29

Generated On: 23 Jun 2014 15:19:04

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

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Exclusion Criteria (1)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:29

Generated On: 23 Jun 2014 15:19:04

Inclusion/Exclusion Criterion Number	1
--------------------------------------	---

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

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

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

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Exclusion Criteria (2)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:29

Generated On: 23 Jun 2014 15:19:04

Inclusion/Exclusion Criterion Number

2

Inclusion/Exclusion Criterion

A subject who is legally incompetent, physically or mentally incapable of giving consent (e.g., emergency situation, under guardianship, , prisoners or subjects who are involuntarily incarcerated).

Result

No

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

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Exclusion Criteria (3)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:29

Generated On: 23 Jun 2014 15:19:04

Inclusion/Exclusion Criterion Number

3

Inclusion/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-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Exclusion Criteria (4)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:29

Generated On: 23 Jun 2014 15:19:04

Inclusion/Exclusion Criterion Number

4

Inclusion/Exclusion Criterion

The subject has a body
mass index (BMI) <18.5 or
≥32.0 kg/m². ☒

Result

No ☒

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

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Exclusion Criteria (5)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:29

Generated On: 23 Jun 2014 15:19:04

Inclusion/Exclusion Criterion Number

5

Inclusion/Exclusion Criterion

As per Investigator judgment, the subject has medical conditions which require or will require in the course of the study, a medical intervention (e.g., start of treatment, surgery, hospitalization) which may interfere with the study participation and/or study results.

Result

No

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

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Exclusion Criteria (6)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:29

Generated On: 23 Jun 2014 15:19:04

Inclusion/Exclusion Criterion Number

6

Inclusion/Exclusion Criterion

The subject has used
nicotine containing
products other than
commercially available
mCC (either tobacco-based
products or
nicotine-replacement
therapy) 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-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Exclusion Criteria (7)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:29

Generated On: 23 Jun 2014 15:19:04

Inclusion/Exclusion Criterion Number

8

Inclusion/Exclusion Criterion

In case the subject
received any medication
(prescribed or over the
counter) within 14 days
prior to Screening or prior
to the Admission Day (Day
-1) it will be decided at the
discretion of the
Investigator if these can
potentially interfere with
the study objectives and
subject's safety.

Result

No

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

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Exclusion Criteria (8)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:29

Generated On: 23 Jun 2014 15:19:04

Inclusion/Exclusion Criterion Number

9

Inclusion/Exclusion Criterion

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

Result

No

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

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Exclusion Criteria (9)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:29

Generated On: 23 Jun 2014 15:19:04

Inclusion/Exclusion Criterion Number	10
--------------------------------------	----

Inclusion/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-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Exclusion Criteria (10)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:29

Generated On: 23 Jun 2014 15:19:04

Inclusion/Exclusion Criterion Number	11
--------------------------------------	----

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

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

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

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Exclusion Criteria (11)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:29

Generated On: 23 Jun 2014 15:19:04

Inclusion/Exclusion Criterion Number	12
--------------------------------------	----

Inclusion/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-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Exclusion Criteria (12)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:29

Generated On: 23 Jun 2014 15:19:04

Inclusion/Exclusion Criterion Number	13
--------------------------------------	----

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

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

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

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Exclusion Criteria (13)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:29

Generated On: 23 Jun 2014 15:19:04

Inclusion/Exclusion Criterion Number	14
--------------------------------------	----

Inclusion/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).
-------------------------------	--

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

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

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Exclusion Criteria (14)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:29

Generated On: 23 Jun 2014 15:19:04

Inclusion/Exclusion Criterion Number	15
--------------------------------------	----

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

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

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

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Exclusion Criteria (15)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:29

Generated On: 23 Jun 2014 15:19:04

Inclusion/Exclusion Criterion Number	16
--------------------------------------	----

Inclusion/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).
-------------------------------	---

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

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

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Exclusion Criteria (16)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:29

Generated On: 23 Jun 2014 15:19:04

Inclusion/Exclusion Criterion Number

17

Inclusion/Exclusion Criterion

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

Result

No ☒

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

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Exclusion Criteria (17)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:29

Generated On: 23 Jun 2014 15:19:04

Inclusion/Exclusion Criterion Number	18
--------------------------------------	----

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

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

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

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Demographics

Data signed: (FumimasaNobuoka) 14 May 2014 06:16:57

Generated On: 23 Jun 2014 15:19:04

Date of Birth	(b) (6)
Sex	Female <input checked="" type="radio"/>
Is the Subject Japanese?	Yes <input checked="" type="radio"/>
Date the Subject signed the Informed Consent	30 SEP 2013 DD/MMM/YYYY
Time the Subject signed the Informed Consent	12:40 hour:min 24-hour clock
Age(Derived)	45

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: THS 2.2 Menthol product demonstration

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:30

Generated On: 23 Jun 2014 15:19:04

Has the subject seen a THS 2.2 Menthol product demonstration?

Yes ☒

If the subject did not see the demonstration please explain

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: NRT product demonstration

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:30

Generated On: 23 Jun 2014 15:19:04

Has the subject seen a NRT product demonstration?

Yes ☒

If the subject did not see the demonstration please
explain

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Identification of Current mCC Brand

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:31

Generated On: 23 Jun 2014 15:19:04

Date	30 SEP 2013 DD/MMM/YYYY
------	----------------------------

Brand name	MEVIUS PREMIUM MENTHOL OPTION 100'S
------------	--

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

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

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107
Folder: Screening
Form: Identification of NRT Gum Brand
Generated On: 23 Jun 2014 15:19:04

Date

~~30 SEP 2013~~
~~DD/MMM/YYYY~~

Was Nicorette® gum 2 mg used?

Yes ☒

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Smoking History

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:31

Generated On: 23 Jun 2014 15:19:04

Date of Assessment	30 SEP 2013 DD/MMM/YYYY
--------------------	----------------------------

Time of Assessment	12:49 hour:min 24-hour clock
--------------------	---------------------------------

1. Does the subject plan to quit smoking during the next 3 months?	No <input type="radio"/>
--	--------------------------

2. Did the subject smoke for at least 3 consecutive years?	Yes <input type="radio"/>
--	---------------------------

3. How many cigarettes per day has the subject smoked on average during the last 4 weeks?	>19 <input type="radio"/>
---	---------------------------

4. Did the subject smoke menthol cigarettes in the last 4 weeks?	Yes <input type="radio"/>
--	---------------------------

5. The subject has used nicotine-containing products other than commercially available CC (either tobacco-based products or nicotine-replacement therapy [NRT]), electronic cigarettes and similar devices, within 4 weeks prior to assessment.	No <input type="radio"/>
---	--------------------------

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: FTND Questionnaire

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:31

Generated On: 23 Jun 2014 15:19:04

Type	FAGERSTROM TEST FOR NICOTINE DEPENDENCE
------	--

Date of assessment	30 SEP 2013
DD/MMM/YYYY	DD/MMM/YYYY

Time of assessment	12:44
hour:min	hour:min 24-hour clock

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

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

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

4. How many cigarettes per day do you smoke?	31 or more <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-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Medical History/Concomitant Disease

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:31

Generated On: 23 Jun 2014 15:19:04

Date of collection

30 SEP 2013
DD/MMM/YYYY

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

No ☒

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Medical History/Concomitant Disease (1)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:31

Generated On: 23 Jun 2014 15:19:04

Date of collection

30 SEP 2013
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-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Physical Examination Screening

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:32

Generated On: 23 Jun 2014 15:19:04

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

30 SEP 2013
DD/MMM/YYYY

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Physical Examination Screening (1)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:32

Generated On: 23 Jun 2014 15:19:04

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

30 SEP 2013
DD/MMM/YYYY

System

General Appearance ☒

Outcome

Normal ☒

Abnormal, please specify: _____

Clinically significant

No ☐

Yes ☐

Not Done

False

Not Done; please specify the reason: _____

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Physical Examination Screening (2)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:32

Generated On: 23 Jun 2014 15:19:04

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

30 SEP 2013
DD/MMM/YYYY

System

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

Outcome

Normal ☒

Abnormal, please specify: _____

Clinically significant

No ☐

Yes ☐

Not Done

False

Not Done; please specify the reason: _____

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Physical Examination Screening (3)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:32

Generated On: 23 Jun 2014 15:19:04

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

30 SEP 2013
DD/MMM/YYYY

System

Thyroid Gland ☒

Outcome

Normal ☒

Abnormal, please specify: _____

Clinically significant

No ☐

Yes ☐

Not Done

False

Not Done; please specify the reason: _____

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Physical Examination Screening (4)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:32

Generated On: 23 Jun 2014 15:19:04

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

30 SEP 2013
DD/MMM/YYYY

System

Heart ☒

Outcome

Normal ☒

Abnormal, please specify: _____

Clinically significant

No ☐

Yes ☐

Not Done

False

Not Done; please specify the reason: _____

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Physical Examination Screening (5)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:32

Generated On: 23 Jun 2014 15:19:04

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

30 SEP 2013
DD/MMM/YYYY

System

Chest ☒

Outcome

Normal ☒

Abnormal, please specify: _____

Clinically significant

No ☐

Yes ☐

Not Done

False

Not Done; please specify the reason: _____

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Physical Examination Screening (6)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:32

Generated On: 23 Jun 2014 15:19:04

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

30 SEP 2013
DD/MMM/YYYY

System

Lungs ☒

Outcome

Normal ☒

Abnormal, please specify: _____

Clinically significant

No ☐

Yes ☐

Not Done

False

Not Done; please specify the reason: _____

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Physical Examination Screening (7)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:32

Generated On: 23 Jun 2014 15:19:04

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

30 SEP 2013
DD/MMM/YYYY

System

Gastrointestinal ☒

Outcome

Normal ☒

Abnormal, please specify: _____

Clinically significant

No ☐

Yes ☐

Not Done

False

Not Done; please specify the reason: _____

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Physical Examination Screening (8)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:32

Generated On: 23 Jun 2014 15:19:04

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

30 SEP 2013
DD/MMM/YYYY

System

Cardiovascular System ☒

Outcome

Normal ☒

Abnormal, please specify: _____

Clinically significant

No ☐

Yes ☐

Not Done

False

Not Done; please specify the reason: _____

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Physical Examination Screening (9)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:32

Generated On: 23 Jun 2014 15:19:04

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

30 SEP 2013
DD/MMM/YYYY

System

Neurologic ☒

Outcome

Normal ☒

Abnormal, please specify: _____

Clinically significant

No ☐

Yes ☐

Not Done

False

Not Done; please specify the reason: _____

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Physical Examination Screening (10)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:32

Generated On: 23 Jun 2014 15:19:04

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

30 SEP 2013
DD/MMM/YYYY

System

Skin ☒

Outcome

Normal ☒

Abnormal, please specify: _____

Clinically significant

No ☐

Yes ☐

Not Done

False

Not Done; please specify the reason: _____

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Physical Examination Screening (11)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:32

Generated On: 23 Jun 2014 15:19:04

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

30 SEP 2013
DD/MMM/YYYY

System

Back ☒

Outcome

Normal ☒

Abnormal, please specify: _____

Clinically significant

No ☐

Yes ☐

Not Done

False

Not Done; please specify the reason: _____

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Physical Examination Screening (12)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:32

Generated On: 23 Jun 2014 15:19:04

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

30 SEP 2013
DD/MMM/YYYY

System

Musculoskeletal ☒

Outcome

Normal ☒

Abnormal, please specify: _____

Clinically significant

No ☐

Yes ☐

Not Done

False

Not Done; please specify the reason: _____

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Physical Examination Screening (13)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:32

Generated On: 23 Jun 2014 15:19:04

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

30 SEP 2013
DD/MMM/YYYY

System

Abdomen ☒

Outcome

Normal ☒

Abnormal, please specify: _____

Clinically significant

No ☐

Yes ☐

Not Done

False

Not Done; please specify the reason: _____

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Physical Examination Screening (14)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:32

Generated On: 23 Jun 2014 15:19:04

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

30 SEP 2013
DD/MMM/YYYY

System

Dentition ☒

Outcome

Normal ☒

Abnormal, please specify: _____

Clinically significant

No ☐

Yes ☐

Not Done

False

Not Done; please specify the reason: _____

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Physical Examination Screening (15)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:32

Generated On: 23 Jun 2014 15:19:04

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

30 SEP 2013
DD/MMM/YYYY

System

Other ☒

Other, Specify _____

Outcome

Normal ☐
Abnormal ☐

Abnormal, please specify: _____

Clinically significant

No ☐
Yes ☐

Not Done

True

Not Done; please specify the reason: _____

NA

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Physical Examination Screening (16)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:32

Generated On: 23 Jun 2014 15:19:04

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

30 SEP 2013
DD/MMM/YYYY

System

Other ☒

Other, Specify _____

Outcome

Normal ☐
Abnormal ☐

Abnormal, please specify: _____

Clinically significant

No ☐
Yes ☐

Not Done

True

Not Done; please specify the reason: _____

NA

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Physical Examination Screening (17)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:32

Generated On: 23 Jun 2014 15:19:04

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

30 SEP 2013
DD/MMM/YYYY

System

Other ☒

Other, Specify _____

Outcome

Normal ☐
Abnormal ☐

Abnormal, please specify: _____

Clinically significant

No ☐
Yes ☐

Not Done

True

Not Done; please specify the reason: _____

NA

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Physical Examination Screening (18)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:32

Generated On: 23 Jun 2014 15:19:04

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

30 SEP 2013
DD/MMM/YYYY

System

Other ☒

Other, Specify _____

Outcome

Normal ☐
Abnormal ☐

Abnormal, please specify: _____

Clinically significant

No ☐
Yes ☐

Not Done

True

Not Done; please specify the reason: _____

NA

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Physical Examination Screening (19)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:32

Generated On: 23 Jun 2014 15:19:04

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

30 SEP 2013
DD/MMM/YYYY

System

Other ☒

Other, Specify _____

Outcome

Normal ☐
Abnormal ☐

Abnormal, please specify: _____

Clinically significant

No ☐
Yes ☐

Not Done

True

Not Done; please specify the reason: _____

NA

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Advice on the risk of smoking and Debriefing

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:38

Generated On: 23 Jun 2014 15:19:04

Has the subject received advices on the risks of
smoking?

Yes ☒

Has a debriefing been performed about THS 2.2
Menthol?

Yes ☒

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Weight and Height

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:38

Generated On: 23 Jun 2014 15:19:04

Measurement(s) assessed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

30 SEP 2013
DD/MMM/YYYY

Weight

57.8
kg

Height

162
cm

BMI (Derived)

22.0
kg/m2

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Vital Signs Screening

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:39

Generated On: 23 Jun 2014 15:19:04

Were vital signs assessed?

Yes ☒

If No, please specify the reason: _____

Has the subject smoked within 15 minutes prior to assessment

No ☒

Date of assessment

30 SEP 2013
DD/MMM/YYYY

Time of assessment

13:22
hour:min 24-hour clock

Pulse rate

62
beats per minute

Respiratory rate

16
breaths per minute

Blood Pressure (systolic)

116
mmHg

Blood Pressure (diastolic)

69
mmHg

Vital Signs Position of Subject

Supine ☒

Final 7.0 (Main CRF) (520)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: ECG (12-Lead Standard) screening

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:39

Generated On: 23 Jun 2014 15:19:04

Was the ECG performed?

Yes ☒

If No, please specify the reason: _____

Date of assessment:

30 SEP 2013
DD/MMM/YYYY

Position

Supine ☒

Heart Rate

53 beats per minute

QRS Interval

96 msec

QT Interval

428 msec

QTcB Interval

405 msec

PR Interval

162 msec

Interpretation

Normal ☒

If Abnormal, Clinical Significance

Not clinically significant ☐

Clinically significant ☐

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

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Spirometry (1)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:40

Generated On: 23 Jun 2014 15:19:04

Was the spirometry performed? Yes ☒

If No, please specify the reason: _____

Category Without short-acting bronchodilator ☒

Date of assessment: 30 SEP 2013
DD/MMM/YYYY

Time of assessment: 14:09
hour:min 24-hour clock

Predicted FVC value 3.06
L

Best measured FVC value 4.15
L

Percent of predicted FVC value 135
%

Best measured FEV1 value 2.88
L

Predicted FEV1 value 2.57
L

Percent of predicted FEV1 value 112
%

Final 7.0 (Main CRF) (520)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Spirometry (1)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:40

Generated On: 23 Jun 2014 15:19:04

Calculated ratio between FEV1/FVC

0.69

Interpretation

Normal ☒

If Abnormal, Clinical Significance

Not clinically significant ☐

Clinically significant ☐

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

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Spirometry (2)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:40

Generated On: 23 Jun 2014 15:19:04

Was the spirometry performed? Yes ☒

If No, please specify the reason: _____

Category With short-acting bronchodilator ☒

Date of assessment: 30 SEP 2013
DD/MMM/YYYY

Time of assessment: 14:16
hour:min 24-hour clock

Name of bronchodilator SULTANOL INHALER 100MG

Dose 100MG

Predicted FVC value 3.06
L

Best measured FVC value 4.01
L

Percent of predicted FVC value 131
%

Best measured FEV1 value 2.91
L

Final 7.0 (Main CRF) (520)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Spirometry (2)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:40

Generated On: 23 Jun 2014 15:19:04

Predicted FEV1 value	2.57 L
----------------------	-----------

Percent of predicted FEV1 value %	113
--------------------------------------	-----

Calculated ratio between FEV1/FVC	0.73
-----------------------------------	------

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

If Abnormal, Clinical Significance	Not clinically significant <input type="radio"/>
	Clinically significant <input type="radio"/>

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

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Chest X-Ray

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:41

Generated On: 23 Jun 2014 15:19:04

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

Yes ☒

If No, please specify the reason: _____

Date of assessment

30 SEP 2013
DD/MMM/YYYY

System

Chest ☒

Interpretation

Normal ☒

Clinically significant

No ☐

Yes ☐

Abnormal, please specify: _____

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Haematology

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:42

Generated On: 23 Jun 2014 15:19:04

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-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Urine analysis

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:42

Generated On: 23 Jun 2014 15:19:04

Were samples collected?

Yes ☒

If No, please specify the reason:

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Clinical Chemistry

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:42

Generated On: 23 Jun 2014 15:19:04

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-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Serology for HIV and Hepatitis B and C

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:42

Generated On: 23 Jun 2014 15:19:04

Not Done

False

If Not Done, please specify the reason:

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Urine Drug Screen screening

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:43

Generated On: 23 Jun 2014 15:19:04

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

If Not Done, please specify the reason: _____

Date of sample collection	30 SEP 2013 DD/MMM/YYYY
---------------------------	----------------------------

Time of sample collection	14:02 hour:min 24-hour clock
---------------------------	---------------------------------

Drug type	Result
Amphetamines	Negative
Barbiturates	Negative
Benzodiazepines	Negative

Final 7.0 (Main CRF) (520)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Urine Drug Screen screening (4)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:43

Generated On: 23 Jun 2014 15:19:04

Drug type	Result
Cannabinoids	Negative
Cocaine	Negative
Opiates	Negative

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Alcohol Breath Test screening

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:44

Generated On: 23 Jun 2014 15:19:04

Was the alcohol breath test performed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

30 SEP 2013
DD/MMM/YYYY

Time of assessment

14:18
hour:min 24-hour clock

Result

Negative ☒

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Urine Pregnancy Test screening

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:45

Generated On: 23 Jun 2014 15:19:04

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

If Not Done, specify reason

Date of Test	30 SEP 2013 DD/MMM/YYYY
--------------	----------------------------

Specify result	Negative <input checked="" type="radio"/>
----------------	---

If unclear, please confirm with FSH test

Specify result of FSH test	< 20 IU/L <input type="radio"/>
	>= 20 IU/L <input type="radio"/>

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Urine Cotinine Test screening

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:45

Generated On: 23 Jun 2014 15:19:04

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

If Not Done, please specify the reason: _____

Date of Sample Collection	30 SEP 2013 DD/MMM/YYYY
---------------------------	----------------------------

Time of Sample Collection	14:02 hour:min 24-hour clock
---------------------------	---------------------------------

Result	Positive ≥ 200 mg/ml <input checked="" type="radio"/>
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ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Lab-BU SEROLOGY(2013/09/30)

Data signed: (FumimasaNobuoka) 14 May 2014 06:16:58

Generated On: 23 Jun 2014 15:19:04

Test Category

SEROLOGY

Date of Sample Collection

~~2013-SEP-30~~

Please document clinically relevant abnormalities in the AE form

Date (BU)

~~2013/09/30~~

Derived Form name

~~SEROLOGY(2013/09/30)~~

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Lab-BU SEROLOGY(2013/09/30)

Data signed: (FumimasaNobuoka) 14 May 2014 06:16:58

Generated On: 23 Jun 2014 15:19:04

Test Category	SEROLOGY
Date of Sample Collection	2013-SEP-30
Time of Blood Sample Collection	13:57
Time of Urine Sample Collection	14:02
Test Name	HEPATITIS C VIRUS
Result	
Text Result	
Unit	
Lower limit	
Upper limit	
Flag	
Clinically Significant?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Comment	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Lab-BU SEROLOGY(2013/09/30)

Data signed: (FumimasaNobuoka) 14 May 2014 06:16:58

Generated On: 23 Jun 2014 15:19:04

Result Category

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

Specimen English Comment 2

Result Supplementary Comment Code 1

Final 7.0 (Main CRF) (520)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Lab-BU SEROLOGY(2013/09/30)

Data signed: (FumimasaNobuoka) 14 May 2014 06:16:58

Generated On: 23 Jun 2014 15:19:04

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004514492

Please document clinically relevant abnormalities in the AE form

Date (BU)

2013/09/30

Blood Sample time(BU)

1357

Urine Sample time(BU)

1402

Derived Form name

SEROLOGY(2013/09/30)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Lab-BU SEROLOGY(2013/09/30)

Data signed: (FumimasaNobuoka) 14 May 2014 06:16:58

Generated On: 23 Jun 2014 15:19:04

Test Category	SEROLOGY
Date of Sample Collection	2013-SEP-30
Time of Blood Sample Collection	13:57
Time of Urine Sample Collection	14:02
Test Name	POS/NEG_HC
Result	
Text Result	NEGATIVE
Unit	
Lower limit	
Upper limit	NEGATIVE
Flag	
Clinically Significant?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Comment	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Lab-BU SEROLOGY(2013/09/30)

Data signed: (FumimasaNobuoka) 14 May 2014 06:16:58

Generated On: 23 Jun 2014 15:19:04

Result Category	S
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	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Lab-BU SEROLOGY(2013/09/30)

Data signed: (FumimasaNobuoka) 14 May 2014 06:16:58

Generated On: 23 Jun 2014 15:19:04

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004514492

Please document clinically relevant abnormalities in the AE form

Date (BU)

2013/09/30

Blood Sample time(BU)

1357

Urine Sample time(BU)

1402

Derived Form name

SEROLOGY(2013/09/30)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Lab-BU SEROLOGY(2013/09/30)

Data signed: (FumimasaNobuoka) 14 May 2014 06:16:58

Generated On: 23 Jun 2014 15:19:04

Test Category	SEROLOGY
Date of Sample Collection	2013-SEP-30
Time of Blood Sample Collection	13:57
Time of Urine Sample Collection	14:02
Test Name	S/CO VALUE
Result	0.08
Text Result	
Unit	S/CO
Lower limit	
Upper limit	1.00
Flag	
Clinically Significant?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Comment	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Lab-BU SEROLOGY(2013/09/30)

Data signed: (FumimasaNobuoka) 14 May 2014 06:16:58

Generated On: 23 Jun 2014 15:19:04

Result Category	N
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Text Result Code	
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Reference Value Category	L
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Timepoint(COHB)	
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Material Code	SERUM
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Chyle Comment Code	
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Chyle Comment English	
-----------------------	--

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

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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Specimen English Comment 2	
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Result Supplementary Comment Code 1	
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Final 7.0 (Main CRF) (520)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Lab-BU SEROLOGY(2013/09/30)

Data signed: (FumimasaNobuoka) 14 May 2014 06:16:58

Generated On: 23 Jun 2014 15:19:04

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004514492

Please document clinically relevant abnormalities in the AE form

Date (BU)

2013/09/30

Blood Sample time(BU)

1357

Urine Sample time(BU)

1402

Derived Form name

SEROLOGY(2013/09/30)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Lab-BU SEROLOGY(2013/09/30)

Data signed: (FumimasaNobuoka) 14 May 2014 06:16:58

Generated On: 23 Jun 2014 15:19:04

Test Category	SEROLOGY
Date of Sample Collection	2013-SEP-30
Time of Blood Sample Collection	13:57
Time of Urine Sample Collection	14:02
Test Name	HBS ANTIGEN
Result	
Text Result	
Unit	
Lower limit	
Upper limit	
Flag	
Clinically Significant?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Comment	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Lab-BU SEROLOGY(2013/09/30)

Data signed: (FumimasaNobuoka) 14 May 2014 06:16:58

Generated On: 23 Jun 2014 15:19:04

Result Category

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

Specimen English Comment 2

Result Supplementary Comment Code 1

Final 7.0 (Main CRF) (520)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Lab-BU SEROLOGY(2013/09/30)

Data signed: (FumimasaNobuoka) 14 May 2014 06:16:58

Generated On: 23 Jun 2014 15:19:04

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004514492

Please document clinically relevant abnormalities in the AE form

Date (BU)

2013/09/30

Blood Sample time(BU)

1357

Urine Sample time(BU)

1402

Derived Form name

SEROLOGY(2013/09/30)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Lab-BU SEROLOGY(2013/09/30)

Data signed: (FumimasaNobuoka) 14 May 2014 06:16:58

Generated On: 23 Jun 2014 15:19:04

Test Category	SEROLOGY
Date of Sample Collection	2013-SEP-30
Time of Blood Sample Collection	13:57
Time of Urine Sample Collection	14:02
Test Name	POS/NEG_HBS
Result	
Text Result	-
Unit	
Lower limit	
Upper limit	-
Flag	
Clinically Significant?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Comment	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Lab-BU SEROLOGY(2013/09/30)

Data signed: (FumimasaNobuoka) 14 May 2014 06:16:58

Generated On: 23 Jun 2014 15:19:04

Result Category	S
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	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Lab-BU SEROLOGY(2013/09/30)

Data signed: (FumimasaNobuoka) 14 May 2014 06:16:58

Generated On: 23 Jun 2014 15:19:04

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004514492

Please document clinically relevant abnormalities in the AE form

Date (BU)

2013/09/30

Blood Sample time(BU)

1357

Urine Sample time(BU)

1402

Derived Form name

SEROLOGY(2013/09/30)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Lab-BU SEROLOGY(2013/09/30)

Data signed: (FumimasaNobuoka) 14 May 2014 06:16:58

Generated On: 23 Jun 2014 15:19:04

Test Category	SEROLOGY
Date of Sample Collection	2013-SEP-30
Time of Blood Sample Collection	13:57
Time of Urine Sample Collection	14:02
Test Name	CONCENTRATION
Result	0.05
Text Result	
Unit	IU/ML
Lower limit	
Upper limit	0.05
Flag	
Clinically Significant?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Comment	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Lab-BU SEROLOGY(2013/09/30)

Data signed: (FumimasaNobuoka) 14 May 2014 06:16:58

Generated On: 23 Jun 2014 15:19:04

Result Category	⌵
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Text Result Code	_____
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Reference Value Category	⌵
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Timepoint(COHB)	_____
-----------------	-------

Material Code	SERUM
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Chyle Comment Code	_____
--------------------	-------

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

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

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

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

Specimen Comment Code 2	_____
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Specimen English Comment 2	_____
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Result Supplementary Comment Code 1	_____
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Final 7.0 (Main CRF) (520)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Lab-BU SEROLOGY(2013/09/30)

Data signed: (FumimasaNobuoka) 14 May 2014 06:16:58

Generated On: 23 Jun 2014 15:19:04

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004514492

Please document clinically relevant abnormalities in the AE form

Date (BU)

2013/09/30

Blood Sample time(BU)

1357

Urine Sample time(BU)

1402

Derived Form name

SEROLOGY(2013/09/30)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Lab-BU BLOOD CHEMISTRY(2013/09/30)

Data signed: (FumimasaNobuoka) 14 May 2014 06:16:59

Generated On: 23 Jun 2014 15:19:04

Test Category

BLOOD CHEMISTRY

Date of Sample Collection

2013 SEP 30

Please document clinically relevant abnormalities in the AE form

Date (BU)

2013/09/30

Derived Form name

BLOOD
CHEMISTRY(2013/09/30)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Lab-BU BLOOD CHEMISTRY(2013/09/30)

Data signed: (FumimasaNobuoka) 14 May 2014 06:16:59

Generated On: 23 Jun 2014 15:19:04

Test Category	BLOOD CHEMISTRY
Date of Sample Collection	2013 SEP 30
Time of Blood Sample Collection	13:57
Time of Urine Sample Collection	14:02
Test Name	TOTAL PROTEIN
Result	7.0
Text Result	
Unit	G/DL
Lower limit	6.7
Upper limit	8.3
Flag	
Clinically Significant?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Comment	

Final 7.0 (Main CRF) (520)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Lab-BU BLOOD CHEMISTRY(2013/09/30)

Data signed: (FumimasaNobuoka) 14 May 2014 06:16:59

Generated On: 23 Jun 2014 15:19:04

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	_____
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Specimen English Comment 1	_____
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Specimen Comment Code 2	_____
-------------------------	-------

Specimen English Comment 2	_____
----------------------------	-------

Result Supplementary Comment Code 1	_____
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Final 7.0 (Main CRF) (520)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Lab-BU BLOOD CHEMISTRY(2013/09/30)

Data signed: (FumimasaNobuoka) 14 May 2014 06:16:59

Generated On: 23 Jun 2014 15:19:04

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004514492

Please document clinically relevant abnormalities in the AE form

Date (BU)

2013/09/30

Blood Sample time(BU)

1357

Urine Sample time(BU)

1402

Derived Form name

BLOOD
CHEMISTRY(2013/09/30)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Lab-BU BLOOD CHEMISTRY(2013/09/30)

Data signed: (FumimasaNobuoka) 14 May 2014 06:16:59

Generated On: 23 Jun 2014 15:19:04

Test Category	BLOOD CHEMISTRY
Date of Sample Collection	2013 SEP 30
Time of Blood Sample Collection	13:57
Time of Urine Sample Collection	14:02
Test Name	ALBUMIN
Result	4.4
Text Result	
Unit	G/DL
Lower limit	3.8
Upper limit	5.3
Flag	
Clinically Significant?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Comment	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Lab-BU BLOOD CHEMISTRY(2013/09/30)

Data signed: (FumimasaNobuoka) 14 May 2014 06:16:59

Generated On: 23 Jun 2014 15:19:04

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	
Specimen English Comment 2	
Result Supplementary Comment Code 1	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Lab-BU BLOOD CHEMISTRY(2013/09/30)

Data signed: (FumimasaNobuoka) 14 May 2014 06:16:59

Generated On: 23 Jun 2014 15:19:04

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004514492

Please document clinically relevant abnormalities in the AE form

Date (BU)

2013/09/30

Blood Sample time(BU)

1357

Urine Sample time(BU)

1402

Derived Form name

BLOOD
CHEMISTRY(2013/09/30)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Lab-BU BLOOD CHEMISTRY(2013/09/30)

Data signed: (FumimasaNobuoka) 14 May 2014 06:16:59

Generated On: 23 Jun 2014 15:19:04

Test Category	BLOOD CHEMISTRY
Date of Sample Collection	2013 SEP 30
Time of Blood Sample Collection	13:57
Time of Urine Sample Collection	14:02
Test Name	TOTAL BILIRUBIN
Result	1.0
Text Result	
Unit	MG/DL
Lower limit	0.2
Upper limit	1.2
Flag	
Clinically Significant?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Comment	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Lab-BU BLOOD CHEMISTRY(2013/09/30)

Data signed: (FumimasaNobuoka) 14 May 2014 06:16:59

Generated On: 23 Jun 2014 15:19:04

Result Category	N
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Text Result Code	_____
------------------	-------

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

Timepoint(COHB)	_____
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Material Code	SERUM
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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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Specimen English Comment 2	_____
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Result Supplementary Comment Code 1	_____
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Final 7.0 (Main CRF) (520)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Lab-BU BLOOD CHEMISTRY(2013/09/30)

Data signed: (FumimasaNobuoka) 14 May 2014 06:16:59

Generated On: 23 Jun 2014 15:19:04

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004514492

Please document clinically relevant abnormalities in the AE form

Date (BU)

2013/09/30

Blood Sample time(BU)

1357

Urine Sample time(BU)

1402

Derived Form name

BLOOD
CHEMISTRY(2013/09/30)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Lab-BU BLOOD CHEMISTRY(2013/09/30)

Data signed: (FumimasaNobuoka) 14 May 2014 06:16:59

Generated On: 23 Jun 2014 15:19:04

Test Category	BLOOD CHEMISTRY
Date of Sample Collection	2013 SEP 30
Time of Blood Sample Collection	13:57
Time of Urine Sample Collection	14:02
Test Name	DIRECT BILIRUBIN
Result	0.2
Text Result	
Unit	MG/DL
Lower limit	0.0
Upper limit	0.3
Flag	
Clinically Significant?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Comment	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Lab-BU BLOOD CHEMISTRY(2013/09/30)

Data signed: (FumimasaNobuoka) 14 May 2014 06:16:59

Generated On: 23 Jun 2014 15:19:04

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	
Specimen English Comment 2	
Result Supplementary Comment Code 1	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Lab-BU BLOOD CHEMISTRY(2013/09/30)

Data signed: (FumimasaNobuoka) 14 May 2014 06:16:59

Generated On: 23 Jun 2014 15:19:04

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004514492

Please document clinically relevant abnormalities in the AE form

Date (BU)

2013/09/30

Blood Sample time(BU)

1357

Urine Sample time(BU)

1402

Derived Form name

BLOOD
CHEMISTRY(2013/09/30)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Lab-BU BLOOD CHEMISTRY(2013/09/30)

Data signed: (FumimasaNobuoka) 14 May 2014 06:16:59

Generated On: 23 Jun 2014 15:19:04

Test Category	BLOOD CHEMISTRY
Date of Sample Collection	2013 SEP 30
Time of Blood Sample Collection	13:57
Time of Urine Sample Collection	14:02
Test Name	AST
Result	15
Text Result	
Unit	U/L
Lower limit	10
Upper limit	40
Flag	
Clinically Significant?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Comment	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Lab-BU BLOOD CHEMISTRY(2013/09/30)

Data signed: (FumimasaNobuoka) 14 May 2014 06:16:59

Generated On: 23 Jun 2014 15:19:04

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	
Specimen English Comment 2	
Result Supplementary Comment Code 1	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Lab-BU BLOOD CHEMISTRY(2013/09/30)

Data signed: (FumimasaNobuoka) 14 May 2014 06:16:59

Generated On: 23 Jun 2014 15:19:04

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004514492

Please document clinically relevant abnormalities in the AE form

Date (BU)

2013/09/30

Blood Sample time(BU)

1357

Urine Sample time(BU)

1402

Derived Form name

BLOOD
CHEMISTRY(2013/09/30)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Lab-BU BLOOD CHEMISTRY(2013/09/30)

Data signed: (FumimasaNobuoka) 14 May 2014 06:16:59

Generated On: 23 Jun 2014 15:19:04

Test Category	BLOOD CHEMISTRY
Date of Sample Collection	2013 SEP 30
Time of Blood Sample Collection	13:57
Time of Urine Sample Collection	14:02
Test Name	ALT
Result	11
Text Result	
Unit	U/L
Lower limit	5
Upper limit	45
Flag	
Clinically Significant?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Comment	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Lab-BU BLOOD CHEMISTRY(2013/09/30)

Data signed: (FumimasaNobuoka) 14 May 2014 06:16:59

Generated On: 23 Jun 2014 15:19:04

Result Category	N
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Text Result Code	_____
------------------	-------

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

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

Material Code	SERUM
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Chyle Comment Code	_____
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Chyle Comment English	_____
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Hemolysis Comment Code	_____
------------------------	-------

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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Specimen English Comment 2	_____
----------------------------	-------

Result Supplementary Comment Code 1	_____
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Final 7.0 (Main CRF) (520)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Lab-BU BLOOD CHEMISTRY(2013/09/30)

Data signed: (FumimasaNobuoka) 14 May 2014 06:16:59

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Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004514492

Please document clinically relevant abnormalities in the AE form

Date (BU)

2013/09/30

Blood Sample time(BU)

1357

Urine Sample time(BU)

1402

Derived Form name

BLOOD
CHEMISTRY(2013/09/30)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Lab-BU BLOOD CHEMISTRY(2013/09/30)

Data signed: (FumimasaNobuoka) 14 May 2014 06:16:59

Generated On: 23 Jun 2014 15:19:04

Test Category	BLOOD CHEMISTRY
Date of Sample Collection	2013 SEP 30
Time of Blood Sample Collection	13:57
Time of Urine Sample Collection	14:02
Test Name	LDH
Result	128
Text Result	
Unit	U/L
Lower limit	120
Upper limit	240
Flag	
Clinically Significant?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Comment	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Lab-BU BLOOD CHEMISTRY(2013/09/30)

Data signed: (FumimasaNobuoka) 14 May 2014 06:16:59

Generated On: 23 Jun 2014 15:19:04

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	
Specimen English Comment 2	
Result Supplementary Comment Code 1	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Lab-BU BLOOD CHEMISTRY(2013/09/30)

Data signed: (FumimasaNobuoka) 14 May 2014 06:16:59

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Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004514492

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Date (BU)

2013/09/30

Blood Sample time(BU)

1357

Urine Sample time(BU)

1402

Derived Form name

BLOOD
CHEMISTRY(2013/09/30)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Lab-BU BLOOD CHEMISTRY(2013/09/30)

Data signed: (FumimasaNobuoka) 14 May 2014 06:16:59

Generated On: 23 Jun 2014 15:19:04

Test Category	BLOOD CHEMISTRY
Date of Sample Collection	2013 SEP 30
Time of Blood Sample Collection	13:57
Time of Urine Sample Collection	14:02
Test Name	AP
Result	217
Text Result	
Unit	U/L
Lower limit	100
Upper limit	325
Flag	
Clinically Significant?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Comment	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Lab-BU BLOOD CHEMISTRY(2013/09/30)

Data signed: (FumimasaNobuoka) 14 May 2014 06:16:59

Generated On: 23 Jun 2014 15:19:04

Result Category	N
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Text Result Code	_____
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Reference Value Category	-
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Timepoint(COHB)	_____
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Material Code	SERUM
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Chyle Comment Code	_____
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Chyle Comment English	_____
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Hemolysis Comment Code	_____
------------------------	-------

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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Specimen English Comment 2	_____
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Result Supplementary Comment Code 1	_____
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Final 7.0 (Main CRF) (520)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Lab-BU BLOOD CHEMISTRY(2013/09/30)

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Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004514492

Please document clinically relevant abnormalities in the AE form

Date (BU)

2013/09/30

Blood Sample time(BU)

1357

Urine Sample time(BU)

1402

Derived Form name

BLOOD
CHEMISTRY(2013/09/30)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Lab-BU BLOOD CHEMISTRY(2013/09/30)

Data signed: (FumimasaNobuoka) 14 May 2014 06:16:59

Generated On: 23 Jun 2014 15:19:04

Test Category	BLOOD CHEMISTRY
Date of Sample Collection	2013 SEP 30
Time of Blood Sample Collection	13:57
Time of Urine Sample Collection	14:02
Test Name	GGT
Result	17
Text Result	
Unit	U/L
Lower limit	
Upper limit	30
Flag	
Clinically Significant?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Comment	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Lab-BU BLOOD CHEMISTRY(2013/09/30)

Data signed: (FumimasaNobuoka) 14 May 2014 06:16:59

Generated On: 23 Jun 2014 15:19:04

Result Category	N
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Text Result Code	_____
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Reference Value Category	E
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Timepoint(COHB)	_____
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Material Code	SERUM
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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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Specimen English Comment 2	_____
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Result Supplementary Comment Code 1	_____
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Final 7.0 (Main CRF) (520)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Lab-BU BLOOD CHEMISTRY(2013/09/30)

Data signed: (FumimasaNobuoka) 14 May 2014 06:16:59

Generated On: 23 Jun 2014 15:19:04

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004514492

Please document clinically relevant abnormalities in the AE form

Date (BU)

2013/09/30

Blood Sample time(BU)

1357

Urine Sample time(BU)

1402

Derived Form name

BLOOD
CHEMISTRY(2013/09/30)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Lab-BU BLOOD CHEMISTRY(2013/09/30)

Data signed: (FumimasaNobuoka) 14 May 2014 06:16:59

Generated On: 23 Jun 2014 15:19:04

Test Category	BLOOD CHEMISTRY
Date of Sample Collection	2013 SEP 30
Time of Blood Sample Collection	13:57
Time of Urine Sample Collection	14:02
Test Name	FASTING GLUCOSE
Result	77
Text Result	
Unit	MG/DL
Lower limit	70
Upper limit	109
Flag	
Clinically Significant?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Comment	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Lab-BU BLOOD CHEMISTRY(2013/09/30)

Data signed: (FumimasaNobuoka) 14 May 2014 06:16:59

Generated On: 23 Jun 2014 15:19:04

Result Category	N
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Text Result Code	_____
------------------	-------

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

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

Material Code	SERUM
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Chyle Comment Code	_____
--------------------	-------

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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Specimen English Comment 2	_____
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Result Supplementary Comment Code 1	_____
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Final 7.0 (Main CRF) (520)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Lab-BU BLOOD CHEMISTRY(2013/09/30)

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Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004514492

Please document clinically relevant abnormalities in the AE form

Date (BU)

2013/09/30

Blood Sample time(BU)

1357

Urine Sample time(BU)

1402

Derived Form name

BLOOD
CHEMISTRY(2013/09/30)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Lab-BU BLOOD CHEMISTRY(2013/09/30)

Data signed: (FumimasaNobuoka) 14 May 2014 06:16:59

Generated On: 23 Jun 2014 15:19:04

Test Category	BLOOD CHEMISTRY
Date of Sample Collection	2013 SEP 30
Time of Blood Sample Collection	13:57
Time of Urine Sample Collection	14:02
Test Name	CREATININE
Result	0.47
Text Result	
Unit	MG/DL
Lower limit	0.47
Upper limit	0.79
Flag	
Clinically Significant?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Comment	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Lab-BU BLOOD CHEMISTRY(2013/09/30)

Data signed: (FumimasaNobuoka) 14 May 2014 06:16:59

Generated On: 23 Jun 2014 15:19:04

Result Category	N
-----------------	---

Text Result Code	_____
------------------	-------

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

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

Material Code	SERUM
---------------	-------

Chyle Comment Code	_____
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Chyle Comment English	_____
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Hemolysis Comment Code	_____
------------------------	-------

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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Specimen English Comment 2	_____
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Result Supplementary Comment Code 1	_____
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Final 7.0 (Main CRF) (520)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Lab-BU BLOOD CHEMISTRY(2013/09/30)

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Generated On: 23 Jun 2014 15:19:04

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004514492

Please document clinically relevant abnormalities in the AE form

Date (BU)

2013/09/30

Blood Sample time(BU)

1357

Urine Sample time(BU)

1402

Derived Form name

BLOOD
CHEMISTRY(2013/09/30)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Lab-BU BLOOD CHEMISTRY(2013/09/30)

Data signed: (FumimasaNobuoka) 14 May 2014 06:16:59

Generated On: 23 Jun 2014 15:19:04

Test Category	BLOOD CHEMISTRY
Date of Sample Collection	2013 SEP 30
Time of Blood Sample Collection	13:57
Time of Urine Sample Collection	14:02
Test Name	BUN
Result	10
Text Result	
Unit	MG/DL
Lower limit	8
Upper limit	23
Flag	
Clinically Significant?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Comment	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Lab-BU BLOOD CHEMISTRY(2013/09/30)

Data signed: (FumimasaNobuoka) 14 May 2014 06:16:59

Generated On: 23 Jun 2014 15:19:04

Result Category	N
-----------------	---

Text Result Code	_____
------------------	-------

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

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

Material Code	SERUM
---------------	-------

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

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

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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Specimen English Comment 2	_____
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Result Supplementary Comment Code 1	_____
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Final 7.0 (Main CRF) (520)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Lab-BU BLOOD CHEMISTRY(2013/09/30)

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Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004514492

Please document clinically relevant abnormalities in the AE form

Date (BU)

2013/09/30

Blood Sample time(BU)

1357

Urine Sample time(BU)

1402

Derived Form name

BLOOD
CHEMISTRY(2013/09/30)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Lab-BU BLOOD CHEMISTRY(2013/09/30)

Data signed: (FumimasaNobuoka) 14 May 2014 06:16:59

Generated On: 23 Jun 2014 15:19:04

Test Category	BLOOD CHEMISTRY
Date of Sample Collection	2013 SEP 30
Time of Blood Sample Collection	13:57
Time of Urine Sample Collection	14:02
Test Name	TRIGLYCERIDES
Result	128
Text Result	
Unit	MG/DL
Lower limit	30
Upper limit	149
Flag	
Clinically Significant?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Comment	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Lab-BU BLOOD CHEMISTRY(2013/09/30)

Data signed: (FumimasaNobuoka) 14 May 2014 06:16:59

Generated On: 23 Jun 2014 15:19:04

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	
Specimen English Comment 2	
Result Supplementary Comment Code 1	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

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Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004514492

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Date (BU)

2013/09/30

Blood Sample time(BU)

1357

Urine Sample time(BU)

1402

Derived Form name

BLOOD
CHEMISTRY(2013/09/30)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Lab-BU BLOOD CHEMISTRY(2013/09/30)

Data signed: (FumimasaNobuoka) 14 May 2014 06:16:59

Generated On: 23 Jun 2014 15:19:04

Test Category	BLOOD CHEMISTRY
Date of Sample Collection	2013 SEP 30
Time of Blood Sample Collection	13:57
Time of Urine Sample Collection	14:02
Test Name	TOTAL CHOLESTEROL
Result	188
Text Result	
Unit	MG/DL
Lower limit	120
Upper limit	219
Flag	
Clinically Significant?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Comment	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Lab-BU BLOOD CHEMISTRY(2013/09/30)

Data signed: (FumimasaNobuoka) 14 May 2014 06:16:59

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Result Category	N
-----------------	---

Text Result Code	_____
------------------	-------

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

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

Material Code	SERUM
---------------	-------

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

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	_____
----------------------------	-------

Specimen Comment Code 2	_____
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Specimen English Comment 2	_____
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Result Supplementary Comment Code 1	_____
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Final 7.0 (Main CRF) (520)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

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Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004514492

Please document clinically relevant abnormalities in the AE form

Date (BU)

2013/09/30

Blood Sample time(BU)

1357

Urine Sample time(BU)

1402

Derived Form name

BLOOD
CHEMISTRY(2013/09/30)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Lab-BU BLOOD CHEMISTRY(2013/09/30)

Data signed: (FumimasaNobuoka) 14 May 2014 06:16:59

Generated On: 23 Jun 2014 15:19:04

Test Category	BLOOD CHEMISTRY
Date of Sample Collection	2013 SEP 30
Time of Blood Sample Collection	13:57
Time of Urine Sample Collection	14:02
Test Name	SODIUM
Result	141
Text Result	
Unit	MEQ/L
Lower limit	137
Upper limit	147
Flag	
Clinically Significant?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Comment	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Lab-BU BLOOD CHEMISTRY(2013/09/30)

Data signed: (FumimasaNobuoka) 14 May 2014 06:16:59

Generated On: 23 Jun 2014 15:19:04

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	
Specimen English Comment 2	
Result Supplementary Comment Code 1	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Lab-BU BLOOD CHEMISTRY(2013/09/30)

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Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004514492

Please document clinically relevant abnormalities in the AE form

Date (BU)

2013/09/30

Blood Sample time(BU)

1357

Urine Sample time(BU)

1402

Derived Form name

BLOOD
CHEMISTRY(2013/09/30)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Lab-BU BLOOD CHEMISTRY(2013/09/30)

Data signed: (FumimasaNobuoka) 14 May 2014 06:16:59

Generated On: 23 Jun 2014 15:19:04

Test Category	BLOOD CHEMISTRY
Date of Sample Collection	2013 SEP 30
Time of Blood Sample Collection	13:57
Time of Urine Sample Collection	14:02
Test Name	POTASSIUM
Result	3.9
Text Result	
Unit	MEQ/L
Lower limit	3.5
Upper limit	5.0
Flag	
Clinically Significant?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Comment	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Lab-BU BLOOD CHEMISTRY(2013/09/30)

Data signed: (FumimasaNobuoka) 14 May 2014 06:16:59

Generated On: 23 Jun 2014 15:19:04

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	
Specimen English Comment 2	
Result Supplementary Comment Code 1	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Lab-BU BLOOD CHEMISTRY(2013/09/30)

Data signed: (FumimasaNobuoka) 14 May 2014 06:16:59

Generated On: 23 Jun 2014 15:19:04

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004514492

Please document clinically relevant abnormalities in the AE form

Date (BU)

2013/09/30

Blood Sample time(BU)

1357

Urine Sample time(BU)

1402

Derived Form name

BLOOD
CHEMISTRY(2013/09/30)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Lab-BU HEMATOLOGY(2013/09/30)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:08

Generated On: 23 Jun 2014 15:19:04

Test Category

HEMATOLOGY

Date of Sample Collection

2013 SEP 30

Please document clinically relevant abnormalities in the AE form

Date (BU)

2013/09/30

Derived Form name

HEMATOLOGY(2013/09/30)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Lab-BU HEMATOLOGY(2013/09/30)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:08

Generated On: 23 Jun 2014 15:19:04

Test Category	HEMATOLOGY
Date of Sample Collection	2013 SEP 30
Time of Blood Sample Collection	13:57
Time of Urine Sample Collection	14:02
Test Name	WBC COUNT
Result	10700
Text Result	
Unit	/UL
Lower limit	3300
Upper limit	9000
Flag	H
Clinically Significant?	No <input checked="" type="radio"/>
Comment	
Result Category	N

Final 7.0 (Main CRF) (520)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Lab-BU HEMATOLOGY(2013/09/30)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:08

Generated On: 23 Jun 2014 15:19:04

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

Specimen English Comment 2

Result Supplementary Comment Code 1

Result Supplementary English Comment Code 1

Final 7.0 (Main CRF) (520)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Lab-BU HEMATOLOGY(2013/09/30)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:08

Generated On: 23 Jun 2014 15:19:04

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004514492

Please document clinically relevant abnormalities in the AE form

Date (BU)

2013/09/30

Blood Sample time(BU)

1357

Urine Sample time(BU)

1402

Derived Form name

HEMATOLOGY(2013/09/30)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Lab-BU HEMATOLOGY(2013/09/30)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:08

Generated On: 23 Jun 2014 15:19:04

Test Category	HEMATOLOGY
Date of Sample Collection	2013 SEP 30
Time of Blood Sample Collection	13:57
Time of Urine Sample Collection	14:02
Test Name	RBC COUNT
Result	423
Text Result	
Unit	10 ⁴ /UL
Lower limit	380
Upper limit	500
Flag	
Clinically Significant?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Comment	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Lab-BU HEMATOLOGY(2013/09/30)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:08

Generated On: 23 Jun 2014 15:19:04

Result Category	N
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Text Result Code	_____
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Reference Value Category	-
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Timepoint(COHB)	_____
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Material Code	BLOOD
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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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Specimen English Comment 2	_____
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Result Supplementary Comment Code 1	_____
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Final 7.0 (Main CRF) (520)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Lab-BU HEMATOLOGY(2013/09/30)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:08

Generated On: 23 Jun 2014 15:19:04

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004514492

Please document clinically relevant abnormalities in the AE form

Date (BU)

2013/09/30

Blood Sample time(BU)

1357

Urine Sample time(BU)

1402

Derived Form name

HEMATOLOGY(2013/09/30)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Lab-BU HEMATOLOGY(2013/09/30)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:08

Generated On: 23 Jun 2014 15:19:04

Test Category	HEMATOLOGY
Date of Sample Collection	2013 SEP 30
Time of Blood Sample Collection	13:57
Time of Urine Sample Collection	14:02
Test Name	HEMOGLOBIN
Result	13.0
Text Result	
Unit	G/DL
Lower limit	11.5
Upper limit	15.0
Flag	
Clinically Significant?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Comment	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Lab-BU HEMATOLOGY(2013/09/30)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:08

Generated On: 23 Jun 2014 15:19:04

Result Category	N
-----------------	---

Text Result Code	_____
------------------	-------

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

Timepoint(COHB)	_____
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Material Code	BLOOD
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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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Specimen English Comment 2	_____
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Result Supplementary Comment Code 1	_____
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Final 7.0 (Main CRF) (520)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Lab-BU HEMATOLOGY(2013/09/30)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:08

Generated On: 23 Jun 2014 15:19:04

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004514492

Please document clinically relevant abnormalities in the AE form

Date (BU)

2013/09/30

Blood Sample time(BU)

1357

Urine Sample time(BU)

1402

Derived Form name

HEMATOLOGY(2013/09/30)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Lab-BU HEMATOLOGY(2013/09/30)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:08

Generated On: 23 Jun 2014 15:19:04

Test Category	HEMATOLOGY
Date of Sample Collection	2013 SEP 30
Time of Blood Sample Collection	13:57
Time of Urine Sample Collection	14:02
Test Name	HEMATOCRIT
Result	37.7
Text Result	
Unit	%
Lower limit	34.8
Upper limit	45.0
Flag	
Clinically Significant?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Comment	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Lab-BU HEMATOLOGY(2013/09/30)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:08

Generated On: 23 Jun 2014 15:19:04

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	
Specimen English Comment 2	
Result Supplementary Comment Code 1	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Lab-BU HEMATOLOGY(2013/09/30)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:08

Generated On: 23 Jun 2014 15:19:04

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004514492

Please document clinically relevant abnormalities in the AE form

Date (BU)

2013/09/30

Blood Sample time(BU)

1357

Urine Sample time(BU)

1402

Derived Form name

HEMATOLOGY(2013/09/30)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Lab-BU HEMATOLOGY(2013/09/30)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:08

Generated On: 23 Jun 2014 15:19:04

Test Category	HEMATOLOGY
Date of Sample Collection	2013 SEP 30
Time of Blood Sample Collection	13:57
Time of Urine Sample Collection	14:02
Test Name	MCV
Result	89
Text Result	
Unit	FL
Lower limit	85
Upper limit	102
Flag	
Clinically Significant?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Comment	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Lab-BU HEMATOLOGY(2013/09/30)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:08

Generated On: 23 Jun 2014 15:19:04

Result Category	N
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Text Result Code	_____
------------------	-------

Reference Value Category	-
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Timepoint(COHB)	_____
-----------------	-------

Material Code	BLOOD
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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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Specimen English Comment 2	_____
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Result Supplementary Comment Code 1	_____
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Final 7.0 (Main CRF) (520)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Lab-BU HEMATOLOGY(2013/09/30)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:08

Generated On: 23 Jun 2014 15:19:04

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004514492

Please document clinically relevant abnormalities in the AE form

Date (BU)

2013/09/30

Blood Sample time(BU)

1357

Urine Sample time(BU)

1402

Derived Form name

HEMATOLOGY(2013/09/30)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Lab-BU HEMATOLOGY(2013/09/30)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:08

Generated On: 23 Jun 2014 15:19:04

Test Category	HEMATOLOGY
Date of Sample Collection	2013 SEP 30
Time of Blood Sample Collection	13:57
Time of Urine Sample Collection	14:02
Test Name	MCH
Result	30.7
Text Result	
Unit	PG
Lower limit	28.0
Upper limit	34.0
Flag	
Clinically Significant?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Comment	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Lab-BU HEMATOLOGY(2013/09/30)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:08

Generated On: 23 Jun 2014 15:19:04

Result Category	N
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Text Result Code	_____
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Reference Value Category	-
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Timepoint(COHB)	_____
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Material Code	BLOOD
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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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Specimen English Comment 2	_____
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Result Supplementary Comment Code 1	_____
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Final 7.0 (Main CRF) (520)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Lab-BU HEMATOLOGY(2013/09/30)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:08

Generated On: 23 Jun 2014 15:19:04

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004514492

Please document clinically relevant abnormalities in the AE form

Date (BU)

2013/09/30

Blood Sample time(BU)

1357

Urine Sample time(BU)

1402

Derived Form name

HEMATOLOGY(2013/09/30)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Lab-BU HEMATOLOGY(2013/09/30)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:08

Generated On: 23 Jun 2014 15:19:04

Test Category	HEMATOLOGY
Date of Sample Collection	2013 SEP 30
Time of Blood Sample Collection	13:57
Time of Urine Sample Collection	14:02
Test Name	MCHC
Result	34.5
Text Result	
Unit	%
Lower limit	30.2
Upper limit	35.1
Flag	
Clinically Significant?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Comment	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Lab-BU HEMATOLOGY(2013/09/30)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:08

Generated On: 23 Jun 2014 15:19:04

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	
Specimen English Comment 2	
Result Supplementary Comment Code 1	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Lab-BU HEMATOLOGY(2013/09/30)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:08

Generated On: 23 Jun 2014 15:19:04

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004514492

Please document clinically relevant abnormalities in the AE form

Date (BU)

2013/09/30

Blood Sample time(BU)

1357

Urine Sample time(BU)

1402

Derived Form name

HEMATOLOGY(2013/09/30)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Lab-BU HEMATOLOGY(2013/09/30)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:08

Generated On: 23 Jun 2014 15:19:04

Test Category	HEMATOLOGY
Date of Sample Collection	2013 SEP 30
Time of Blood Sample Collection	13:57
Time of Urine Sample Collection	14:02
Test Name	PLATELET COUNT
Result	25.5
Text Result	
Unit	10 ⁴ /UL
Lower limit	14.0
Upper limit	34.0
Flag	
Clinically Significant?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Comment	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Lab-BU HEMATOLOGY(2013/09/30)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:08

Generated On: 23 Jun 2014 15:19:04

Result Category	N
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Text Result Code	_____
------------------	-------

Reference Value Category	-
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Timepoint(COHB)	_____
-----------------	-------

Material Code	BLOOD
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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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Specimen English Comment 2	_____
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Result Supplementary Comment Code 1	_____
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Final 7.0 (Main CRF) (520)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Lab-BU HEMATOLOGY(2013/09/30)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:08

Generated On: 23 Jun 2014 15:19:04

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004514492

Please document clinically relevant abnormalities in the AE form

Date (BU)

2013/09/30

Blood Sample time(BU)

1357

Urine Sample time(BU)

1402

Derived Form name

HEMATOLOGY(2013/09/30)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Lab-BU HEMATOLOGY(2013/09/30)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:08

Generated On: 23 Jun 2014 15:19:04

Test Category	HEMATOLOGY
Date of Sample Collection	2013 SEP 30
Time of Blood Sample Collection	13:57
Time of Urine Sample Collection	14:02
Test Name	DIFFERENTIAL WBC
Result	
Text Result	
Unit	
Lower limit	
Upper limit	
Flag	
Clinically Significant?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Comment	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Lab-BU HEMATOLOGY(2013/09/30)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:08

Generated On: 23 Jun 2014 15:19:04

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

Specimen English Comment 2

Result Supplementary Comment Code 1

Final 7.0 (Main CRF) (520)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Lab-BU HEMATOLOGY(2013/09/30)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:08

Generated On: 23 Jun 2014 15:19:04

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004514492

Please document clinically relevant abnormalities in the AE form

Date (BU)

2013/09/30

Blood Sample time(BU)

1357

Urine Sample time(BU)

1402

Derived Form name

HEMATOLOGY(2013/09/30)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Lab-BU HEMATOLOGY(2013/09/30)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:08

Generated On: 23 Jun 2014 15:19:04

Test Category	HEMATOLOGY
Date of Sample Collection	2013 SEP 30
Time of Blood Sample Collection	13:57
Time of Urine Sample Collection	14:02
Test Name	NEUTROPHILS (REL)
Result	55.0
Text Result	
Unit	%
Lower limit	40.0
Upper limit	75.0
Flag	
Clinically Significant?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Comment	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Lab-BU HEMATOLOGY(2013/09/30)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:08

Generated On: 23 Jun 2014 15:19:04

Result Category	N
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Text Result Code	_____
------------------	-------

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

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

Material Code	BLOOD
---------------	-------

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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Specimen English Comment 2	_____
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Result Supplementary Comment Code 1	_____
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Final 7.0 (Main CRF) (520)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Lab-BU HEMATOLOGY(2013/09/30)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:08

Generated On: 23 Jun 2014 15:19:04

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004514492

Please document clinically relevant abnormalities in the AE form

Date (BU)

2013/09/30

Blood Sample time(BU)

1357

Urine Sample time(BU)

1402

Derived Form name

HEMATOLOGY(2013/09/30)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Lab-BU HEMATOLOGY(2013/09/30)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:08

Generated On: 23 Jun 2014 15:19:04

Test Category	HEMATOLOGY
Date of Sample Collection	2013 SEP 30
Time of Blood Sample Collection	13:57
Time of Urine Sample Collection	14:02
Test Name	LYMPHOCYTES (REL)
Result	39.1
Text Result	
Unit	%
Lower limit	18.0
Upper limit	49.0
Flag	
Clinically Significant?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Comment	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Lab-BU HEMATOLOGY(2013/09/30)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:08

Generated On: 23 Jun 2014 15:19:04

Result Category	N
-----------------	---

Text Result Code	_____
------------------	-------

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

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

Material Code	BLOOD
---------------	-------

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

Chyle Comment English	_____
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Hemolysis Comment Code	_____
------------------------	-------

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

Specimen Comment Code 1	_____
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Specimen English Comment 1	_____
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Specimen Comment Code 2	_____
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Specimen English Comment 2	_____
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Result Supplementary Comment Code 1	_____
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Final 7.0 (Main CRF) (520)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Lab-BU HEMATOLOGY(2013/09/30)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:08

Generated On: 23 Jun 2014 15:19:04

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004514492

Please document clinically relevant abnormalities in the AE form

Date (BU)

2013/09/30

Blood Sample time(BU)

1357

Urine Sample time(BU)

1402

Derived Form name

HEMATOLOGY(2013/09/30)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Lab-BU HEMATOLOGY(2013/09/30)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:08

Generated On: 23 Jun 2014 15:19:04

Test Category	HEMATOLOGY
Date of Sample Collection	2013 SEP 30
Time of Blood Sample Collection	13:57
Time of Urine Sample Collection	14:02
Test Name	MONOCYTES (REL)
Result	4.2
Text Result	
Unit	%
Lower limit	2.0
Upper limit	10.0
Flag	
Clinically Significant?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Comment	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Lab-BU HEMATOLOGY(2013/09/30)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:08

Generated On: 23 Jun 2014 15:19:04

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	
Specimen English Comment 2	
Result Supplementary Comment Code 1	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Lab-BU HEMATOLOGY(2013/09/30)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:08

Generated On: 23 Jun 2014 15:19:04

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004514492

Please document clinically relevant abnormalities in the AE form

Date (BU)

2013/09/30

Blood Sample time(BU)

1357

Urine Sample time(BU)

1402

Derived Form name

HEMATOLOGY(2013/09/30)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Lab-BU HEMATOLOGY(2013/09/30)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:08

Generated On: 23 Jun 2014 15:19:04

Test Category	HEMATOLOGY
Date of Sample Collection	2013 SEP 30
Time of Blood Sample Collection	13:57
Time of Urine Sample Collection	14:02
Test Name	EOSINOPHILS (REL)
Result	1.3
Text Result	
Unit	%
Lower limit	0.0
Upper limit	8.0
Flag	
Clinically Significant?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Comment	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Lab-BU HEMATOLOGY(2013/09/30)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:08

Generated On: 23 Jun 2014 15:19:04

Result Category	N
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Text Result Code	_____
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Reference Value Category	-
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Timepoint(COHB)	_____
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Material Code	BLOOD
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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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Specimen English Comment 2	_____
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Result Supplementary Comment Code 1	_____
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Final 7.0 (Main CRF) (520)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Lab-BU HEMATOLOGY(2013/09/30)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:08

Generated On: 23 Jun 2014 15:19:04

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004514492

Please document clinically relevant abnormalities in the AE form

Date (BU)

2013/09/30

Blood Sample time(BU)

1357

Urine Sample time(BU)

1402

Derived Form name

HEMATOLOGY(2013/09/30)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Lab-BU HEMATOLOGY(2013/09/30)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:08

Generated On: 23 Jun 2014 15:19:04

Test Category	HEMATOLOGY
Date of Sample Collection	2013 SEP 30
Time of Blood Sample Collection	13:57
Time of Urine Sample Collection	14:02
Test Name	BASOPHILS (REL)
Result	0.4
Text Result	
Unit	%
Lower limit	0.0
Upper limit	2.0
Flag	
Clinically Significant?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Comment	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Lab-BU HEMATOLOGY(2013/09/30)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:08

Generated On: 23 Jun 2014 15:19:04

Result Category	N
-----------------	---

Text Result Code	_____
------------------	-------

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

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

Material Code	BLOOD
---------------	-------

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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Specimen English Comment 2	_____
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Result Supplementary Comment Code 1	_____
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Final 7.0 (Main CRF) (520)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Lab-BU HEMATOLOGY(2013/09/30)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:08

Generated On: 23 Jun 2014 15:19:04

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004514492

Please document clinically relevant abnormalities in the AE form

Date (BU)

2013/09/30

Blood Sample time(BU)

1357

Urine Sample time(BU)

1402

Derived Form name

HEMATOLOGY(2013/09/30)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Lab-BU HEMATOLOGY(2013/09/30)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:08

Generated On: 23 Jun 2014 15:19:04

Test Category	HEMATOLOGY
Date of Sample Collection	2013 SEP 30
Time of Blood Sample Collection	13:57
Time of Urine Sample Collection	14:02
Test Name	NEUTROPHILS (ABS)
Result	5900
Text Result	
Unit	/UL
Lower limit	
Upper limit	
Flag	
Clinically Significant?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Comment	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Lab-BU HEMATOLOGY(2013/09/30)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:08

Generated On: 23 Jun 2014 15:19:04

Result Category	N
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Text Result Code	<hr/>
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Reference Value Category	<hr/>
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Timepoint(COHB)	<hr/>
-----------------	-------

Material Code	BLOOD
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Chyle Comment Code	<hr/>
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Chyle Comment English	<hr/>
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Hemolysis Comment Code	<hr/>
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Hemolysis Comment English	<hr/>
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Specimen Comment Code 1	<hr/>
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Specimen English Comment 1	<hr/>
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Specimen Comment Code 2	<hr/>
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Specimen English Comment 2	<hr/>
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Result Supplementary Comment Code 1	<hr/>
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Final 7.0 (Main CRF) (520)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Lab-BU HEMATOLOGY(2013/09/30)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:08

Generated On: 23 Jun 2014 15:19:04

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004514492

Please document clinically relevant abnormalities in the AE form

Date (BU)

2013/09/30

Blood Sample time(BU)

1357

Urine Sample time(BU)

1402

Derived Form name

HEMATOLOGY(2013/09/30)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Lab-BU HEMATOLOGY(2013/09/30)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:08

Generated On: 23 Jun 2014 15:19:04

Test Category	HEMATOLOGY
Date of Sample Collection	2013 SEP 30
Time of Blood Sample Collection	13:57
Time of Urine Sample Collection	14:02
Test Name	LYMPHOCYTES (ABS)
Result	4200
Text Result	
Unit	/UL
Lower limit	
Upper limit	
Flag	
Clinically Significant?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Comment	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Lab-BU HEMATOLOGY(2013/09/30)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:08

Generated On: 23 Jun 2014 15:19:04

Result Category	N
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Text Result Code	<hr/>
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Reference Value Category	<hr/>
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Timepoint(COHB)	<hr/>
-----------------	-------

Material Code	BLOOD
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Chyle Comment Code	<hr/>
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Chyle Comment English	<hr/>
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Hemolysis Comment Code	<hr/>
------------------------	-------

Hemolysis Comment English	<hr/>
---------------------------	-------

Specimen Comment Code 1	<hr/>
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Specimen English Comment 1	<hr/>
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Specimen Comment Code 2	<hr/>
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Specimen English Comment 2	<hr/>
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Result Supplementary Comment Code 1	<hr/>
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Final 7.0 (Main CRF) (520)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Lab-BU HEMATOLOGY(2013/09/30)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:08

Generated On: 23 Jun 2014 15:19:04

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004514492

Please document clinically relevant abnormalities in the AE form

Date (BU)

2013/09/30

Blood Sample time(BU)

1357

Urine Sample time(BU)

1402

Derived Form name

HEMATOLOGY(2013/09/30)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Lab-BU HEMATOLOGY(2013/09/30)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:08

Generated On: 23 Jun 2014 15:19:04

Test Category	HEMATOLOGY
Date of Sample Collection	2013 SEP 30
Time of Blood Sample Collection	13:57
Time of Urine Sample Collection	14:02
Test Name	MONOCYTES (ABS)
Result	450
Text Result	
Unit	/UL
Lower limit	
Upper limit	
Flag	
Clinically Significant?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Comment	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Lab-BU HEMATOLOGY(2013/09/30)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:08

Generated On: 23 Jun 2014 15:19:04

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	
Specimen English Comment 2	
Result Supplementary Comment Code 1	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Lab-BU HEMATOLOGY(2013/09/30)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:08

Generated On: 23 Jun 2014 15:19:04

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004514492

Please document clinically relevant abnormalities in the AE form

Date (BU)

2013/09/30

Blood Sample time(BU)

1357

Urine Sample time(BU)

1402

Derived Form name

HEMATOLOGY(2013/09/30)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Lab-BU HEMATOLOGY(2013/09/30)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:08

Generated On: 23 Jun 2014 15:19:04

Test Category	HEMATOLOGY
Date of Sample Collection	2013 SEP 30
Time of Blood Sample Collection	13:57
Time of Urine Sample Collection	14:02
Test Name	EOSINOPHILS (ABS)
Result	140
Text Result	
Unit	/UL
Lower limit	
Upper limit	
Flag	
Clinically Significant?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Comment	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Lab-BU HEMATOLOGY(2013/09/30)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:08

Generated On: 23 Jun 2014 15:19:04

Result Category	N
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Text Result Code	<hr/>
------------------	-------

Reference Value Category	<hr/>
--------------------------	-------

Timepoint(COHB)	<hr/>
-----------------	-------

Material Code	BLOOD
---------------	-------

Chyle Comment Code	<hr/>
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Chyle Comment English	<hr/>
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Hemolysis Comment Code	<hr/>
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Hemolysis Comment English	<hr/>
---------------------------	-------

Specimen Comment Code 1	<hr/>
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Specimen English Comment 1	<hr/>
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Specimen Comment Code 2	<hr/>
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Specimen English Comment 2	<hr/>
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Result Supplementary Comment Code 1	<hr/>
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Final 7.0 (Main CRF) (520)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Lab-BU HEMATOLOGY(2013/09/30)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:08

Generated On: 23 Jun 2014 15:19:04

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004514492

Please document clinically relevant abnormalities in the AE form

Date (BU)

2013/09/30

Blood Sample time(BU)

1357

Urine Sample time(BU)

1402

Derived Form name

HEMATOLOGY(2013/09/30)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Lab-BU HEMATOLOGY(2013/09/30)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:08

Generated On: 23 Jun 2014 15:19:04

Test Category	HEMATOLOGY
Date of Sample Collection	2013 SEP 30
Time of Blood Sample Collection	13:57
Time of Urine Sample Collection	14:02
Test Name	BASOPHILS (ABS)
Result	43
Text Result	
Unit	/UL
Lower limit	
Upper limit	
Flag	
Clinically Significant?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Comment	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Lab-BU HEMATOLOGY(2013/09/30)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:08

Generated On: 23 Jun 2014 15:19:04

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	
Specimen English Comment 2	
Result Supplementary Comment Code 1	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Lab-BU HEMATOLOGY(2013/09/30)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:08

Generated On: 23 Jun 2014 15:19:04

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004514492

Please document clinically relevant abnormalities in the AE form

Date (BU)

2013/09/30

Blood Sample time(BU)

1357

Urine Sample time(BU)

1402

Derived Form name

HEMATOLOGY(2013/09/30)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Lab-BU URINALYSIS(2013/09/30)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:20

Generated On: 23 Jun 2014 15:19:04

Test Category

URINALYSIS

Date of Sample Collection

2013 SEP 30

Please document clinically relevant abnormalities in the AE form

Date (BU)

2013/09/30

Derived Form name

URINALYSIS(2013/09/30)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Lab-BU URINALYSIS(2013/09/30)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:20

Generated On: 23 Jun 2014 15:19:04

Test Category	URINALYSIS
Date of Sample Collection	2013 SEP 30
Time of Blood Sample Collection	13:57
Time of Urine Sample Collection	14:02
Test Name	SPECIFIC GRAVITY
Result	1.010
Text Result	
Unit	
Lower limit	1.002
Upper limit	1.030
Flag	
Clinically Significant?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Comment	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Lab-BU URINALYSIS(2013/09/30)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:20

Generated On: 23 Jun 2014 15:19:04

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	
Specimen English Comment 2	
Result Supplementary Comment Code 1	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Lab-BU URINALYSIS(2013/09/30)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:20

Generated On: 23 Jun 2014 15:19:04

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004514492

Please document clinically relevant abnormalities in the AE form

Date (BU)

2013/09/30

Blood Sample time(BU)

1357

Urine Sample time(BU)

1402

Derived Form name

URINALYSIS(2013/09/30)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Lab-BU URINALYSIS(2013/09/30)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:20

Generated On: 23 Jun 2014 15:19:04

Test Category	URINALYSIS
Date of Sample Collection	2013 SEP 30
Time of Blood Sample Collection	13:57
Time of Urine Sample Collection	14:02
Test Name	PH
Result	6.5
Text Result	
Unit	
Lower limit	5.0
Upper limit	8.0
Flag	
Clinically Significant?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Comment	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Lab-BU URINALYSIS(2013/09/30)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:20

Generated On: 23 Jun 2014 15:19:04

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	
Specimen English Comment 2	
Result Supplementary Comment Code 1	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Lab-BU URINALYSIS(2013/09/30)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:20

Generated On: 23 Jun 2014 15:19:04

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004514492

Please document clinically relevant abnormalities in the AE form

Date (BU)

2013/09/30

Blood Sample time(BU)

1357

Urine Sample time(BU)

1402

Derived Form name

URINALYSIS(2013/09/30)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Lab-BU URINALYSIS(2013/09/30)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:20

Generated On: 23 Jun 2014 15:19:04

Test Category	URINALYSIS
Date of Sample Collection	2013 SEP 30
Time of Blood Sample Collection	13:57
Time of Urine Sample Collection	14:02
Test Name	GLUCOSE
Result	
Text Result	-
Unit	
Lower limit	
Upper limit	-
Flag	
Clinically Significant?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Comment	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Lab-BU URINALYSIS(2013/09/30)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:20

Generated On: 23 Jun 2014 15:19:04

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	
Specimen English Comment 2	
Result Supplementary Comment Code 1	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Lab-BU URINALYSIS(2013/09/30)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:20

Generated On: 23 Jun 2014 15:19:04

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004514492

Please document clinically relevant abnormalities in the AE form

Date (BU)

2013/09/30

Blood Sample time(BU)

1357

Urine Sample time(BU)

1402

Derived Form name

URINALYSIS(2013/09/30)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Lab-BU URINALYSIS(2013/09/30)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:20

Generated On: 23 Jun 2014 15:19:04

Test Category	URINALYSIS
Date of Sample Collection	2013 SEP 30
Time of Blood Sample Collection	13:57
Time of Urine Sample Collection	14:02
Test Name	PROTEIN
Result	
Text Result	-
Unit	
Lower limit	
Upper limit	-
Flag	
Clinically Significant?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Comment	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Lab-BU URINALYSIS(2013/09/30)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:20

Generated On: 23 Jun 2014 15:19:04

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	
Specimen English Comment 2	
Result Supplementary Comment Code 1	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Lab-BU URINALYSIS(2013/09/30)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:20

Generated On: 23 Jun 2014 15:19:04

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004514492

Please document clinically relevant abnormalities in the AE form

Date (BU)

2013/09/30

Blood Sample time(BU)

1357

Urine Sample time(BU)

1402

Derived Form name

URINALYSIS(2013/09/30)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Lab-BU URINALYSIS(2013/09/30)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:20

Generated On: 23 Jun 2014 15:19:04

Test Category	URINALYSIS
Date of Sample Collection	2013 SEP 30
Time of Blood Sample Collection	13:57
Time of Urine Sample Collection	14:02
Test Name	BILIRUBIN
Result	
Text Result	-
Unit	
Lower limit	
Upper limit	-
Flag	
Clinically Significant?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Comment	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Lab-BU URINALYSIS(2013/09/30)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:20

Generated On: 23 Jun 2014 15:19:04

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	
Specimen English Comment 2	
Result Supplementary Comment Code 1	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Lab-BU URINALYSIS(2013/09/30)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:20

Generated On: 23 Jun 2014 15:19:04

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004514492

Please document clinically relevant abnormalities in the AE form

Date (BU)

2013/09/30

Blood Sample time(BU)

1357

Urine Sample time(BU)

1402

Derived Form name

URINALYSIS(2013/09/30)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Lab-BU URINALYSIS(2013/09/30)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:20

Generated On: 23 Jun 2014 15:19:04

Test Category	URINALYSIS
Date of Sample Collection	2013 SEP 30
Time of Blood Sample Collection	13:57
Time of Urine Sample Collection	14:02
Test Name	NITRITE
Result	
Text Result	-
Unit	
Lower limit	
Upper limit	-
Flag	
Clinically Significant?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Comment	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Lab-BU URINALYSIS(2013/09/30)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:20

Generated On: 23 Jun 2014 15:19:04

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	
Specimen English Comment 2	
Result Supplementary Comment Code 1	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Lab-BU URINALYSIS(2013/09/30)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:20

Generated On: 23 Jun 2014 15:19:04

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004514492

Please document clinically relevant abnormalities in the AE form

Date (BU)

2013/09/30

Blood Sample time(BU)

1357

Urine Sample time(BU)

1402

Derived Form name

URINALYSIS(2013/09/30)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Lab-BU URINALYSIS(2013/09/30)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:20

Generated On: 23 Jun 2014 15:19:04

Test Category	URINALYSIS
Date of Sample Collection	2013 SEP 30
Time of Blood Sample Collection	13:57
Time of Urine Sample Collection	14:02
Test Name	OCCULT BLOOD
Result	
Text Result	1+
Unit	
Lower limit	
Upper limit	-
Flag	!
Clinically Significant?	No <input checked="" type="radio"/>
Comment	
Result Category	S

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Lab-BU URINALYSIS(2013/09/30)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:20

Generated On: 23 Jun 2014 15:19:04

Text Result Code	116
------------------	-----

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

Specimen English Comment 2	
----------------------------	--

Result Supplementary Comment Code 1	
-------------------------------------	--

Result Supplementary English Comment Code 1	
---	--

Final 7.0 (Main CRF) (520)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Screening

Form: Lab-BU URINALYSIS(2013/09/30)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:20

Generated On: 23 Jun 2014 15:19:04

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004514492

Please document clinically relevant abnormalities in the AE form

Date (BU)

2013/09/30

Blood Sample time(BU)

1357

Urine Sample time(BU)

1402

Derived Form name

URINALYSIS(2013/09/30)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Admission

Form: Date of Visit

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:45

Generated On: 23 Jun 2014 15:19:04

Date of Visit

11 OCT 2013
DD/MMM/YYYY

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Admission

Form: Inclusion Criteria <Admission/>

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:45

Generated On: 23 Jun 2014 15:19:04

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

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Admission

Form: Inclusion Criteria <Admission/> (1)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:45

Generated On: 23 Jun 2014 15:19:04

Inclusion/Exclusion Criterion Number	3
--------------------------------------	---

Inclusion/Exclusion 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-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Admission

Form: Inclusion Criteria <Admission/> (2)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:45

Generated On: 23 Jun 2014 15:19:04

Inclusion/Exclusion Criterion Number

4

Inclusion/Exclusion Criterion

Smoking, healthy subject
as judged by the
Investigator based on all
available assessments in
the Screening period/day
of Admission (e.g., safety
laboratory, spirometry*
[forced expiratory volume
in 1 second {FEV1}/forced
vital capacity {FVC} >0.7
at post bronchodilator
basal spirometry, post
bronchodilator FEV1 >80%
predicted value, and post
bronchodilator FVC >0.8],
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-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Admission

Form: Inclusion Criteria <Admission/> (3)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:45

Generated On: 23 Jun 2014 15:19:04

Inclusion/Exclusion Criterion Number	6
--------------------------------------	---

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

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

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

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Admission

Form: Inclusion Criteria <Admission/> (4)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:45

Generated On: 23 Jun 2014 15:19:04

Inclusion/Exclusion Criterion Number	7
--------------------------------------	---

Inclusion/Exclusion Criterion	The subject is ready to accept interruptions of smoking for up to 4 days.
-------------------------------	---

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

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

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Admission

Form: Inclusion Criteria <Admission/> (5)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:45

Generated On: 23 Jun 2014 15:19:04

Inclusion/Exclusion Criterion Number	8
--------------------------------------	---

Inclusion/Exclusion Criterion	The subject is ready to accept using both the THS 2.2 Menthol and NRT gum products.
-------------------------------	---

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

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

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Admission

Form: Inclusion Criteria <Admission/> (6)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:45

Generated On: 23 Jun 2014 15:19:04

Inclusion/Exclusion Criterion Number

5

Inclusion/Exclusion Criterion

Subject smokes at least 10 commercially available menthol CCs 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 3 consecutive years. The smoking status will be verified based on a urinary cotinine test (cotinine ≥ 200 ng/mL).

Result

Yes

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

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Admission

Form: Exclusion Criteria <Admission/>

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:46

Generated On: 23 Jun 2014 15:19:04

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

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Admission

Form: Exclusion Criteria <Admission/> (1)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:46

Generated On: 23 Jun 2014 15:19:04

Inclusion/Exclusion Criterion Number	1
--------------------------------------	---

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

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

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

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Admission

Form: Exclusion Criteria <Admission/> (2)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:46

Generated On: 23 Jun 2014 15:19:04

Inclusion/Exclusion Criterion Number

3

Inclusion/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-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Admission

Form: Exclusion Criteria <Admission/> (3)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:46

Generated On: 23 Jun 2014 15:19:04

Inclusion/Exclusion Criterion Number	4
--------------------------------------	---

Inclusion/Exclusion Criterion	The subject has a body mass index (BMI) <18.5 or ≥32.0 kg/m2.
-------------------------------	---

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

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

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Admission

Form: Exclusion Criteria <Admission/> (4)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:46

Generated On: 23 Jun 2014 15:19:04

Inclusion/Exclusion Criterion Number

5

Inclusion/Exclusion Criterion

As per Investigator judgment, the subject has medical conditions which require or will require in the course of the study, a medical intervention (e.g., start of treatment, surgery, hospitalization) which may interfere with the study participation and/or study results.

Result

No

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

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Admission

Form: Exclusion Criteria <Admission/> (5)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:46

Generated On: 23 Jun 2014 15:19:04

Inclusion/Exclusion Criterion Number

6

Inclusion/Exclusion Criterion

The subject has used
nicotine containing
products other than
commercially available
mCC (either tobacco-based
products or
nicotine-replacement
therapy) 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-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Admission

Form: Exclusion Criteria <Admission/> (6)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:46

Generated On: 23 Jun 2014 15:19:04

Inclusion/Exclusion Criterion Number

7

Inclusion/Exclusion Criterion

The subject has received medication (prescription or over-the-counter) within 14 days or within 5 half-lives of the drug prior to the Admission Day (Day -1; whichever is longer) that has an impact on CYP2A6 activity.

Result

No

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

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Admission

Form: Exclusion Criteria <Admission/> (7)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:46

Generated On: 23 Jun 2014 15:19:04

Inclusion/Exclusion Criterion Number

8

Inclusion/Exclusion Criterion

In case the subject
received any medication
(prescribed or over the
counter) within 14 days
prior to Screening or prior
to the Admission Day (Day
-1) it will be decided at the
discretion of the
Investigator if these can
potentially interfere with
the study objectives and
subject's safety.

Result

No

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

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Admission

Form: Exclusion Criteria <Admission/> (8)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:46

Generated On: 23 Jun 2014 15:19:04

Inclusion/Exclusion Criterion Number	9
--------------------------------------	---

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

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

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

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Admission

Form: Exclusion Criteria <Admission/> (9)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:46

Generated On: 23 Jun 2014 15:19:04

Inclusion/Exclusion Criterion Number	10
--------------------------------------	----

Inclusion/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-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Admission

Form: Exclusion Criteria <Admission/> (10)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:46

Generated On: 23 Jun 2014 15:19:04

Inclusion/Exclusion Criterion Number	12
--------------------------------------	----

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

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

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

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Admission

Form: Exclusion Criteria <Admission/> (11)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:46

Generated On: 23 Jun 2014 15:19:04

Inclusion/Exclusion Criterion Number	17
--------------------------------------	----

Inclusion/Exclusion Criterion	For women only: <input checked="" type="radio"/>
	Subject is pregnant (does not have negative pregnancy tests at Screening and at Admission) or is breast feeding.

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

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

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Admission

Form: Exclusion Criteria <Admission/> (12)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:46

Generated On: 23 Jun 2014 15:19:04

Inclusion/Exclusion Criterion Number	18
--------------------------------------	----

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

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

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

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Admission

Form: THS 2.2 Menthol product test

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:46

Generated On: 23 Jun 2014 15:19:04

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-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Admission

Form: NRT gum product test

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:46

Generated On: 23 Jun 2014 15:19:04

Was the NRT gum product trial performed?

Yes ☒

If the NRT gum product trial was not performed, please
explain

How many NRT gum did the subject take on this day?

1

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

Yes ☒

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Admission

Form: Identification of Current mCC Brand

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:47

Generated On: 23 Jun 2014 15:19:04

Brand name	MEVIUS PREMIUM MENTHOL OPTION 100'S
------------	--

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

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

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Admission

Form: Identification of NRT Gum Brand

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:47

Generated On: 23 Jun 2014 15:19:04

Was Nicorette® gum 2 mg used?

Yes ☒

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Admission

Form: Smoking History

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:47

Generated On: 23 Jun 2014 15:19:04

Time of Assessment

11:00
hour:min 24-hour clock

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

Yes ☐

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

>19 ☐

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

Yes ☐

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Admission

Form: Advice on the risk of smoking and Debriefing

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:47

Generated On: 23 Jun 2014 15:19:04

Has the subject received advices on the risks of smoking?

Yes ☒

Has a debriefing been performed about THS 2.2 Menthol?

Yes ☒

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Admission

Form: Physical Examination

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:47

Generated On: 23 Jun 2014 15:19:04

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Time of Assessment

10:53
hour:min 24-hour clock

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Admission

Form: Physical Examination (1)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:47

Generated On: 23 Jun 2014 15:19:04

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Time of Assessment

10:53
hour:min 24-hour clock

System

General Appearance ☒

Outcome

Normal ☒

Abnormal, please specify: _____

Clinically significant

No ☐

Yes ☐

Not Done

False

Not Done; please specify the reason: _____

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Admission

Form: Physical Examination (2)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:47

Generated On: 23 Jun 2014 15:19:04

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Time of Assessment

10:53
hour:min 24-hour clock

System

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

Outcome

Normal ☒

Abnormal, please specify: _____

Clinically significant

No ☐

Yes ☐

Not Done

False

Not Done; please specify the reason: _____

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Admission

Form: Physical Examination (3)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:47

Generated On: 23 Jun 2014 15:19:04

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Time of Assessment

10:53
hour:min 24-hour clock

System

Thyroid Gland ☒

Outcome

Normal ☒

Abnormal, please specify: _____

Clinically significant

No ☐

Yes ☐

Not Done

False

Not Done; please specify the reason: _____

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Admission

Form: Physical Examination (4)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:47

Generated On: 23 Jun 2014 15:19:04

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Time of Assessment

10:53
hour:min 24-hour clock

System

Heart ☒

Outcome

Normal ☒

Abnormal, please specify: _____

Clinically significant

No ☐

Yes ☐

Not Done

False

Not Done; please specify the reason: _____

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Admission

Form: Physical Examination (5)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:47

Generated On: 23 Jun 2014 15:19:04

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Time of Assessment

10:53
hour:min 24-hour clock

System

Chest ☒

Outcome

Normal ☒

Abnormal, please specify: _____

Clinically significant

No ☐

Yes ☐

Not Done

False

Not Done; please specify the reason: _____

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Admission

Form: Physical Examination (6)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:47

Generated On: 23 Jun 2014 15:19:04

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Time of Assessment

10:53
hour:min 24-hour clock

System

Lungs ☒

Outcome

Normal ☒

Abnormal, please specify: _____

Clinically significant

No ☐

Yes ☐

Not Done

False

Not Done; please specify the reason: _____

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Admission

Form: Physical Examination (7)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:47

Generated On: 23 Jun 2014 15:19:04

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Time of Assessment

10:53
hour:min 24-hour clock

System

Gastrointestinal ☒

Outcome

Normal ☒

Abnormal, please specify: _____

Clinically significant

No ☐

Yes ☐

Not Done

False

Not Done; please specify the reason: _____

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Admission

Form: Physical Examination (8)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:47

Generated On: 23 Jun 2014 15:19:04

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Time of Assessment

10:53
hour:min 24-hour clock

System

Cardiovascular System ☒

Outcome

Normal ☒

Abnormal, please specify: _____

Clinically significant

No ☐

Yes ☐

Not Done

False

Not Done; please specify the reason: _____

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Admission

Form: Physical Examination (9)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:47

Generated On: 23 Jun 2014 15:19:04

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Time of Assessment

10:53
hour:min 24-hour clock

System

Neurologic ☒

Outcome

Normal ☒

Abnormal, please specify: _____

Clinically significant

No ☐

Yes ☐

Not Done

False

Not Done; please specify the reason: _____

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Admission

Form: Physical Examination (10)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:47

Generated On: 23 Jun 2014 15:19:04

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Time of Assessment

10:53
hour:min 24-hour clock

System

Skin ☒

Outcome

Normal ☒

Abnormal, please specify: _____

Clinically significant

No ☐

Yes ☐

Not Done

False

Not Done; please specify the reason: _____

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Admission

Form: Physical Examination (11)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:47

Generated On: 23 Jun 2014 15:19:04

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Time of Assessment

10:53
hour:min 24-hour clock

System

Back ☒

Outcome

Normal ☒

Abnormal, please specify: _____

Clinically significant

No ☐

Yes ☐

Not Done

False

Not Done; please specify the reason: _____

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Admission

Form: Physical Examination (12)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:47

Generated On: 23 Jun 2014 15:19:04

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Time of Assessment

10:53
hour:min 24-hour clock

System

Musculoskeletal ☒

Outcome

Normal ☒

Abnormal, please specify: _____

Clinically significant

No ☐

Yes ☐

Not Done

False

Not Done; please specify the reason: _____

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Admission

Form: Physical Examination (13)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:47

Generated On: 23 Jun 2014 15:19:04

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Time of Assessment

10:53
hour:min 24-hour clock

System

Abdomen ☒

Outcome

Normal ☒

Abnormal, please specify: _____

Clinically significant

No ☐

Yes ☐

Not Done

False

Not Done; please specify the reason: _____

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Admission

Form: Physical Examination (14)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:47

Generated On: 23 Jun 2014 15:19:04

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Time of Assessment

10:53
hour:min 24-hour clock

System

Dentition ☒

Outcome

Normal ☒

Abnormal, please specify: _____

Clinically significant

No ☐

Yes ☐

Not Done

False

Not Done; please specify the reason: _____

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Admission

Form: Physical Examination (15)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:47

Generated On: 23 Jun 2014 15:19:04

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Time of Assessment

10:53
hour:min 24-hour clock

System

Other ☒

Other, Specify _____

Outcome

Normal ☐
Abnormal ☐

Abnormal, please specify: _____

Clinically significant

No ☐
Yes ☐

Not Done

True

Not Done; please specify the reason: _____

NA

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Admission

Form: Physical Examination (16)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:47

Generated On: 23 Jun 2014 15:19:04

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Time of Assessment

10:53
hour:min 24-hour clock

System

Other ☒

Other, Specify _____

Outcome

Normal ☐
Abnormal ☐

Abnormal, please specify: _____

Clinically significant

No ☐
Yes ☐

Not Done

True

Not Done; please specify the reason: _____

NA

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Admission

Form: Physical Examination (17)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:47

Generated On: 23 Jun 2014 15:19:04

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Time of Assessment

10:53
hour:min 24-hour clock

System

Other ☒

Other, Specify _____

Outcome

Normal ☐
Abnormal ☐

Abnormal, please specify: _____

Clinically significant

No ☐
Yes ☐

Not Done

True

Not Done; please specify the reason: _____

NA

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Admission

Form: Physical Examination (18)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:47

Generated On: 23 Jun 2014 15:19:04

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Time of Assessment

10:53
hour:min 24-hour clock

System

Other ☒

Other, Specify _____

Outcome

Normal ☐
Abnormal ☐

Abnormal, please specify: _____

Clinically significant

No ☐
Yes ☐

Not Done

True

Not Done; please specify the reason: _____

NA

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Admission

Form: Physical Examination (19)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:47

Generated On: 23 Jun 2014 15:19:04

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Time of Assessment

10:53
hour:min 24-hour clock

System

Other ☒

Other, Specify _____

Outcome

Normal ☐
Abnormal ☐

Abnormal, please specify: _____

Clinically significant

No ☐
Yes ☐

Not Done

True

Not Done; please specify the reason: _____

NA

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Admission

Form: Weight

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:50

Generated On: 23 Jun 2014 15:19:04

Measurement(s) assessed?

Yes ☒

If No, please specify the reason: _____

Time of assessment

10:28
hour:min 24-hour clock

Weight

58.3
kg

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Admission

Form: Vital Signs

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:50

Generated On: 23 Jun 2014 15:19:04

Were vital signs assessed? Yes ☒

If No, please specify the reason: _____

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

Time of assessment 10:23
hour:min 24-hour clock

Pulse rate 53
beats per minute

Respiratory rate 12
breaths per minute

Blood Pressure (systolic) 101
mmHg

Blood Pressure (diastolic) 62
mmHg

Vital Signs Position of Subject Supine ☒

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Admission

Form: Spirometry without a short-acting bronchodilator

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:50

Generated On: 23 Jun 2014 15:19:04

Was the spirometry performed? Yes ☒

If No, please specify the reason: _____

Category Without short-acting bronchodilator ☒

Date of assessment: 11 OCT 2013
DD/MMM/YYYY

Time of assessment: 07:46
hour:min 24-hour clock

Predicted FVC value 3.06
L

Best measured FVC value 4.09
L

Percent of predicted FVC value 133.6
%

Best measured FEV1 value 2.92
L

Predicted FEV1 value 2.57
L

Percent of predicted FEV1 value 113.6
%

Final 7.0 (Main CRF) (520)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Admission

Form: Spirometry without a short-acting bronchodilator

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:50

Generated On: 23 Jun 2014 15:19:04

Interpretation

Normal ☒

If Abnormal, Clinical Significance

Not clinically significant ☐

Clinically significant ☐

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

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Admission

Form: Haematology

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:50

Generated On: 23 Jun 2014 15:19:04

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-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Admission

Form: Urine analysis

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:50

Generated On: 23 Jun 2014 15:19:04

Were samples collected?

Yes ☒

If No, please specify the reason:

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Admission

Form: Clinical Chemistry

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:50

Generated On: 23 Jun 2014 15:19:04

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-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Admission

Form: Urine Drug Screen

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:50

Generated On: 23 Jun 2014 15:19:04

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

If Not Done, please specify the reason: _____

Time of sample collection	08:43
	hour:min 24-hour clock

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

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

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

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

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

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

Final 7.0 (Main CRF) (520)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Admission

Form: Urine Drug Screen (6)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:50

Generated On: 23 Jun 2014 15:19:04

Drug type	Result
Opiates	Negative

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Admission

Form: Alcohol Breath Test

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:51

Generated On: 23 Jun 2014 15:19:04

Was the alcohol breath test performed?

Yes ☒

If No, please specify the reason: _____

Time of assessment

10:10
hour:min 24-hour clock

Result

Negative ☒

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Admission

Form: Urine Pregnancy Test

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:52

Generated On: 23 Jun 2014 15:19:04

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

If Not Done, specify reason

Specify result

Negative ☒

If unclear, please confirm with FSH test

Specify result of FSH test

< 20 IU/L ☐

>= 20 IU/L ☐

Time of Test

08:43

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Admission

Form: Urine Cotinine Test

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:51

Generated On: 23 Jun 2014 15:19:04

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

If Not Done, please specify the reason: _____

Time of Sample Collection	08:43
	hour:min 24-hour clock

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

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Admission

Form: CO Breath Test <NR/>

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:51

Generated On: 23 Jun 2014 15:19:04

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

If not done, please specify the reason: _____

Actual Time of Assessment	10:08
	hour:min 24-hour clock

Result	8 ppm
--------	-------

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Admission

Form: CYP2A6 activity samples

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:51

Generated On: 23 Jun 2014 15:19:04

Not Done

False

If Not Done, please specify the reason:

Was the sample taken prior to smoking?

Yes ☒

Date of Sample Collection

Time of Sample Collection

Parameter

11 OCT 2013
DD/MMM/YYYY

07:58
hour:min 24-hour clock

trans-3'-hydroxyc
otinine

11 OCT 2013
DD/MMM/YYYY

07:58
hour:min 24-hour clock

cotinine

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Admission

Form: Lab-BU BLOOD CHEMISTRY(2013/10/11)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:52

Generated On: 23 Jun 2014 15:19:04

Test Category

BLOOD CHEMISTRY

Date of Sample Collection

2013 OCT 11

Please document clinically relevant abnormalities in the AE form

Date (BU)

2013/10/11

Derived Form name

BLOOD
CHEMISTRY(2013/10/11)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Admission

Form: Lab-BU BLOOD CHEMISTRY(2013/10/11)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:52

Generated On: 23 Jun 2014 15:19:04

Test Category	BLOOD CHEMISTRY
Date of Sample Collection	2013 OCT 11
Time of Blood Sample Collection	07:58
Time of Urine Sample Collection	08:43
Test Name	TOTAL PROTEIN
Result	6.6
Text Result	
Unit	G/DL
Lower limit	6.7
Upper limit	8.3
Flag	L
Clinically Significant?	No <input checked="" type="radio"/>
Comment	
Result Category	N

Final 7.0 (Main CRF) (520)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Admission

Form: Lab-BU BLOOD CHEMISTRY(2013/10/11)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:52

Generated On: 23 Jun 2014 15:19:04

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

Specimen English Comment 2

Result Supplementary Comment Code 1

Result Supplementary English Comment Code 1

Final 7.0 (Main CRF) (520)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Admission

Form: Lab-BU BLOOD CHEMISTRY(2013/10/11)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:52

Generated On: 23 Jun 2014 15:19:04

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004514684

Please document clinically relevant abnormalities in the AE form

Date (BU)

2013/10/11

Blood Sample time(BU)

0758

Urine Sample time(BU)

0843

Derived Form name

BLOOD
CHEMISTRY(2013/10/11)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Admission

Form: Lab-BU BLOOD CHEMISTRY(2013/10/11)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:52

Generated On: 23 Jun 2014 15:19:04

Test Category	BLOOD CHEMISTRY
Date of Sample Collection	2013 OCT 11
Time of Blood Sample Collection	07:58
Time of Urine Sample Collection	08:43
Test Name	ALBUMIN
Result	4.2
Text Result	
Unit	G/DL
Lower limit	3.8
Upper limit	5.3
Flag	
Clinically Significant?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Comment	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Admission

Form: Lab-BU BLOOD CHEMISTRY(2013/10/11)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:52

Generated On: 23 Jun 2014 15:19:04

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	
Specimen English Comment 2	
Result Supplementary Comment Code 1	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Admission

Form: Lab-BU BLOOD CHEMISTRY(2013/10/11)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:52

Generated On: 23 Jun 2014 15:19:04

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004514684

Please document clinically relevant abnormalities in the AE form

Date (BU)

2013/10/11

Blood Sample time(BU)

0758

Urine Sample time(BU)

0843

Derived Form name

BLOOD
CHEMISTRY(2013/10/11)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Admission

Form: Lab-BU BLOOD CHEMISTRY(2013/10/11)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:52

Generated On: 23 Jun 2014 15:19:04

Test Category	BLOOD CHEMISTRY
Date of Sample Collection	2013 OCT 11
Time of Blood Sample Collection	07:58
Time of Urine Sample Collection	08:43
Test Name	TOTAL BILIRUBIN
Result	0.9
Text Result	
Unit	MG/DL
Lower limit	0.2
Upper limit	1.2
Flag	
Clinically Significant?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Comment	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Admission

Form: Lab-BU BLOOD CHEMISTRY(2013/10/11)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:52

Generated On: 23 Jun 2014 15:19:04

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	
Specimen English Comment 2	
Result Supplementary Comment Code 1	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Admission

Form: Lab-BU BLOOD CHEMISTRY(2013/10/11)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:52

Generated On: 23 Jun 2014 15:19:04

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004514684

Please document clinically relevant abnormalities in the AE form

Date (BU)

2013/10/11

Blood Sample time(BU)

0758

Urine Sample time(BU)

0843

Derived Form name

BLOOD
CHEMISTRY(2013/10/11)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Admission

Form: Lab-BU BLOOD CHEMISTRY(2013/10/11)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:52

Generated On: 23 Jun 2014 15:19:04

Test Category	BLOOD CHEMISTRY
Date of Sample Collection	2013 OCT 11
Time of Blood Sample Collection	07:58
Time of Urine Sample Collection	08:43
Test Name	DIRECT BILIRUBIN
Result	0.2
Text Result	
Unit	MG/DL
Lower limit	0.0
Upper limit	0.3
Flag	
Clinically Significant?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Comment	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Admission

Form: Lab-BU BLOOD CHEMISTRY(2013/10/11)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:52

Generated On: 23 Jun 2014 15:19:04

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	
Specimen English Comment 2	
Result Supplementary Comment Code 1	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Admission

Form: Lab-BU BLOOD CHEMISTRY(2013/10/11)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:52

Generated On: 23 Jun 2014 15:19:04

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004514684

Please document clinically relevant abnormalities in the AE form

Date (BU)

2013/10/11

Blood Sample time(BU)

0758

Urine Sample time(BU)

0843

Derived Form name

BLOOD
CHEMISTRY(2013/10/11)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Admission

Form: Lab-BU BLOOD CHEMISTRY(2013/10/11)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:52

Generated On: 23 Jun 2014 15:19:04

Test Category	BLOOD CHEMISTRY
Date of Sample Collection	2013 OCT 11
Time of Blood Sample Collection	07:58
Time of Urine Sample Collection	08:43
Test Name	AST
Result	19
Text Result	
Unit	U/L
Lower limit	10
Upper limit	40
Flag	
Clinically Significant?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Comment	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Admission

Form: Lab-BU BLOOD CHEMISTRY(2013/10/11)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:52

Generated On: 23 Jun 2014 15:19:04

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	
Specimen English Comment 2	
Result Supplementary Comment Code 1	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Admission

Form: Lab-BU BLOOD CHEMISTRY(2013/10/11)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:52

Generated On: 23 Jun 2014 15:19:04

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004514684

Please document clinically relevant abnormalities in the AE form

Date (BU)

2013/10/11

Blood Sample time(BU)

0758

Urine Sample time(BU)

0843

Derived Form name

BLOOD
CHEMISTRY(2013/10/11)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Admission

Form: Lab-BU BLOOD CHEMISTRY(2013/10/11)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:52

Generated On: 23 Jun 2014 15:19:04

Test Category	BLOOD CHEMISTRY
Date of Sample Collection	2013 OCT 11
Time of Blood Sample Collection	07:58
Time of Urine Sample Collection	08:43
Test Name	ALT
Result	12
Text Result	
Unit	U/L
Lower limit	5
Upper limit	45
Flag	
Clinically Significant?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Comment	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Admission

Form: Lab-BU BLOOD CHEMISTRY(2013/10/11)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:52

Generated On: 23 Jun 2014 15:19:04

Result Category	N
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Text Result Code	_____
------------------	-------

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

Timepoint(COHB)	_____
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Material Code	SERUM
---------------	-------

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

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

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

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

Specimen Comment Code 1	_____
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Specimen English Comment 1	_____
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Specimen Comment Code 2	_____
-------------------------	-------

Specimen English Comment 2	_____
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Result Supplementary Comment Code 1	_____
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Final 7.0 (Main CRF) (520)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Admission

Form: Lab-BU BLOOD CHEMISTRY(2013/10/11)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:52

Generated On: 23 Jun 2014 15:19:04

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004514684

Please document clinically relevant abnormalities in the AE form

Date (BU)

2013/10/11

Blood Sample time(BU)

0758

Urine Sample time(BU)

0843

Derived Form name

BLOOD
CHEMISTRY(2013/10/11)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Admission

Form: Lab-BU BLOOD CHEMISTRY(2013/10/11)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:52

Generated On: 23 Jun 2014 15:19:04

Test Category	BLOOD CHEMISTRY
Date of Sample Collection	2013 OCT 11
Time of Blood Sample Collection	07:58
Time of Urine Sample Collection	08:43
Test Name	LDH
Result	125
Text Result	
Unit	U/L
Lower limit	120
Upper limit	240
Flag	
Clinically Significant?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Comment	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Admission

Form: Lab-BU BLOOD CHEMISTRY(2013/10/11)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:52

Generated On: 23 Jun 2014 15:19:04

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	
Specimen English Comment 2	
Result Supplementary Comment Code 1	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Admission

Form: Lab-BU BLOOD CHEMISTRY(2013/10/11)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:52

Generated On: 23 Jun 2014 15:19:04

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004514684

Please document clinically relevant abnormalities in the AE form

Date (BU)

2013/10/11

Blood Sample time(BU)

0758

Urine Sample time(BU)

0843

Derived Form name

BLOOD
CHEMISTRY(2013/10/11)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Admission

Form: Lab-BU BLOOD CHEMISTRY(2013/10/11)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:52

Generated On: 23 Jun 2014 15:19:04

Test Category	BLOOD CHEMISTRY
Date of Sample Collection	2013 OCT 11
Time of Blood Sample Collection	07:58
Time of Urine Sample Collection	08:43
Test Name	AP
Result	230
Text Result	
Unit	U/L
Lower limit	100
Upper limit	325
Flag	
Clinically Significant?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Comment	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Admission

Form: Lab-BU BLOOD CHEMISTRY(2013/10/11)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:52

Generated On: 23 Jun 2014 15:19:04

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	
Specimen English Comment 2	
Result Supplementary Comment Code 1	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Admission

Form: Lab-BU BLOOD CHEMISTRY(2013/10/11)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:52

Generated On: 23 Jun 2014 15:19:04

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004514684

Please document clinically relevant abnormalities in the AE form

Date (BU)

2013/10/11

Blood Sample time(BU)

0758

Urine Sample time(BU)

0843

Derived Form name

BLOOD
CHEMISTRY(2013/10/11)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Admission

Form: Lab-BU BLOOD CHEMISTRY(2013/10/11)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:52

Generated On: 23 Jun 2014 15:19:04

Test Category	BLOOD CHEMISTRY
Date of Sample Collection	2013 OCT 11
Time of Blood Sample Collection	07:58
Time of Urine Sample Collection	08:43
Test Name	GGT
Result	15
Text Result	
Unit	U/L
Lower limit	
Upper limit	30
Flag	
Clinically Significant?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Comment	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Admission

Form: Lab-BU BLOOD CHEMISTRY(2013/10/11)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:52

Generated On: 23 Jun 2014 15:19:04

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	_____
-------------------------	-------

Specimen English Comment 2	_____
----------------------------	-------

Result Supplementary Comment Code 1	_____
-------------------------------------	-------

Final 7.0 (Main CRF) (520)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Admission

Form: Lab-BU BLOOD CHEMISTRY(2013/10/11)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:52

Generated On: 23 Jun 2014 15:19:04

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004514684

Please document clinically relevant abnormalities in the AE form

Date (BU)

2013/10/11

Blood Sample time(BU)

0758

Urine Sample time(BU)

0843

Derived Form name

BLOOD
CHEMISTRY(2013/10/11)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Admission

Form: Lab-BU BLOOD CHEMISTRY(2013/10/11)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:52

Generated On: 23 Jun 2014 15:19:04

Test Category	BLOOD CHEMISTRY
Date of Sample Collection	2013 OCT 11
Time of Blood Sample Collection	07:58
Time of Urine Sample Collection	08:43
Test Name	FASTING GLUCOSE
Result	88
Text Result	
Unit	MG/DL
Lower limit	70
Upper limit	109
Flag	
Clinically Significant?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Comment	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Admission

Form: Lab-BU BLOOD CHEMISTRY(2013/10/11)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:52

Generated On: 23 Jun 2014 15:19:04

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	_____
-------------------------	-------

Specimen English Comment 2	_____
----------------------------	-------

Result Supplementary Comment Code 1	_____
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Final 7.0 (Main CRF) (520)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Admission

Form: Lab-BU BLOOD CHEMISTRY(2013/10/11)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:52

Generated On: 23 Jun 2014 15:19:04

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004514684

Please document clinically relevant abnormalities in the AE form

Date (BU)

2013/10/11

Blood Sample time(BU)

0758

Urine Sample time(BU)

0843

Derived Form name

BLOOD
CHEMISTRY(2013/10/11)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Admission

Form: Lab-BU BLOOD CHEMISTRY(2013/10/11)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:52

Generated On: 23 Jun 2014 15:19:04

Test Category	BLOOD CHEMISTRY
Date of Sample Collection	2013 OCT 11
Time of Blood Sample Collection	07:58
Time of Urine Sample Collection	08:43
Test Name	CREATININE
Result	0.51
Text Result	
Unit	MG/DL
Lower limit	0.47
Upper limit	0.79
Flag	
Clinically Significant?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Comment	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Admission

Form: Lab-BU BLOOD CHEMISTRY(2013/10/11)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:52

Generated On: 23 Jun 2014 15:19:04

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	
Specimen English Comment 2	
Result Supplementary Comment Code 1	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Admission

Form: Lab-BU BLOOD CHEMISTRY(2013/10/11)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:52

Generated On: 23 Jun 2014 15:19:04

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004514684

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Date (BU)

2013/10/11

Blood Sample time(BU)

0758

Urine Sample time(BU)

0843

Derived Form name

BLOOD
CHEMISTRY(2013/10/11)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Admission

Form: Lab-BU BLOOD CHEMISTRY(2013/10/11)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:52

Generated On: 23 Jun 2014 15:19:04

Test Category	BLOOD CHEMISTRY
Date of Sample Collection	2013 OCT 11
Time of Blood Sample Collection	07:58
Time of Urine Sample Collection	08:43
Test Name	BUN
Result	11
Text Result	
Unit	MG/DL
Lower limit	8
Upper limit	23
Flag	
Clinically Significant?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Comment	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Admission

Form: Lab-BU BLOOD CHEMISTRY(2013/10/11)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:52

Generated On: 23 Jun 2014 15:19:04

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	
Specimen English Comment 2	
Result Supplementary Comment Code 1	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Admission

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Result Supplementary English Comment Code 2

Accession No.

000004514684

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Date (BU)

2013/10/11

Blood Sample time(BU)

0758

Urine Sample time(BU)

0843

Derived Form name

BLOOD
CHEMISTRY(2013/10/11)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Admission

Form: Lab-BU BLOOD CHEMISTRY(2013/10/11)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:52

Generated On: 23 Jun 2014 15:19:04

Test Category	BLOOD CHEMISTRY
Date of Sample Collection	2013 OCT 11
Time of Blood Sample Collection	07:58
Time of Urine Sample Collection	08:43
Test Name	TRIGLYCERIDES
Result	85
Text Result	
Unit	MG/DL
Lower limit	30
Upper limit	149
Flag	
Clinically Significant?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Comment	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

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Data signed: (FumimasaNobuoka) 14 May 2014 06:17:52

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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	
Specimen English Comment 2	
Result Supplementary Comment Code 1	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

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Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

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2013/10/11

Blood Sample time(BU)

0758

Urine Sample time(BU)

0843

Derived Form name

BLOOD
CHEMISTRY(2013/10/11)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Admission

Form: Lab-BU BLOOD CHEMISTRY(2013/10/11)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:52

Generated On: 23 Jun 2014 15:19:04

Test Category	BLOOD CHEMISTRY
Date of Sample Collection	2013 OCT 11
Time of Blood Sample Collection	07:58
Time of Urine Sample Collection	08:43
Test Name	TOTAL CHOLESTEROL
Result	202
Text Result	
Unit	MG/DL
Lower limit	120
Upper limit	219
Flag	
Clinically Significant?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Comment	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Admission

Form: Lab-BU BLOOD CHEMISTRY(2013/10/11)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:52

Generated On: 23 Jun 2014 15:19:04

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	
Specimen English Comment 2	
Result Supplementary Comment Code 1	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Admission

Form: Lab-BU BLOOD CHEMISTRY(2013/10/11)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:52

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Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

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Date (BU)

2013/10/11

Blood Sample time(BU)

0758

Urine Sample time(BU)

0843

Derived Form name

BLOOD
CHEMISTRY(2013/10/11)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Admission

Form: Lab-BU BLOOD CHEMISTRY(2013/10/11)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:52

Generated On: 23 Jun 2014 15:19:04

Test Category	BLOOD CHEMISTRY
Date of Sample Collection	2013 OCT 11
Time of Blood Sample Collection	07:58
Time of Urine Sample Collection	08:43
Test Name	SODIUM
Result	141
Text Result	
Unit	MEQ/L
Lower limit	137
Upper limit	147
Flag	
Clinically Significant?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Comment	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Admission

Form: Lab-BU BLOOD CHEMISTRY(2013/10/11)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:52

Generated On: 23 Jun 2014 15:19:04

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	
Specimen English Comment 2	
Result Supplementary Comment Code 1	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Admission

Form: Lab-BU BLOOD CHEMISTRY(2013/10/11)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:52

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Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004514684

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Date (BU)

2013/10/11

Blood Sample time(BU)

0758

Urine Sample time(BU)

0843

Derived Form name

BLOOD
CHEMISTRY(2013/10/11)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Admission

Form: Lab-BU BLOOD CHEMISTRY(2013/10/11)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:52

Generated On: 23 Jun 2014 15:19:04

Test Category	BLOOD CHEMISTRY
Date of Sample Collection	2013 OCT 11
Time of Blood Sample Collection	07:58
Time of Urine Sample Collection	08:43
Test Name	POTASSIUM
Result	4.4
Text Result	
Unit	MEQ/L
Lower limit	3.5
Upper limit	5.0
Flag	
Clinically Significant?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Comment	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Admission

Form: Lab-BU BLOOD CHEMISTRY(2013/10/11)

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Generated On: 23 Jun 2014 15:19:04

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	
Specimen English Comment 2	
Result Supplementary Comment Code 1	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

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Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

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Date (BU)

2013/10/11

Blood Sample time(BU)

0758

Urine Sample time(BU)

0843

Derived Form name

BLOOD
CHEMISTRY(2013/10/11)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Admission

Form: Lab-BU HEMATOLOGY(2013/10/11)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:58

Generated On: 23 Jun 2014 15:19:04

Test Category

HEMATOLOGY

Date of Sample Collection

2013 OCT 11

Please document clinically relevant abnormalities in the AE form

Date (BU)

2013/10/11

Derived Form name

HEMATOLOGY(2013/10/11)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Admission

Form: Lab-BU HEMATOLOGY(2013/10/11)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:58

Generated On: 23 Jun 2014 15:19:04

Test Category	HEMATOLOGY
Date of Sample Collection	2013 OCT 11
Time of Blood Sample Collection	07:58
Time of Urine Sample Collection	08:43
Test Name	WBC COUNT
Result	8600
Text Result	
Unit	/UL
Lower limit	3300
Upper limit	9000
Flag	
Clinically Significant?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Comment	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Admission

Form: Lab-BU HEMATOLOGY(2013/10/11)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:58

Generated On: 23 Jun 2014 15:19:04

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	
Specimen English Comment 2	
Result Supplementary Comment Code 1	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Admission

Form: Lab-BU HEMATOLOGY(2013/10/11)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:58

Generated On: 23 Jun 2014 15:19:04

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004514684

Please document clinically relevant abnormalities in the AE form

Date (BU)

2013/10/11

Blood Sample time(BU)

0758

Urine Sample time(BU)

0843

Derived Form name

HEMATOLOGY(2013/10/11)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Admission

Form: Lab-BU HEMATOLOGY(2013/10/11)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:58

Generated On: 23 Jun 2014 15:19:04

Test Category	HEMATOLOGY
Date of Sample Collection	2013 OCT 11
Time of Blood Sample Collection	07:58
Time of Urine Sample Collection	08:43
Test Name	RBC COUNT
Result	413
Text Result	
Unit	10 ⁴ /UL
Lower limit	380
Upper limit	500
Flag	
Clinically Significant?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Comment	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Admission

Form: Lab-BU HEMATOLOGY(2013/10/11)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:58

Generated On: 23 Jun 2014 15:19:04

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	
Specimen English Comment 2	
Result Supplementary Comment Code 1	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Admission

Form: Lab-BU HEMATOLOGY(2013/10/11)

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Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

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Date (BU)

2013/10/11

Blood Sample time(BU)

0758

Urine Sample time(BU)

0843

Derived Form name

HEMATOLOGY(2013/10/11)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Admission

Form: Lab-BU HEMATOLOGY(2013/10/11)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:58

Generated On: 23 Jun 2014 15:19:04

Test Category	HEMATOLOGY
Date of Sample Collection	2013 OCT 11
Time of Blood Sample Collection	07:58
Time of Urine Sample Collection	08:43
Test Name	HEMOGLOBIN
Result	12.5
Text Result	
Unit	G/DL
Lower limit	11.5
Upper limit	15.0
Flag	
Clinically Significant?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Comment	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Admission

Form: Lab-BU HEMATOLOGY(2013/10/11)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:58

Generated On: 23 Jun 2014 15:19:04

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	
Specimen English Comment 2	
Result Supplementary Comment Code 1	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Admission

Form: Lab-BU HEMATOLOGY(2013/10/11)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:58

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Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

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Date (BU)

2013/10/11

Blood Sample time(BU)

0758

Urine Sample time(BU)

0843

Derived Form name

HEMATOLOGY(2013/10/11)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Admission

Form: Lab-BU HEMATOLOGY(2013/10/11)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:58

Generated On: 23 Jun 2014 15:19:04

Test Category	HEMATOLOGY
Date of Sample Collection	2013 OCT 11
Time of Blood Sample Collection	07:58
Time of Urine Sample Collection	08:43
Test Name	HEMATOCRIT
Result	36.9
Text Result	
Unit	%
Lower limit	34.8
Upper limit	45.0
Flag	
Clinically Significant?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Comment	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Admission

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Data signed: (FumimasaNobuoka) 14 May 2014 06:17:58

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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	
Specimen English Comment 2	
Result Supplementary Comment Code 1	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

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Result Supplementary English Comment Code 2

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Blood Sample time(BU)

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Urine Sample time(BU)

0843

Derived Form name

HEMATOLOGY(2013/10/11)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Admission

Form: Lab-BU HEMATOLOGY(2013/10/11)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:58

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Test Category	HEMATOLOGY
Date of Sample Collection	2013 OCT 11
Time of Blood Sample Collection	07:58
Time of Urine Sample Collection	08:43
Test Name	MCV
Result	89
Text Result	
Unit	FL
Lower limit	85
Upper limit	102
Flag	
Clinically Significant?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Comment	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

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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	
Specimen English Comment 2	
Result Supplementary Comment Code 1	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

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2013/10/11

Blood Sample time(BU)

0758

Urine Sample time(BU)

0843

Derived Form name

HEMATOLOGY(2013/10/11)

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Data signed: (FumimasaNobuoka) 14 May 2014 06:17:58

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Test Category	HEMATOLOGY
Date of Sample Collection	2013 OCT 11
Time of Blood Sample Collection	07:58
Time of Urine Sample Collection	08:43
Test Name	MCH
Result	30.3
Text Result	
Unit	PG
Lower limit	28.0
Upper limit	34.0
Flag	
Clinically Significant?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Comment	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

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Result Category	N
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Text Result Code	_____
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Reference Value Category	-
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Timepoint(COHB)	_____
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Material Code	BLOOD
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Chyle Comment Code	_____
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Chyle Comment English	_____
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Hemolysis Comment Code	_____
------------------------	-------

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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Specimen English Comment 2	_____
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Result Supplementary Comment Code 1	_____
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Final 7.0 (Main CRF) (520)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

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0758

Urine Sample time(BU)

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Derived Form name

HEMATOLOGY(2013/10/11)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

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Form: Lab-BU HEMATOLOGY(2013/10/11)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:58

Generated On: 23 Jun 2014 15:19:04

Test Category	HEMATOLOGY
Date of Sample Collection	2013 OCT 11
Time of Blood Sample Collection	07:58
Time of Urine Sample Collection	08:43
Test Name	MCHC
Result	33.9
Text Result	
Unit	%
Lower limit	30.2
Upper limit	35.1
Flag	
Clinically Significant?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Comment	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Admission

Form: Lab-BU HEMATOLOGY(2013/10/11)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:58

Generated On: 23 Jun 2014 15:19:04

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	
Specimen English Comment 2	
Result Supplementary Comment Code 1	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

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Form: Lab-BU HEMATOLOGY(2013/10/11)

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Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

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Date (BU)

2013/10/11

Blood Sample time(BU)

0758

Urine Sample time(BU)

0843

Derived Form name

HEMATOLOGY(2013/10/11)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Admission

Form: Lab-BU HEMATOLOGY(2013/10/11)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:58

Generated On: 23 Jun 2014 15:19:04

Test Category	HEMATOLOGY
Date of Sample Collection	2013 OCT 11
Time of Blood Sample Collection	07:58
Time of Urine Sample Collection	08:43
Test Name	PLATELET COUNT
Result	27.9
Text Result	
Unit	10 ⁴ /UL
Lower limit	14.0
Upper limit	34.0
Flag	
Clinically Significant?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Comment	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Admission

Form: Lab-BU HEMATOLOGY(2013/10/11)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:58

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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	
Specimen English Comment 2	
Result Supplementary Comment Code 1	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Admission

Form: Lab-BU HEMATOLOGY(2013/10/11)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:58

Generated On: 23 Jun 2014 15:19:04

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004514684

Please document clinically relevant abnormalities in the AE form

Date (BU)

2013/10/11

Blood Sample time(BU)

0758

Urine Sample time(BU)

0843

Derived Form name

HEMATOLOGY(2013/10/11)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Admission

Form: Lab-BU HEMATOLOGY(2013/10/11)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:58

Generated On: 23 Jun 2014 15:19:04

Test Category	HEMATOLOGY
Date of Sample Collection	2013 OCT 11
Time of Blood Sample Collection	07:58
Time of Urine Sample Collection	08:43
Test Name	DIFFERENTIAL WBC
Result	
Text Result	
Unit	
Lower limit	
Upper limit	
Flag	
Clinically Significant?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Comment	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Admission

Form: Lab-BU HEMATOLOGY(2013/10/11)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:58

Generated On: 23 Jun 2014 15:19:04

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

Specimen English Comment 2

Result Supplementary Comment Code 1

Final 7.0 (Main CRF) (520)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Admission

Form: Lab-BU HEMATOLOGY(2013/10/11)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:58

Generated On: 23 Jun 2014 15:19:04

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004514684

Please document clinically relevant abnormalities in the AE form

Date (BU)

2013/10/11

Blood Sample time(BU)

0758

Urine Sample time(BU)

0843

Derived Form name

HEMATOLOGY(2013/10/11)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Admission

Form: Lab-BU HEMATOLOGY(2013/10/11)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:58

Generated On: 23 Jun 2014 15:19:04

Test Category	HEMATOLOGY
Date of Sample Collection	2013 OCT 11
Time of Blood Sample Collection	07:58
Time of Urine Sample Collection	08:43
Test Name	NEUTROPHILS (REL)
Result	64.0
Text Result	
Unit	%
Lower limit	40.0
Upper limit	75.0
Flag	
Clinically Significant?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Comment	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Admission

Form: Lab-BU HEMATOLOGY(2013/10/11)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:58

Generated On: 23 Jun 2014 15:19:04

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	
Specimen English Comment 2	
Result Supplementary Comment Code 1	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Admission

Form: Lab-BU HEMATOLOGY(2013/10/11)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:58

Generated On: 23 Jun 2014 15:19:04

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004514684

Please document clinically relevant abnormalities in the AE form

Date (BU)

2013/10/11

Blood Sample time(BU)

0758

Urine Sample time(BU)

0843

Derived Form name

HEMATOLOGY(2013/10/11)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Admission

Form: Lab-BU HEMATOLOGY(2013/10/11)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:58

Generated On: 23 Jun 2014 15:19:04

Test Category	HEMATOLOGY
Date of Sample Collection	2013 OCT 11
Time of Blood Sample Collection	07:58
Time of Urine Sample Collection	08:43
Test Name	LYMPHOCYTES (REL)
Result	30.0
Text Result	
Unit	%
Lower limit	18.0
Upper limit	49.0
Flag	
Clinically Significant?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Comment	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Admission

Form: Lab-BU HEMATOLOGY(2013/10/11)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:58

Generated On: 23 Jun 2014 15:19:04

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	
Specimen English Comment 2	
Result Supplementary Comment Code 1	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Admission

Form: Lab-BU HEMATOLOGY(2013/10/11)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:58

Generated On: 23 Jun 2014 15:19:04

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004514684

Please document clinically relevant abnormalities in the AE form

Date (BU)

2013/10/11

Blood Sample time(BU)

0758

Urine Sample time(BU)

0843

Derived Form name

HEMATOLOGY(2013/10/11)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Admission

Form: Lab-BU HEMATOLOGY(2013/10/11)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:58

Generated On: 23 Jun 2014 15:19:04

Test Category	HEMATOLOGY
Date of Sample Collection	2013 OCT 11
Time of Blood Sample Collection	07:58
Time of Urine Sample Collection	08:43
Test Name	MONOCYTES (REL)
Result	3.0
Text Result	
Unit	%
Lower limit	2.0
Upper limit	10.0
Flag	
Clinically Significant?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Comment	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Admission

Form: Lab-BU HEMATOLOGY(2013/10/11)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:58

Generated On: 23 Jun 2014 15:19:04

Result Category	N
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Text Result Code	_____
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Reference Value Category	-
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Timepoint(COHB)	_____
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Material Code	BLOOD
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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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Specimen English Comment 2	_____
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Result Supplementary Comment Code 1	_____
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Final 7.0 (Main CRF) (520)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Admission

Form: Lab-BU HEMATOLOGY(2013/10/11)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:58

Generated On: 23 Jun 2014 15:19:04

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004514684

Please document clinically relevant abnormalities in the AE form

Date (BU)

2013/10/11

Blood Sample time(BU)

0758

Urine Sample time(BU)

0843

Derived Form name

HEMATOLOGY(2013/10/11)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Admission

Form: Lab-BU HEMATOLOGY(2013/10/11)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:58

Generated On: 23 Jun 2014 15:19:04

Test Category	HEMATOLOGY
Date of Sample Collection	2013 OCT 11
Time of Blood Sample Collection	07:58
Time of Urine Sample Collection	08:43
Test Name	EOSINOPHILS (REL)
Result	2.0
Text Result	
Unit	%
Lower limit	0.0
Upper limit	8.0
Flag	
Clinically Significant?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Comment	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Admission

Form: Lab-BU HEMATOLOGY(2013/10/11)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:58

Generated On: 23 Jun 2014 15:19:04

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	
Specimen English Comment 2	
Result Supplementary Comment Code 1	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Admission

Form: Lab-BU HEMATOLOGY(2013/10/11)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:58

Generated On: 23 Jun 2014 15:19:04

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004514684

Please document clinically relevant abnormalities in the AE form

Date (BU)

2013/10/11

Blood Sample time(BU)

0758

Urine Sample time(BU)

0843

Derived Form name

HEMATOLOGY(2013/10/11)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Admission

Form: Lab-BU HEMATOLOGY(2013/10/11)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:58

Generated On: 23 Jun 2014 15:19:04

Test Category	HEMATOLOGY
Date of Sample Collection	2013 OCT 11
Time of Blood Sample Collection	07:58
Time of Urine Sample Collection	08:43
Test Name	BASOPHILS (REL)
Result	1.0
Text Result	
Unit	%
Lower limit	0.0
Upper limit	2.0
Flag	
Clinically Significant?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Comment	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Admission

Form: Lab-BU HEMATOLOGY(2013/10/11)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:58

Generated On: 23 Jun 2014 15:19:04

Result Category	N
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Text Result Code	_____
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Reference Value Category	-
--------------------------	---

Timepoint(COHB)	_____
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Material Code	BLOOD
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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	_____
---------------------------	-------

Specimen Comment Code 1	_____
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Specimen English Comment 1	_____
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Specimen Comment Code 2	_____
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Specimen English Comment 2	_____
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Result Supplementary Comment Code 1	_____
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Final 7.0 (Main CRF) (520)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Admission

Form: Lab-BU HEMATOLOGY(2013/10/11)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:58

Generated On: 23 Jun 2014 15:19:04

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004514684

Please document clinically relevant abnormalities in the AE form

Date (BU)

2013/10/11

Blood Sample time(BU)

0758

Urine Sample time(BU)

0843

Derived Form name

HEMATOLOGY(2013/10/11)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Admission

Form: Lab-BU HEMATOLOGY(2013/10/11)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:58

Generated On: 23 Jun 2014 15:19:04

Test Category	HEMATOLOGY
Date of Sample Collection	2013 OCT 11
Time of Blood Sample Collection	07:58
Time of Urine Sample Collection	08:43
Test Name	NEUTROPHILS (ABS)
Result	5500
Text Result	
Unit	/UL
Lower limit	
Upper limit	
Flag	
Clinically Significant?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Comment	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Admission

Form: Lab-BU HEMATOLOGY(2013/10/11)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:58

Generated On: 23 Jun 2014 15:19:04

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	
Specimen English Comment 2	
Result Supplementary Comment Code 1	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Admission

Form: Lab-BU HEMATOLOGY(2013/10/11)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:58

Generated On: 23 Jun 2014 15:19:04

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004514684

Please document clinically relevant abnormalities in the AE form

Date (BU)

2013/10/11

Blood Sample time(BU)

0758

Urine Sample time(BU)

0843

Derived Form name

HEMATOLOGY(2013/10/11)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Admission

Form: Lab-BU HEMATOLOGY(2013/10/11)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:58

Generated On: 23 Jun 2014 15:19:04

Test Category	HEMATOLOGY
Date of Sample Collection	2013 OCT 11
Time of Blood Sample Collection	07:58
Time of Urine Sample Collection	08:43
Test Name	LYMPHOCYTES (ABS)
Result	2600
Text Result	
Unit	/UL
Lower limit	
Upper limit	
Flag	
Clinically Significant?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Comment	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Admission

Form: Lab-BU HEMATOLOGY(2013/10/11)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:58

Generated On: 23 Jun 2014 15:19:04

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	
Specimen English Comment 2	
Result Supplementary Comment Code 1	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Admission

Form: Lab-BU HEMATOLOGY(2013/10/11)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:58

Generated On: 23 Jun 2014 15:19:04

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004514684

Please document clinically relevant abnormalities in the AE form

Date (BU)

2013/10/11

Blood Sample time(BU)

0758

Urine Sample time(BU)

0843

Derived Form name

HEMATOLOGY(2013/10/11)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Admission

Form: Lab-BU HEMATOLOGY(2013/10/11)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:58

Generated On: 23 Jun 2014 15:19:04

Test Category	HEMATOLOGY
Date of Sample Collection	2013 OCT 11
Time of Blood Sample Collection	07:58
Time of Urine Sample Collection	08:43
Test Name	MONOCYTES (ABS)
Result	260
Text Result	
Unit	/UL
Lower limit	
Upper limit	
Flag	
Clinically Significant?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Comment	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Admission

Form: Lab-BU HEMATOLOGY(2013/10/11)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:58

Generated On: 23 Jun 2014 15:19:04

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	
Specimen English Comment 2	
Result Supplementary Comment Code 1	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Admission

Form: Lab-BU HEMATOLOGY(2013/10/11)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:58

Generated On: 23 Jun 2014 15:19:04

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004514684

Please document clinically relevant abnormalities in the AE form

Date (BU)

2013/10/11

Blood Sample time(BU)

0758

Urine Sample time(BU)

0843

Derived Form name

HEMATOLOGY(2013/10/11)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Admission

Form: Lab-BU HEMATOLOGY(2013/10/11)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:58

Generated On: 23 Jun 2014 15:19:04

Test Category	HEMATOLOGY
Date of Sample Collection	2013 OCT 11
Time of Blood Sample Collection	07:58
Time of Urine Sample Collection	08:43
Test Name	EOSINOPHILS (ABS)
Result	170
Text Result	
Unit	/UL
Lower limit	
Upper limit	
Flag	
Clinically Significant?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Comment	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Admission

Form: Lab-BU HEMATOLOGY(2013/10/11)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:58

Generated On: 23 Jun 2014 15:19:04

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	
Specimen English Comment 2	
Result Supplementary Comment Code 1	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Admission

Form: Lab-BU HEMATOLOGY(2013/10/11)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:58

Generated On: 23 Jun 2014 15:19:04

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004514684

Please document clinically relevant abnormalities in the AE form

Date (BU)

2013/10/11

Blood Sample time(BU)

0758

Urine Sample time(BU)

0843

Derived Form name

HEMATOLOGY(2013/10/11)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Admission

Form: Lab-BU HEMATOLOGY(2013/10/11)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:58

Generated On: 23 Jun 2014 15:19:04

Test Category	HEMATOLOGY
Date of Sample Collection	2013 OCT 11
Time of Blood Sample Collection	07:58
Time of Urine Sample Collection	08:43
Test Name	BASOPHILS (ABS)
Result	86
Text Result	
Unit	/UL
Lower limit	
Upper limit	
Flag	
Clinically Significant?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Comment	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Admission

Form: Lab-BU HEMATOLOGY(2013/10/11)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:58

Generated On: 23 Jun 2014 15:19:04

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	
Specimen English Comment 2	
Result Supplementary Comment Code 1	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Admission

Form: Lab-BU HEMATOLOGY(2013/10/11)

Data signed: (FumimasaNobuoka) 14 May 2014 06:17:58

Generated On: 23 Jun 2014 15:19:04

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004514684

Please document clinically relevant abnormalities in the AE form

Date (BU)

2013/10/11

Blood Sample time(BU)

0758

Urine Sample time(BU)

0843

Derived Form name

HEMATOLOGY(2013/10/11)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Admission

Form: Lab-BU URINALYSIS(2013/10/11)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:05

Generated On: 23 Jun 2014 15:19:04

Test Category	URINALYSIS
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Date of Sample Collection	2013 OCT 11
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Please document clinically relevant abnormalities in the AE form

Date (BU)	2013/10/11
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Derived Form name	URINALYSIS(2013/10/11)
-------------------	------------------------

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Admission

Form: Lab-BU URINALYSIS(2013/10/11)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:05

Generated On: 23 Jun 2014 15:19:04

Test Category	URINALYSIS
Date of Sample Collection	2013 OCT 11
Time of Blood Sample Collection	07:58
Time of Urine Sample Collection	08:43
Test Name	SPECIFIC GRAVITY
Result	1.021
Text Result	
Unit	
Lower limit	1.002
Upper limit	1.030
Flag	
Clinically Significant?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Comment	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Admission

Form: Lab-BU URINALYSIS(2013/10/11)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:05

Generated On: 23 Jun 2014 15:19:04

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	
Specimen English Comment 2	
Result Supplementary Comment Code 1	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Admission

Form: Lab-BU URINALYSIS(2013/10/11)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:05

Generated On: 23 Jun 2014 15:19:04

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004514684

Please document clinically relevant abnormalities in the AE form

Date (BU)

2013/10/11

Blood Sample time(BU)

0758

Urine Sample time(BU)

0843

Derived Form name

URINALYSIS(2013/10/11)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Admission

Form: Lab-BU URINALYSIS(2013/10/11)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:05

Generated On: 23 Jun 2014 15:19:04

Test Category	URINALYSIS
Date of Sample Collection	2013 OCT 11
Time of Blood Sample Collection	07:58
Time of Urine Sample Collection	08:43
Test Name	PH
Result	6.0
Text Result	
Unit	
Lower limit	5.0
Upper limit	8.0
Flag	
Clinically Significant?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Comment	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Admission

Form: Lab-BU URINALYSIS(2013/10/11)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:05

Generated On: 23 Jun 2014 15:19:04

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	
Specimen English Comment 2	
Result Supplementary Comment Code 1	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Admission

Form: Lab-BU URINALYSIS(2013/10/11)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:05

Generated On: 23 Jun 2014 15:19:04

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004514684

Please document clinically relevant abnormalities in the AE form

Date (BU)

2013/10/11

Blood Sample time(BU)

0758

Urine Sample time(BU)

0843

Derived Form name

URINALYSIS(2013/10/11)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Admission

Form: Lab-BU URINALYSIS(2013/10/11)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:05

Generated On: 23 Jun 2014 15:19:04

Test Category	URINALYSIS
Date of Sample Collection	2013 OCT 11
Time of Blood Sample Collection	07:58
Time of Urine Sample Collection	08:43
Test Name	GLUCOSE
Result	
Text Result	-
Unit	
Lower limit	
Upper limit	-
Flag	
Clinically Significant?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Comment	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Admission

Form: Lab-BU URINALYSIS(2013/10/11)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:05

Generated On: 23 Jun 2014 15:19:04

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	
Specimen English Comment 2	
Result Supplementary Comment Code 1	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Admission

Form: Lab-BU URINALYSIS(2013/10/11)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:05

Generated On: 23 Jun 2014 15:19:04

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004514684

Please document clinically relevant abnormalities in the AE form

Date (BU)

2013/10/11

Blood Sample time(BU)

0758

Urine Sample time(BU)

0843

Derived Form name

URINALYSIS(2013/10/11)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Admission

Form: Lab-BU URINALYSIS(2013/10/11)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:05

Generated On: 23 Jun 2014 15:19:04

Test Category	URINALYSIS
Date of Sample Collection	2013 OCT 11
Time of Blood Sample Collection	07:58
Time of Urine Sample Collection	08:43
Test Name	PROTEIN
Result	
Text Result	-
Unit	
Lower limit	
Upper limit	-
Flag	
Clinically Significant?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Comment	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Admission

Form: Lab-BU URINALYSIS(2013/10/11)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:05

Generated On: 23 Jun 2014 15:19:04

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	
Specimen English Comment 2	
Result Supplementary Comment Code 1	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Admission

Form: Lab-BU URINALYSIS(2013/10/11)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:05

Generated On: 23 Jun 2014 15:19:04

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004514684

Please document clinically relevant abnormalities in the AE form

Date (BU)

2013/10/11

Blood Sample time(BU)

0758

Urine Sample time(BU)

0843

Derived Form name

URINALYSIS(2013/10/11)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Admission

Form: Lab-BU URINALYSIS(2013/10/11)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:05

Generated On: 23 Jun 2014 15:19:04

Test Category	URINALYSIS
Date of Sample Collection	2013 OCT 11
Time of Blood Sample Collection	07:58
Time of Urine Sample Collection	08:43
Test Name	BILIRUBIN
Result	
Text Result	-
Unit	
Lower limit	
Upper limit	-
Flag	
Clinically Significant?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Comment	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Admission

Form: Lab-BU URINALYSIS(2013/10/11)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:05

Generated On: 23 Jun 2014 15:19:04

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	
Specimen English Comment 2	
Result Supplementary Comment Code 1	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Admission

Form: Lab-BU URINALYSIS(2013/10/11)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:05

Generated On: 23 Jun 2014 15:19:04

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004514684

Please document clinically relevant abnormalities in the AE form

Date (BU)

2013/10/11

Blood Sample time(BU)

0758

Urine Sample time(BU)

0843

Derived Form name

URINALYSIS(2013/10/11)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Admission

Form: Lab-BU URINALYSIS(2013/10/11)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:05

Generated On: 23 Jun 2014 15:19:04

Test Category	URINALYSIS
Date of Sample Collection	2013 OCT 11
Time of Blood Sample Collection	07:58
Time of Urine Sample Collection	08:43
Test Name	NITRITE
Result	
Text Result	-
Unit	
Lower limit	
Upper limit	-
Flag	
Clinically Significant?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Comment	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Admission

Form: Lab-BU URINALYSIS(2013/10/11)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:05

Generated On: 23 Jun 2014 15:19:04

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	
Specimen English Comment 2	
Result Supplementary Comment Code 1	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Admission

Form: Lab-BU URINALYSIS(2013/10/11)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:05

Generated On: 23 Jun 2014 15:19:04

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004514684

Please document clinically relevant abnormalities in the AE form

Date (BU)

2013/10/11

Blood Sample time(BU)

0758

Urine Sample time(BU)

0843

Derived Form name

URINALYSIS(2013/10/11)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Admission

Form: Lab-BU URINALYSIS(2013/10/11)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:05

Generated On: 23 Jun 2014 15:19:04

Test Category	URINALYSIS
Date of Sample Collection	2013 OCT 11
Time of Blood Sample Collection	07:58
Time of Urine Sample Collection	08:43
Test Name	OCCULT BLOOD
Result	
Text Result	3+
Unit	
Lower limit	
Upper limit	-
Flag	!
Clinically Significant?	No <input checked="" type="radio"/>
Comment	
Result Category	S

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Admission

Form: Lab-BU URINALYSIS(2013/10/11)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:05

Generated On: 23 Jun 2014 15:19:04

Text Result Code	070
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	
Specimen English Comment 2	
Result Supplementary Comment Code 1	
Result Supplementary English Comment Code 1	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Admission

Form: Lab-BU URINALYSIS(2013/10/11)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:05

Generated On: 23 Jun 2014 15:19:04

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004514684

Please document clinically relevant abnormalities in the AE form

Date (BU)

2013/10/11

Blood Sample time(BU)

0758

Urine Sample time(BU)

0843

Derived Form name

URINALYSIS(2013/10/11)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Admission

Form: Biomarker(Blood)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:08

Generated On: 23 Jun 2014 15:19:04

Sample type

PLASMA

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Admission

Form: Biomarker(Blood) (1)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:08

Generated On: 23 Jun 2014 15:19:04

Sample type	PLASMA
Sample Barcode	05112010000102
Analyte	COTININE
Result	427
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	AA99122-02
Date of Collection	2013-OCT-11
Timepoint-minutes	0
Urine Start Day	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Admission

Form: Biomarker(Blood) (1)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:08

Generated On: 23 Jun 2014 15:19:04

Urine End Day

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Admission

Form: Biomarker(Blood) (2)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:08

Generated On: 23 Jun 2014 15:19:04

Sample type	PLASMA
Sample Barcode	05112010000102
Analyte	TRANS-3-HYDROXYCOTININE
Result	87.9
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	AA99122-02
Date of Collection	2013-OCT-11
Timepoint-minutes	0
Urine Start Day	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Admission

Form: Biomarker(Blood) (2)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:08

Generated On: 23 Jun 2014 15:19:04

Urine End Day

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Wash-out 1 (Day 0)

Form: Date of Visit

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:08

Generated On: 23 Jun 2014 15:19:04

Date of Visit

12 OCT 2013
DD/MMM/YYYY

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Wash-out 1 (Day 0)

Form: Randomization

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:08

Generated On: 23 Jun 2014 15:19:04

Randomization number (4 digits)	1093
---------------------------------	------

Sequence Subject randomised to:	Sequence 1 THS 2.2 <input checked="" type="radio"/>
	Menthol- mCC

Nicotine level	<= 0.6mg <input checked="" type="radio"/>
----------------	---

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Wash-out 1 (Day 0)

Form: Vital Signs

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:08

Generated On: 23 Jun 2014 15:19:04

Were vital signs assessed? Yes ☒

If No, please specify the reason: _____

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

Time of assessment 10:08
hour:min 24-hour clock

Pulse rate 52
beats per minute

Respiratory rate 16
breaths per minute

Blood Pressure (systolic) 112
mmHg

Blood Pressure (diastolic) 62
mmHg

Vital Signs Position of Subject Supine ☒

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Wash-out 1 (Day 0)

Form: CO Breath Test <Wash-out/> (1)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:08

Generated On: 23 Jun 2014 15:19:04

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

If not done, please specify the reason: _____

Scheduled Time	08:00 - 09:30 <input checked="" type="radio"/>
----------------	--

Actual Time of Assessment hour:min 24-hour clock	09:08
---	-------

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

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Wash-out 1 (Day 0)

Form: CO Breath Test <Wash-out/> (2)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:08

Generated On: 23 Jun 2014 15:19:04

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	12:08
---	-------

Result(ppm)	4
-------------	---

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Wash-out 1 (Day 0)

Form: CO Breath Test <Wash-out/> (3)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:08

Generated On: 23 Jun 2014 15:19:04

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

If not done, please specify the reason: _____

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

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

Result(ppm)	4
-------------	---

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Wash-out 1 (Day 0)

Form: CO Breath Test <Wash-out/> (4)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:08

Generated On: 23 Jun 2014 15:19:04

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

If not done, please specify the reason: _____

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

Actual Time of Assessment hour:min 24-hour clock	20:08
---	-------

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

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Wash-out 1 (Day 0)

Form: Cough Assessment

Generated On: 23 Jun 2014 15:19:04

Date of Birth
YYYY MMM DD

(b) (6)

Date of assessment
YYYY MMM DD

2013 OCT 12
YYYY MMM DD

Time of assessment
hour:min 24-hour clock

08:34
hour:min 24-hour clock

Assessment Status

Completed ☒

Have you experienced a regular need to cough e.g.
coughing several times in the last 24 hrs?

Yes ☒

If YES, please answer the following questions:

First Question: Cough Impact Scale
How much is your cough bothering you?

15

Second Question: Cough Intensity Scale:
How intense is your cough?

Very mild ☒

Third Question: Cough Frequency Scale:
How frequently do you normally have to cough each
day?

Sometimes ☒

Fourth Question: Sputum Production
To what extent do you produce sputum when coughing?

A moderate amount of
sputum ☒

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Single use 1 (Day 1)

Form: Date of Visit

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:08

Generated On: 23 Jun 2014 15:19:04

Date of Visit

13 OCT 2013
DD/MMM/YYYY

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Single use 1 (Day 1)

Form: Vital Signs

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:08

Generated On: 23 Jun 2014 15:19:04

Were vital signs assessed?

Yes ☒

If No, please specify the reason: _____

Has the subject smoked within 15 minutes prior to
assessment

No ☒

Time of assessment

10:23
hour:min 24-hour clock

Pulse rate

54
beats per minute

Respiratory rate

16
breaths per minute

Blood Pressure (systolic)

102
mmHg

Blood Pressure (diastolic)

61
mmHg

Vital Signs Position of Subject

Supine ☒

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Single use 1 (Day 1)

Form: ECG (12-Lead Standard)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:08

Generated On: 23 Jun 2014 15:19:04

Was the ECG performed? Yes ☒

If No, please specify the reason: _____

Time of assessment 10:39

Position Supine ☒

Heart Rate 50 beats per minute

QRS Interval 94 msec

QT Interval 432 msec

QTcB Interval 396 msec

PR Interval 164 msec

Interpretation Normal ☒

If Abnormal, Clinical Significance Not clinically significant ☐
Clinically significant ☐

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

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Single use 1 (Day 1)

Form: Plasma Nicotine Sample(D1/3) (1)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:09

Generated On: 23 Jun 2014 15:19:04

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	13 OCT 2013
---------------------	-------------

Scheduled Time	T0 -15 min <input checked="" type="radio"/>
----------------	---

Time hour:min:seconds 24-hour clock	07:53
--	-------

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Single use 1 (Day 1)

Form: Plasma Nicotine Sample(D1/3) (2)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:09

Generated On: 23 Jun 2014 15:19:04

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	13 OCT 2013
---------------------	-------------

Scheduled Time	T1 <input checked="" type="radio"/>
----------------	-------------------------------------

Time hour:min:seconds 24-hour clock	07:58
--	-------

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Single use 1 (Day 1)

Form: Plasma Nicotine Sample(D1/3) (3)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:09

Generated On: 23 Jun 2014 15:19:04

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	13 OCT 2013
---------------------	-------------

Scheduled Time	T2 <input checked="" type="radio"/>
----------------	-------------------------------------

Time hour:min:seconds 24-hour clock	08:00
--	-------

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Single use 1 (Day 1)

Form: Plasma Nicotine Sample(D1/3) (4)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:09

Generated On: 23 Jun 2014 15:19:04

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	13 OCT 2013
---------------------	-------------

Scheduled Time	T3 <input checked="" type="radio"/>
----------------	-------------------------------------

Time hour:min:seconds 24-hour clock	08:02
--	-------

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Single use 1 (Day 1)

Form: Plasma Nicotine Sample(D1/3) (5)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:09

Generated On: 23 Jun 2014 15:19:04

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	13 OCT 2013
---------------------	-------------

Scheduled Time	T4 <input checked="" type="radio"/>
----------------	-------------------------------------

Time hour:min:seconds 24-hour clock	08:04
--	-------

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Single use 1 (Day 1)

Form: Plasma Nicotine Sample(D1/3) (6)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:09

Generated On: 23 Jun 2014 15:19:04

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	13 OCT 2013
---------------------	-------------

Scheduled Time	T5 <input checked="" type="radio"/>
----------------	-------------------------------------

Time hour:min:seconds 24-hour clock	08:06
--	-------

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Single use 1 (Day 1)

Form: Plasma Nicotine Sample(D1/3) (7)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:09

Generated On: 23 Jun 2014 15:19:04

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	13 OCT 2013
---------------------	-------------

Scheduled Time	T6 <input checked="" type="radio"/>
----------------	-------------------------------------

Time hour:min:seconds 24-hour clock	08:11
--	-------

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Single use 1 (Day 1)

Form: Plasma Nicotine Sample(D1/3) (8)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:09

Generated On: 23 Jun 2014 15:19:04

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	13 OCT 2013
---------------------	-------------

Scheduled Time	T7 <input checked="" type="radio"/>
----------------	-------------------------------------

Time hour:min:seconds 24-hour clock	08:26
--	-------

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Single use 1 (Day 1)

Form: Plasma Nicotine Sample(D1/3) (9)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:09

Generated On: 23 Jun 2014 15:19:04

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	13 OCT 2013
---------------------	-------------

Scheduled Time	T8 <input checked="" type="radio"/>
----------------	-------------------------------------

Time hour:min:seconds 24-hour clock	08:41
--	-------

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Single use 1 (Day 1)

Form: Plasma Nicotine Sample(D1/3) (10)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:09

Generated On: 23 Jun 2014 15:19:04

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	13 OCT 2013
---------------------	-------------

Scheduled Time	T9 <input checked="" type="radio"/>
----------------	-------------------------------------

Time hour:min:seconds 24-hour clock	08:56
--	-------

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Single use 1 (Day 1)

Form: Plasma Nicotine Sample(D1/3) (11)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:09

Generated On: 23 Jun 2014 15:19:04

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	13 OCT 2013
---------------------	-------------

Scheduled Time	T10 <input checked="" type="radio"/>
----------------	--------------------------------------

Time hour:min:seconds 24-hour clock	09:56
--	-------

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Single use 1 (Day 1)

Form: Plasma Nicotine Sample(D1/3) (12)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:09

Generated On: 23 Jun 2014 15:19:04

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	13 OCT 2013
---------------------	-------------

Scheduled Time	T11 <input checked="" type="radio"/>
----------------	--------------------------------------

Time hour:min:seconds 24-hour clock	11:56
--	-------

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Single use 1 (Day 1)

Form: Plasma Nicotine Sample(D1/3) (13)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:09

Generated On: 23 Jun 2014 15:19:04

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

If Not Done, please specify the reason: _____

Date DD/MMM/YYYY	13 Oct 2013
---------------------	-------------

Scheduled Time	T12 <input checked="" type="radio"/>
----------------	--------------------------------------

Time hour:min:seconds 24-hour clock	13:30
--	-------

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Single use 1 (Day 1)

Form: Plasma Nicotine Sample(D1/3) (14)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:09

Generated On: 23 Jun 2014 15:19:04

Not Done	True
----------	------

If Not Done, please specify the reason:	DUE TO THE EARLY TERMINATION.
---	----------------------------------

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

Scheduled Time	T13 <input checked="" type="radio"/>
----------------	--------------------------------------

Time hour:min:seconds 24-hour clock	
--	--

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Single use 1 (Day 1)

Form: Plasma Nicotine Sample(D1/3) (15)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:09

Generated On: 23 Jun 2014 15:19:04

Not Done	True
----------	------

If Not Done, please specify the reason:	DUE TO THE EARLY TERMINATION.
---	----------------------------------

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

Scheduled Time	T14 <input checked="" type="radio"/>
----------------	--------------------------------------

Time hour:min:seconds 24-hour clock	
--	--

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Single use 1 (Day 1)

Form: CoHb Blood Sample (1)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:11

Generated On: 23 Jun 2014 15:19:04

Not Done

False

If Not Done, please specify the reason: _____

Scheduled Time

T0 -15 min ☒

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Single use 1 (Day 1)

Form: CoHb Blood Sample (2)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:11

Generated On: 23 Jun 2014 15:19:04

Not Done

False

If Not Done, please specify the reason:

Scheduled Time

T1 ☒

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Single use 1 (Day 1)

Form: CoHb Blood Sample (3)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:11

Generated On: 23 Jun 2014 15:19:04

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

If Not Done, please specify the reason: _____

Scheduled Time	T2 <input checked="" type="radio"/>
----------------	-------------------------------------

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Single use 1 (Day 1)

Form: CoHb Blood Sample (4)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:11

Generated On: 23 Jun 2014 15:19:04

Not Done

False

If Not Done, please specify the reason: _____

Scheduled Time

T3 ☒

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Single use 1 (Day 1)

Form: CoHb Blood Sample (5)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:11

Generated On: 23 Jun 2014 15:19:04

Not Done

True

If Not Done, please specify the reason:

DUE TO THE EARLY
TERMINATION.

Scheduled Time

T4 ☒

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Single use 1 (Day 1)

Form: CO Breath Test <Product/> (1)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:11

Generated On: 23 Jun 2014 15:19:04

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

If not done, please specify the reason: _____

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

Actual Time of Assessment hour:min 24-hour clock	07:51
---	-------

Result(ppm)	2
-------------	---

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Single use 1 (Day 1)

Form: CO Breath Test <Product/> (2)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:11

Generated On: 23 Jun 2014 15:19:04

Assessment not done	True
---------------------	------

If not done, please specify the reason:	DUE TO THE EARLY TERMINATION.
---	----------------------------------

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

Actual Time of Assessment hour:min 24-hour clock	<hr/>
---	-------

Result(ppm)	<hr/>
-------------	-------

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Single use 1 (Day 1)

Form: CO Breath Test <Product/> (3)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:11

Generated On: 23 Jun 2014 15:19:04

Assessment not done	True
---------------------	------

If not done, please specify the reason:	DUE TO THE EARLY TERMINATION.
---	----------------------------------

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

Actual Time of Assessment hour:min 24-hour clock	<hr/>
---	-------

Result(ppm)	<hr/>
-------------	-------

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Single use 1 (Day 1)

Form: CO Breath Test <Product/> (4)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:11

Generated On: 23 Jun 2014 15:19:04

Assessment not done	True
---------------------	------

If not done, please specify the reason:	DUE TO THE EARLY TERMINATION.
---	----------------------------------

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

Actual Time of Assessment hour:min 24-hour clock	<hr/>
---	-------

Result(ppm)	<hr/>
-------------	-------

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Single use 1 (Day 1)

Form: Questionnaire on smoking urges (QSU)

Generated On: 23 Jun 2014 15:19:04

Type	Date of Birth YYYY MMM DD	Date of assessment YYYY MMM DD	Assessment Window	Time of assessment hour:m in 24-hour clock	Assessment Status	1. I have a desire for a cigarette right now	2. Nothing would be better than smoking a cigarette right now	3. If it were possible I would probably smoke now	4. I could control things better now if I could smoke	5. All I want right now is a cigarette	6. I have an urge for a cigarette	7. A cigarette would taste good now	8. I would do almost anything for a cigarette now	9. Smoking would make less of a depressed	10. I am going to smoke as soon as possible
QSU	(b) (6)	2013 OCT YYYY MMM DD	Initial Assessment w 1 QSU	07:47 hour:m in 24-hour clock	Completed	Strongly agree	Strongly agree	Strongly agree	Somewhat agree	Somewhat agree	Strongly agree	Strongly agree	Somewhat agree	Somewhat agree	Strongly agree
QSU	(b) (6)	2013 OCT YYYY MMM DD	Window 1	08:12 hour:m in 24-hour clock	Completed	Somewhat agree	Do not agree or disagree	Agree	Do not agree or disagree	Somewhat agree	Somewhat agree	Somewhat agree	Somewhat agree	Somewhat agree	Agree

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Single use 1 (Day 1)

Form: Questionnaire on smoking urges (QSU) (3)

Generated On: 23 Jun 2014 15:19:04

Type	Date of Birth YYYY MMM DD	Date of assessment YYYY MMM DD	Assessment Window	Time of assessment hour:m in 24-hou r clock	Assessment Status	1. I have a desire for a cigarette e right now	2. Nothin g would be better than smokin g a cigarett e right now	3. If it were possibl e I would probabl y smoke now	4. I could control things better now if I could smoke	5. All I want now is a cigarette	6. I have an urgee for a cigarett e	7. A cigarett e would taste good now	8. I would do almost anythin g for a cigarett e now	9. Smokin g would make me less depressed	10. I am going to smoke as soon as possibl e
QSU	(b) (6)	2013 OCT 13 YYYY MMM DD	Windo w 2	08:27 hour:m in 24-hou r clock	Comple ted	Somew hat agree	Do not agree or disagree	Strongl y agree	Do not agree or disagree	Somew hat disagree	Agree	Somew hat agree	Disagre e	Disagre e	Agree

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Single use 1 (Day 1)

Form: Questionnaire on smoking urges (QSU) (4)

Generated On: 23 Jun 2014 15:19:04

Type	Date of Birth YYYY MMM DD	Date of assessment YYYY MMM DD	Assessment Window	Time of assessment hour:m in 24-hou r clock	Assessment Status	1. I have a desire for a cigarette right now	2. Nothing would be better than smoking a cigarette right now	3. If it were possible I would probably smoke now	4. I could control things better now if I could smoke	5. All I want now is a cigarette	6. I have an urge for a cigarette	7. A cigarette would taste good now	8. I would do almost anything for a cigarette now	9. Smoking would make less of a depressed	10. I am going to smoke as soon as possible
QSU	(b) (6)	2013 OCT 13 YYYY MMM DD	Window 3	08:42 hour:m in 24-hou r clock	Completed	Agree	Do not agree or disagree	Strongly agree or disagree	Do not agree or disagree	Disagree	Agree	Agree	Disagree	Disagree	Agree

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Single use 1 (Day 1)

Form: Questionnaire on smoking urges (QSU) (5)

Generated On: 23 Jun 2014 15:19:04

Type	Date of Birth YYYY MMM DD	Date of assessment YYYY MMM DD	Assessment Window	Time of assessment hour:m in 24-hou r clock	Assessment Status	1. I have a desire for a cigarette right now	2. Nothing would be better than smoking a cigarette right now	3. If it were possible I would probably smoke now	4. I could control things better now if I could smoke	5. All I want now is a cigarette	6. I have an urge for a cigarette	7. A cigarette would taste good now	8. I would do almost anything for a cigarette now	9. Smoking would make less of a depressed	10. I am going to smoke as soon as possible
QSU	(b) (6)	2013 OCT 13 YYYY MMM DD	Window 4	08:58 hour:m in 24-hou r clock	Completed	Agree	Do not agree or disagree	Strongly agree	Disagree	Disagree	Strongly agree	Agree	Disagree	Disagree	Strongly agree

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Single use 1 (Day 1)

Form: Questionnaire on smoking urges (QSU) (6)

Generated On: 23 Jun 2014 15:19:04

Type	Date of Birth YYYY MMM DD	Date of assessment YYYY MMM DD	Assessment Window	Time of assessment hour:m in 24-hou r clock	Assessment Status	1. I have a desire for a cigarette e right now	2. Nothin g would be better than smokin g a cigarett e right now	3. If it were possibl e I would probabl y smoke now	4. I could control things better now if I could smoke	5. All I want now is a cigarette	6. I have an urgee for a cigarette	7. A cigarett would taste good now	8. I would do almost anythin g for a cigarette now	9. Smokin g would make me less as depressed	10. I am going to smoke as soon as possibl e
QSU	(b) (6)	2013 OCT 13 YYYY MMM DD	Windo w 5	09:57 hour:m in 24-hou r clock	Comple ted	Strongl y agree	Agree	Strongl y agreee	Disagre	Somew hat agree	Strongl y agree	Somew hat agree	Disagre e	Disagre e	Strongl y agree

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Single use 1 (Day 1)

Form: Questionnaire on smoking urges (QSU) (7)

Generated On: 23 Jun 2014 15:19:04

Type	Date of Birth YYYY MMM DD	Date of assessment YYYY MMM DD	Assessment Window w	Time of assessment hour:m in 24-hou r clock	Assessment Status	1. I have a desire for a cigarette e right now	2. Nothin g would be better than smokin g a cigarett e right now	3. If it were possibl e I would probabl y smoke now	4. I could control things better now if I could smoke	5. All I want now is a cigarette	6. I have an urgee for a cigarette	7. A cigarett e would taste good now	8. I would do almost anythin g for a cigarette now	9. Smokin g would make me less depressed	10. I am going to smoke as soon as possibl e
QSU	(b) (6)	2013 OCT 13 YYYY MMM DD	Windo w 6	11:58 hour:m in 24-hou r clock	Comple ted	Agree	Somew hat agree	Strongl y agreee	Disagre e	Disagre e	Strongl y agreee	Strongl y agreee	Disagre e	Disagre e	Strongl y agree

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Single use 1 (Day 1)

Form: Cough Assessment

Generated On: 23 Jun 2014 15:19:04

Date of Birth
YYYY MMM DD

(b) (6)

Date of assessment
YYYY MMM DD

2013 OCT 13
YYYY MMM DD

Time of assessment
hour:min 24-hour clock

07:48
hour:min 24-hour clock

Assessment Status

Completed ☒

Have you experienced a regular need to cough e.g.
coughing several times in the last 24 hrs?

Yes ☒

If YES, please answer the following questions:

First Question: Cough Impact Scale
How much is your cough bothering you?

69

Second Question: Cough Intensity Scale:
How intense is your cough?

Severe ☒

Third Question: Cough Frequency Scale:
How frequently do you normally have to cough each
day?

Fairly often ☒

Fourth Question: Sputum Production
To what extent do you produce sputum when coughing?

A moderate amount of
sputum ☒

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Single use 1 (Day 1)

Form: Lab-BU BIOMARKER(2013/10/13)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:12

Generated On: 23 Jun 2014 15:19:04

Test Category

BIOMARKER

Date of Sample Collection

2013 OCT 13

Please document clinically relevant abnormalities in the AE form

Date (BU)

2013/10/13

Derived Form name

BIOMARKER(2013/10/13)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Single use 1 (Day 1)

Form: Lab-BU BIOMARKER(2013/10/13)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:12

Generated On: 23 Jun 2014 15:19:04

Test Category	BIOMARKER
Date of Sample Collection	2013 OCT 13
Time of Blood Sample Collection	07:53
Time of Urine Sample Collection	
Test Name	COHB
Result	2.4
Text Result	
Unit	%
Lower limit	
Upper limit	
Flag	
Clinically Significant?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Comment	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Single use 1 (Day 1)

Form: Lab-BU BIOMARKER(2013/10/13)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:12

Generated On: 23 Jun 2014 15:19:04

Result Category	N
Text Result Code	
Reference Value Category	
Timepoint(COHB)	15 MIN PRIOR
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	
Specimen English Comment 2	
Result Supplementary Comment Code 1	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Single use 1 (Day 1)

Form: Lab-BU BIOMARKER(2013/10/13)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:12

Generated On: 23 Jun 2014 15:19:04

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004514752

Please document clinically relevant abnormalities in the AE form

Date (BU)

2013/10/13

Blood Sample time(BU)

0753

Urine Sample time(BU)

Derived Form name

BIOMARKER(2013/10/13)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Single use 1 (Day 1)

Form: Lab-BU BIOMARKER(2013/10/13)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:12

Generated On: 23 Jun 2014 15:19:04

Test Category	BIOMARKER
Date of Sample Collection	2013 OCT 13
Time of Blood Sample Collection	08:11
Time of Urine Sample Collection	
Test Name	COHB
Result	2.5
Text Result	
Unit	%
Lower limit	
Upper limit	
Flag	
Clinically Significant?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Comment	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Single use 1 (Day 1)

Form: Lab-BU BIOMARKER(2013/10/13)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:12

Generated On: 23 Jun 2014 15:19:04

Result Category	N
Text Result Code	
Reference Value Category	
Timepoint(COHB)	15 MIN
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	
Specimen English Comment 2	
Result Supplementary Comment Code 1	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Single use 1 (Day 1)

Form: Lab-BU BIOMARKER(2013/10/13)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:12

Generated On: 23 Jun 2014 15:19:04

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004514814

Please document clinically relevant abnormalities in the AE form

Date (BU)

2013/10/13

Blood Sample time(BU)

0811

Urine Sample time(BU)

Derived Form name

BIOMARKER(2013/10/13)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Single use 1 (Day 1)

Form: Lab-BU BIOMARKER(2013/10/13)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:12

Generated On: 23 Jun 2014 15:19:04

Test Category	BIOMARKER
Date of Sample Collection	2013 OCT 13
Time of Blood Sample Collection	08:56
Time of Urine Sample Collection	
Test Name	COHB
Result	2.8
Text Result	
Unit	%
Lower limit	
Upper limit	
Flag	
Clinically Significant?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Comment	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Single use 1 (Day 1)

Form: Lab-BU BIOMARKER(2013/10/13)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:12

Generated On: 23 Jun 2014 15:19:04

Result Category	N
Text Result Code	
Reference Value Category	
Timepoint(COHB)	60 MIN
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	
Specimen English Comment 2	
Result Supplementary Comment Code 1	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Single use 1 (Day 1)

Form: Lab-BU BIOMARKER(2013/10/13)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:12

Generated On: 23 Jun 2014 15:19:04

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004514876

Please document clinically relevant abnormalities in the AE form

Date (BU)

2013/10/13

Blood Sample time(BU)

0856

Urine Sample time(BU)

Derived Form name

BIOMARKER(2013/10/13)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Single use 1 (Day 1)

Form: Lab-BU BIOMARKER(2013/10/13)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:12

Generated On: 23 Jun 2014 15:19:04

Test Category	BIOMARKER
Date of Sample Collection	2013 OCT 13
Time of Blood Sample Collection	11:56
Time of Urine Sample Collection	
Test Name	COHB
Result	2.7
Text Result	
Unit	%
Lower limit	
Upper limit	
Flag	
Clinically Significant?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Comment	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Single use 1 (Day 1)

Form: Lab-BU BIOMARKER(2013/10/13)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:12

Generated On: 23 Jun 2014 15:19:04

Result Category	N
Text Result Code	
Reference Value Category	
Timepoint(COHB)	4 HRS
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	
Specimen English Comment 2	
Result Supplementary Comment Code 1	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Single use 1 (Day 1)

Form: Lab-BU BIOMARKER(2013/10/13)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:12

Generated On: 23 Jun 2014 15:19:04

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004514951

Please document clinically relevant abnormalities in the AE form

Date (BU)

2013/10/13

Blood Sample time(BU)

1156

Urine Sample time(BU)

Derived Form name

BIOMARKER(2013/10/13)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Single use 1 (Day 1)

Form: Biomarker(Blood)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:14

Generated On: 23 Jun 2014 15:19:04

Sample type

PLASMA

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Single use 1 (Day 1)

Form: Biomarker(Blood) (1)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:14

Generated On: 23 Jun 2014 15:19:04

Sample type	PLASMA
Sample Barcode	05110800002609
Analyte	NICOTINE
Result	0.212
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	AA99122-01
Date of Collection	2013-OCT-13
Timepoint-minutes	-15
Urine Start Day	

Final 7.0 (Main CRF) (520)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Single use 1 (Day 1)

Form: Biomarker(Blood) (1)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:14

Generated On: 23 Jun 2014 15:19:04

Urine End Day

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Single use 1 (Day 1)

Form: Biomarker(Blood) (2)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:14

Generated On: 23 Jun 2014 15:19:04

Sample type	PLASMA
Sample Barcode	05110800002610
Analyte	NICOTINE
Result	5.01
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	AA99122-01
Date of Collection	2013-OCT-13
Timepoint-minutes	2
Urine Start Day	

Final 7.0 (Main CRF) (520)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Single use 1 (Day 1)

Form: Biomarker(Blood) (2)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:14

Generated On: 23 Jun 2014 15:19:04

Urine End Day

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Single use 1 (Day 1)

Form: Biomarker(Blood) (3)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:14

Generated On: 23 Jun 2014 15:19:04

Sample type	PLASMA
Sample Barcode	05110800002611
Analyte	NICOTINE
Result	11.8
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	AA99122-01
Date of Collection	2013-OCT-13
Timepoint-minutes	4
Urine Start Day	

Final 7.0 (Main CRF) (520)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Single use 1 (Day 1)

Form: Biomarker(Blood) (3)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:14

Generated On: 23 Jun 2014 15:19:04

Urine End Day

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Single use 1 (Day 1)

Form: Biomarker(Blood) (4)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:14

Generated On: 23 Jun 2014 15:19:04

Sample type	PLASMA
Sample Barcode	05110800002612
Analyte	NICOTINE
Result	11.4
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	AA99122-01
Date of Collection	2013-OCT-13
Timepoint-minutes	6
Urine Start Day	

Final 7.0 (Main CRF) (520)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Single use 1 (Day 1)

Form: Biomarker(Blood) (4)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:14

Generated On: 23 Jun 2014 15:19:04

Urine End Day

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Single use 1 (Day 1)

Form: Biomarker(Blood) (5)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:14

Generated On: 23 Jun 2014 15:19:04

Sample type	PLASMA
Sample Barcode	05110800002613
Analyte	NICOTINE
Result	9.86
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	AA99122-01
Date of Collection	2013-OCT-13
Timepoint-minutes	8
Urine Start Day	

Final 7.0 (Main CRF) (520)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Single use 1 (Day 1)

Form: Biomarker(Blood) (5)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:14

Generated On: 23 Jun 2014 15:19:04

Urine End Day

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Single use 1 (Day 1)

Form: Biomarker(Blood) (6)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:14

Generated On: 23 Jun 2014 15:19:04

Sample type	PLASMA
Sample Barcode	05110800002614
Analyte	NICOTINE
Result	9.39
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	AA99122-01
Date of Collection	2013-OCT-13
Timepoint-minutes	10
Urine Start Day	

Final 7.0 (Main CRF) (520)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Single use 1 (Day 1)

Form: Biomarker(Blood) (6)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:14

Generated On: 23 Jun 2014 15:19:04

Urine End Day

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Single use 1 (Day 1)

Form: Biomarker(Blood) (7)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:14

Generated On: 23 Jun 2014 15:19:04

Sample type	PLASMA
Sample Barcode	05110800002615
Analyte	NICOTINE
Result	7.60
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	AA99122-01
Date of Collection	2013-OCT-13
Timepoint-minutes	15
Urine Start Day	

Final 7.0 (Main CRF) (520)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Single use 1 (Day 1)

Form: Biomarker(Blood) (7)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:14

Generated On: 23 Jun 2014 15:19:04

Urine End Day

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Single use 1 (Day 1)

Form: Biomarker(Blood) (8)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:14

Generated On: 23 Jun 2014 15:19:04

Sample type	PLASMA
Sample Barcode	05110800002616
Analyte	NICOTINE
Result	5.95
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	AA99122-01
Date of Collection	2013-OCT-13
Timepoint-minutes	30
Urine Start Day	

Final 7.0 (Main CRF) (520)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Single use 1 (Day 1)

Form: Biomarker(Blood) (8)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:14

Generated On: 23 Jun 2014 15:19:04

Urine End Day

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Single use 1 (Day 1)

Form: Biomarker(Blood) (9)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:14

Generated On: 23 Jun 2014 15:19:04

Sample type	PLASMA
Sample Barcode	05110800002617
Analyte	NICOTINE
Result	4.59
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	AA99122-01
Date of Collection	2013-OCT-13
Timepoint-minutes	45
Urine Start Day	

Final 7.0 (Main CRF) (520)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Single use 1 (Day 1)

Form: Biomarker(Blood) (9)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:14

Generated On: 23 Jun 2014 15:19:04

Urine End Day

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Single use 1 (Day 1)

Form: Biomarker(Blood) (10)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:14

Generated On: 23 Jun 2014 15:19:04

Sample type	PLASMA
Sample Barcode	05110800002618
Analyte	NICOTINE
Result	4.76
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	1
Day of Visit	1
Celerion Study Number	AA99122-01
Date of Collection	2013-OCT-13
Timepoint-minutes	0
Urine Start Day	

Final 7.0 (Main CRF) (520)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Single use 1 (Day 1)

Form: Biomarker(Blood) (10)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:14

Generated On: 23 Jun 2014 15:19:04

Urine End Day

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Single use 1 (Day 1)

Form: Biomarker(Blood) (11)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:14

Generated On: 23 Jun 2014 15:19:04

Sample type	PLASMA
Sample Barcode	05110800002619
Analyte	NICOTINE
Result	3.16
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	2
Day of Visit	1
Celerion Study Number	AA99122-01
Date of Collection	2013-OCT-13
Timepoint-minutes	0
Urine Start Day	

Final 7.0 (Main CRF) (520)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Single use 1 (Day 1)

Form: Biomarker(Blood) (11)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:14

Generated On: 23 Jun 2014 15:19:04

Urine End Day

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Single use 1 (Day 1)

Form: Biomarker(Blood) (12)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:14

Generated On: 23 Jun 2014 15:19:04

Sample type	PLASMA
Sample Barcode	05110800002620
Analyte	NICOTINE
Result	1.87
Result Unit	NG/ML
Lab Status	OK
Sample comment	
Detection method	LC-MS/MS
Planned time point (Hour)	4
Day of Visit	1
Celerion Study Number	AA99122-01
Date of Collection	2013-OCT-13
Timepoint-minutes	0
Urine Start Day	

Final 7.0 (Main CRF) (520)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Single use 1 (Day 1)

Form: Biomarker(Blood) (12)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:14

Generated On: 23 Jun 2014 15:19:04

Urine End Day

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Single use 1 (Day 1)

Form: Biomarker(Blood) (13)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:14

Generated On: 23 Jun 2014 15:19:04

Sample type	PLASMA
Sample Barcode	05110800002592
Analyte	NICOTINE
Result	1.13
Result Unit	NG/ML
Lab Status	OK
Sample comment	ET
Detection method	LC-MS/MS
Planned time point (Hour)	6
Day of Visit	1
Celerion Study Number	AA99122-01
Date of Collection	2013-OCT-13
Timepoint-minutes	0
Urine Start Day	

Final 7.0 (Main CRF) (520)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Single use 1 (Day 1)

Form: Biomarker(Blood) (13)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:14

Generated On: 23 Jun 2014 15:19:04

Urine End Day

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Wash-out 2 (Day 2)

Form: Date of Visit

Generated On: 23 Jun 2014 15:19:04

Date of Visit

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Wash-out 2 (Day 2)

Form: Vital Signs

Generated On: 23 Jun 2014 15:19:04

Were vital signs assessed?

No ☐

Yes ☐

If No, please specify the reason: _____

Has the subject smoked within 15 minutes prior to
assessment

No ☐

Yes ☐

Time of assessment _____

Pulse rate _____

Respiratory rate _____

Blood Pressure (systolic) _____

Blood Pressure (diastolic) _____

Vital Signs Position of Subject

Supine ☒

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107
Folder: Wash-out 2 (Day 2)
Form: Plasma Nicotine Sample (1)
Generated On: 23 Jun 2014 15:19:04

Not Done

If Not Done, please specify the reason:

Date
DD/MMM/YYYY

Scheduled Time

T15(T0 + 24) ☒


Time
hour:min 24-hour clock

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107
Folder: Wash-out 2 (Day 2)
Form: CO Breath Test <Wash-out/> (1)
Generated On: 23 Jun 2014 15:19:04

Assessment not done

If not done, please specify the reason:

Scheduled Time

08:00—09:30 

Actual Time of Assessment
hour:min 24-hour clock

Result(ppm)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107
Folder: Wash-out 2 (Day 2)
Form: CO Breath Test <Wash-out/> (2)
Generated On: 23 Jun 2014 15:19:04

Assessment not done

If not done, please specify the reason:

Scheduled Time

12:00—13:30 ☒

Actual Time of Assessment
hour:min 24-hour clock

Result(ppm)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107
Folder: Wash-out 2 (Day 2)
Form: CO Breath Test <Wash-out/> (3)
Generated On: 23 Jun 2014 15:19:04

Assessment not done

If not done, please specify the reason:

Scheduled Time

16:00—17:30



Actual Time of Assessment
hour:min 24-hour clock

Result(ppm)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107
Folder: Wash-out 2 (Day 2)
Form: CO Breath Test <Wash-out/> (4)
Generated On: 23 Jun 2014 15:19:04

Assessment not done

If not done, please specify the reason:

Scheduled Time

20:00—21:30 ☒

Actual Time of Assessment
hour:min 24-hour clock

Result(ppm)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Single use 2 (Day 3)

Form: Date of Visit

Generated On: 23 Jun 2014 15:19:04

Date of Visit

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Single use 2 (Day 3)

Form: Vital Signs

Generated On: 23 Jun 2014 15:19:04

Were vital signs assessed?

No ☐

Yes ☐

If No, please specify the reason: _____

Has the subject smoked within 15 minutes prior to
assessment

No ☐

Yes ☐

Time of assessment _____

Pulse rate _____

Respiratory rate _____

Blood Pressure (systolic) _____

Blood Pressure (diastolic) _____

Vital Signs Position of Subject

Supine ☒

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Single use 2 (Day 3)

Form: ECG (12-Lead Standard)

Generated On: 23 Jun 2014 15:19:04

Was the ECG performed?

No ☐

Yes ☐

If No, please specify the reason: _____

Time of assessment _____

Position

Supine ☒

Heart Rate _____

QRS Interval _____

QT Interval _____

QTcB Interval _____

PR Interval _____

Interpretation

Normal ☐

Abnormal ☐

If Abnormal, Clinical Significance

Not clinically significant ☐

Clinically significant ☐

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

Final 7.0 (Main CRF) (520)


ZRHM-PK-05-JP: Ageo Medical Clinic: 0107
Folder: Single use 2 (Day 3)
Form: Plasma Nicotine Sample(D1/3) (1)
Generated On: 23 Jun 2014 15:19:04

Not Done

If Not Done, please specify the reason:

Date
DD/MMM/YYYY

Scheduled Time

T0 - 15 min 

Time
hour:min:seconds 24-hour clock

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107
Folder: Single use 2 (Day 3)
Form: Plasma Nicotine Sample(D1/3) (2)
Generated On: 23 Jun 2014 15:19:04

Not Done

If Not Done, please specify the reason:

Date
DD/MMM/YYYY

Scheduled Time

T1 ☒

Time
hour:min:seconds 24-hour clock

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107
Folder: Single use 2 (Day 3)
Form: Plasma Nicotine Sample(D1/3) (3)
Generated On: 23 Jun 2014 15:19:04

Not Done

If Not Done, please specify the reason:

Date
DD/MMM/YYYY

Scheduled Time

T2 ☒

Time
hour:min:seconds 24-hour clock

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107
Folder: Single use 2 (Day 3)
Form: Plasma Nicotine Sample(D1/3) (4)
Generated On: 23 Jun 2014 15:19:04

Not Done

If Not Done, please specify the reason:

Date
DD/MMM/YYYY

Scheduled Time

T3 ☒

Time
hour:min:seconds 24-hour clock

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107
Folder: Single use 2 (Day 3)
Form: Plasma Nicotine Sample(D1/3) (5)
Generated On: 23 Jun 2014 15:19:04

Not Done

If Not Done, please specify the reason:

Date
DD/MMM/YYYY

Scheduled Time

T4 ☒

Time
hour:min:seconds 24-hour clock

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107
Folder: Single use 2 (Day 3)
Form: Plasma Nicotine Sample(D1/3) (6)
Generated On: 23 Jun 2014 15:19:04

Not Done

If Not Done, please specify the reason:

Date
DD/MMM/YYYY

Scheduled Time

T5 ☒

Time
hour:min:seconds 24-hour clock

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107
Folder: Single use 2 (Day 3)
Form: Plasma Nicotine Sample(D1/3) (7)
Generated On: 23 Jun 2014 15:19:04

Not Done

If Not Done, please specify the reason:

Date
DD/MMM/YYYY

Scheduled Time

T6 

Time
hour:min:seconds 24-hour clock

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107
Folder: Single use 2 (Day 3)
Form: Plasma Nicotine Sample(D1/3) (8)
Generated On: 23 Jun 2014 15:19:04

Not Done

If Not Done, please specify the reason:

Date
DD/MMM/YYYY

Scheduled Time

17 

Time
hour:min:seconds 24-hour clock

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107
Folder: Single use 2 (Day 3)
Form: Plasma Nicotine Sample(D1/3) (9)
Generated On: 23 Jun 2014 15:19:04

Not Done

If Not Done, please specify the reason:

Date
DD/MMM/YYYY

Scheduled Time

T8 

Time
hour:min:seconds 24-hour clock

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107
Folder: Single use 2 (Day 3)
Form: Plasma Nicotine Sample(D1/3) (10)
Generated On: 23 Jun 2014 15:19:04

Not Done

If Not Done, please specify the reason:

Date
DD/MMM/YYYY

Scheduled Time

T9 ☒

Time
hour:min:seconds 24-hour clock


ZRHM-PK-05-JP: Ageo Medical Clinic: 0107
Folder: Single use 2 (Day 3)
Form: Plasma Nicotine Sample(D1/3) (11)
Generated On: 23 Jun 2014 15:19:04

Not Done

If Not Done, please specify the reason:

Date
DD/MMM/YYYY

Scheduled Time

T10 

Time
hour:min:seconds 24-hour clock


ZRHM-PK-05-JP: Ageo Medical Clinic: 0107
Folder: Single use 2 (Day 3)
Form: Plasma Nicotine Sample(D1/3) (12)
Generated On: 23 Jun 2014 15:19:04

Not Done

If Not Done, please specify the reason:

Date
DD/MMM/YYYY

Scheduled Time

T11 

Time
hour:min:seconds 24-hour clock


ZRHM-PK-05-JP: Ageo Medical Clinic: 0107
Folder: Single use 2 (Day 3)
Form: Plasma Nicotine Sample(D1/3) (13)
Generated On: 23 Jun 2014 15:19:04

Not Done

If Not Done, please specify the reason:

Date
DD/MMM/YYYY

Scheduled Time

T12 

Time
hour:min:seconds 24-hour clock


ZRHM-PK-05-JP: Ageo Medical Clinic: 0107
Folder: Single use 2 (Day 3)
Form: Plasma Nicotine Sample(D1/3) (14)
Generated On: 23 Jun 2014 15:19:04

Not Done

If Not Done, please specify the reason:

Date
DD/MMM/YYYY

Scheduled Time

T13 

Time
hour:min:seconds 24-hour clock


ZRHM-PK-05-JP: Ageo Medical Clinic: 0107
Folder: Single use 2 (Day 3)
Form: Plasma Nicotine Sample(D1/3) (15)
Generated On: 23 Jun 2014 15:19:04

Not Done

If Not Done, please specify the reason:

Date
DD/MMM/YYYY

Scheduled Time

T14 

Time
hour:min:seconds 24-hour clock

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107
Folder: Single use 2 (Day 3)
Form: CoHb Blood Sample (1)
Generated On: 23 Jun 2014 15:19:04

Not Done

If Not Done, please specify the reason:

Scheduled Time

T0 - 15 min ☒

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107
Folder: Single use 2 (Day 3)
Form: CoHb Blood Sample (2)
Generated On: 23 Jun 2014 15:19:04

Not Done

If Not Done, please specify the reason:

Scheduled Time

T1 ☒

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Single use 2 (Day 3)

Form: CoHb Blood Sample (3)

Generated On: 23 Jun 2014 15:19:04

Not Done

If Not Done, please specify the reason:

Scheduled Time

T2 ☒

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Single use 2 (Day 3)

Form: CoHb Blood Sample (4)

Generated On: 23 Jun 2014 15:19:04

Not Done

If Not Done, please specify the reason:

Scheduled Time

T3 ☒

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107
Folder: Single use 2 (Day 3)
Form: CoHb Blood Sample (5)
Generated On: 23 Jun 2014 15:19:04

Not Done

If Not Done, please specify the reason:

Scheduled Time

T4 ☒

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107
Folder: Single use 2 (Day 3)
Form: CO Breath Test <Product/> (1)
Generated On: 23 Jun 2014 15:19:04

Assessment not done

If not done, please specify the reason:

Scheduled Time

Within 15 min prior to ☒ smoking

Actual Time of Assessment
hour:min 24-hour clock

Result(ppm)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107
Folder: Single use 2 (Day 3)
Form: CO Breath Test <Product/> (2)
Generated On: 23 Jun 2014 15:19:04

Assessment not done

If not done, please specify the reason:

Scheduled Time

12:00—13:30 ☒

Actual Time of Assessment
hour:min 24-hour clock

Result(ppm)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107
Folder: Single use 2 (Day 3)
Form: CO Breath Test <Product/> (3)
Generated On: 23 Jun 2014 15:19:04

Assessment not done

If not done, please specify the reason:

Scheduled Time

16:00—17:30



Actual Time of Assessment
hour:min 24-hour clock

Result(ppm)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107
Folder: Single use 2 (Day 3)
Form: CO Breath Test <Product/> (4)
Generated On: 23 Jun 2014 15:19:04

Assessment not done

If not done, please specify the reason:

Scheduled Time

20:00—21:30 ☒

Actual Time of Assessment
hour:min 24-hour clock

Result(ppm)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107
Folder: Single use 2 (Day 3)
Form: Biomarker(Blood)
Generated On: 23 Jun 2014 15:19:04

Sample type

PLASMA

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107
Folder: Single use 2 (Day 3)
Form: Biomarker(Blood) (1)
Generated On: 23 Jun 2014 15:19:04

Sample type	PLASMA
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Sample Barcode	05110800002592
----------------	----------------

Analyte	NICOTINE
---------	----------

Result	1.13
--------	------

Result Unit	NG/ML
-------------	-------

Lab Status	OK
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Sample comment	
----------------	--

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

Planned time point (Hour)	24
---------------------------	----

Day of Visit	3
--------------	---

Celerion Study Number	AA99122-01
-----------------------	------------

Date of Collection	2013-OCT-13
--------------------	-------------

Timepoint-minutes	0
-------------------	---

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

Final 7.0 (Main CRF) (520)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107
Folder: Single use 2 (Day 3)
Form: Biomarker(Blood) (1)
Generated On: 23 Jun 2014 15:19:04

Urine End Day

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Day 4

Form: Date of Visit

Generated On: 23 Jun 2014 15:19:04

Date of Visit

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Day 4

Form: Plasma Nicotine Sample (1)

Generated On: 23 Jun 2014 15:19:04

Not Done

If Not Done, please specify the reason:

Date
DD/MMM/YYYY

Scheduled Time

T15(T0 + 24) ☒

Time
hour:min 24-hour clock

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Product Use

Form: Product administration-NRT gum (1)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:15

Generated On: 23 Jun 2014 15:19:04

Date of product use	11 Oct 2013 DD/MMM/YYYY
---------------------	----------------------------

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

Type of Product Use	NRT Gum <input checked="" type="radio"/>
---------------------	--

If different from the randomization please explain	<hr/>
--	-------

Time of distribution	14:45
hour:min 24-hour clock	

Time of NRT gum intake	14:46:00
hour:min 24-hour clock	

Time of product return	15:20
hour:min 24-hour clock	

Time of last chew/removal	15:20:00
hour:min 24-hour clock	

Comment	<hr/>
---------	-------

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Product Use

Form: Product administration-mCC (1)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:15

Generated On: 23 Jun 2014 15:19:04

Date of product use DD/MMM/YYYY	11 OCT 2013
------------------------------------	-------------

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

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If Type of Product Use different from the randomization
please explain _____

hour:min 24-hour clock	Time of distribution	08:07
------------------------	----------------------	-------

Time of lighting hour:min:sec 24-hour clock	08:08:00
--	----------

Time of butt return hour:min 24-hour clock	08:14
---	-------

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

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Product Use

Form: Product administration-mCC (2)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:15

Generated On: 23 Jun 2014 15:19:04

Date of product use DD/MMM/YYYY	11 OCT 2013
------------------------------------	-------------

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

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If Type of Product Use different from the randomization
please explain _____

hour:min 24-hour clock	Time of distribution	13:39
------------------------	----------------------	-------

Time of lighting hour:min:sec 24-hour clock	13:40:00
--	----------

Time of butt return hour:min 24-hour clock	13:46
---	-------

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

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Product Use

Form: Product administration-mCC (3)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:15

Generated On: 23 Jun 2014 15:19:04

Date of product use DD/MMM/YYYY	11 OCT 2013
------------------------------------	-------------

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

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If Type of Product Use different from the randomization
please explain _____

hour:min 24-hour clock	Time of distribution	13:47
------------------------	----------------------	-------

Time of lighting hour:min:sec 24-hour clock	13:48:00
--	----------

Time of butt return hour:min 24-hour clock	13:51
---	-------

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

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Product Use

Form: Product administration-mCC (4)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:15

Generated On: 23 Jun 2014 15:19:04

Date of product use DD/MMM/YYYY	11 OCT 2013
------------------------------------	-------------

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

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If Type of Product Use different from the randomization
please explain _____

hour:min 24-hour clock	15:36
------------------------	-------

Time of lighting hour:min:sec 24-hour clock	15:37:00
--	----------

Time of butt return hour:min 24-hour clock	15:42
---	-------

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

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Product Use

Form: Product administration-mCC (5)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:15

Generated On: 23 Jun 2014 15:19:04

Date of product use DD/MMM/YYYY	11 OCT 2013
------------------------------------	-------------

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

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If Type of Product Use different from the randomization
please explain _____

hour:min 24-hour clock	Time of distribution	16:47
------------------------	----------------------	-------

Time of lighting hour:min:sec 24-hour clock	16:48:00
--	----------

Time of butt return hour:min 24-hour clock	16:53
---	-------

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

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Product Use

Form: Product administration-mCC (6)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:15

Generated On: 23 Jun 2014 15:19:04

Date of product use DD/MMM/YYYY	11 OCT 2013
------------------------------------	-------------

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

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If Type of Product Use different from the randomization
please explain _____

hour:min 24-hour clock	Time of distribution	16:53
------------------------	----------------------	-------

Time of lighting hour:min:sec 24-hour clock	16:54:00
--	----------

Time of butt return hour:min 24-hour clock	16:58
---	-------

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

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Product Use

Form: Product administration-mCC (7)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:15

Generated On: 23 Jun 2014 15:19:04

Date of product use DD/MMM/YYYY	11 OCT 2013
------------------------------------	-------------

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

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If Type of Product Use different from the randomization
please explain _____

hour:min 24-hour clock	18:28
------------------------	-------

Time of lighting hour:min:sec 24-hour clock	18:29:00
--	----------

Time of butt return hour:min 24-hour clock	18:34
---	-------

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

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Product Use

Form: Product administration-mCC (8)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:15

Generated On: 23 Jun 2014 15:19:04

Date of product use DD/MMM/YYYY	11 OCT 2013
------------------------------------	-------------

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

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If Type of Product Use different from the randomization
please explain _____

hour:min 24-hour clock	Time of distribution	19:45
------------------------	----------------------	-------

Time of lighting hour:min:sec 24-hour clock	19:46:00
--	----------

Time of butt return hour:min 24-hour clock	19:52
---	-------

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

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Product Use

Form: Product administration-mCC (9)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:15

Generated On: 23 Jun 2014 15:19:04

Date of product use DD/MMM/YYYY	11 OCT 2013
------------------------------------	-------------

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

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

If Type of Product Use different from the randomization
please explain _____

hour:min 24-hour clock	Time of distribution	21:16
------------------------	----------------------	-------

Time of lighting hour:min:sec 24-hour clock	21:17:00
--	----------

Time of butt return hour:min 24-hour clock	21:22
---	-------

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

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Product Use

Form: Product administration-THS 2.2 Menthol (1)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:16

Generated On: 23 Jun 2014 15:19:04

Date of product use DD/MMM/YYYY	13 OCT 2013
------------------------------------	-------------

Visit	Day1 <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 hour:min 24-hour clock	07:55
--	-------

Time of 1st puff taken hour:min 24-hour clock	07:56:00
--	----------

Time of product return hour:min 24-hour clock	07:59
--	-------

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

Batch Number	B-05775
--------------	---------

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Product Use

Form: Product administration-THS 2.2 Menthol (2)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:16

Generated On: 23 Jun 2014 15:19:04

Date of product use DD/MMM/YYYY	11 Oct 2013
------------------------------------	-------------

Visit	Admission <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 hour:min 24-hour clock	14:15
--	-------

Time of 1st puff taken hour:min 24-hour clock	14:16:00
--	----------

Time of product return hour:min 24-hour clock	14:21
--	-------

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

Batch Number	B-05775
--------------	---------

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Discharge

Form: Date of Discharge

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:19

Generated On: 23 Jun 2014 15:19:04

Date of Visit

13 OCT 2013
DD/MMM/YYYY

Discharge Time

14:45
hour:min 24-hour clock

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Discharge

Form: Advice on the risk of smoking and Debriefing

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:20

Generated On: 23 Jun 2014 15:19:04

Has the subject received advices on the risks of
smoking?

Yes ☒

Has a debriefing been performed about THS 2.2
Menthol?

Yes ☒

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Discharge

Form: Physical Examination

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:20

Generated On: 23 Jun 2014 15:19:04

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Time of Assessment

14:00
hour:min 24-hour clock

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Discharge

Form: Physical Examination (1)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:20

Generated On: 23 Jun 2014 15:19:04

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Time of Assessment

14:00
hour:min 24-hour clock

System

General Appearance ☒

Outcome

Normal ☒

Abnormal, please specify: _____

Clinically significant

No ☐

Yes ☐

Not Done

False

Not Done; please specify the reason: _____

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Discharge

Form: Physical Examination (2)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:20

Generated On: 23 Jun 2014 15:19:04

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Time of Assessment

14:00
hour:min 24-hour clock

System

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

Outcome

Normal ☒

Abnormal, please specify: _____

Clinically significant

No ☐

Yes ☐

Not Done

False

Not Done; please specify the reason: _____

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Discharge

Form: Physical Examination (3)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:20

Generated On: 23 Jun 2014 15:19:04

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Time of Assessment

14:00
hour:min 24-hour clock

System

Thyroid Gland ☒

Outcome

Normal ☒

Abnormal, please specify: _____

Clinically significant

No ☐

Yes ☐

Not Done

False

Not Done; please specify the reason: _____

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Discharge

Form: Physical Examination (4)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:20

Generated On: 23 Jun 2014 15:19:04

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Time of Assessment

14:00
hour:min 24-hour clock

System

Heart ☒

Outcome

Normal ☒

Abnormal, please specify: _____

Clinically significant

No ☐

Yes ☐

Not Done

False

Not Done; please specify the reason: _____

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Discharge

Form: Physical Examination (5)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:20

Generated On: 23 Jun 2014 15:19:04

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Time of Assessment

14:00
hour:min 24-hour clock

System

Chest ☒

Outcome

Normal ☒

Abnormal, please specify: _____

Clinically significant

No ☐

Yes ☐

Not Done

False

Not Done; please specify the reason: _____

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Discharge

Form: Physical Examination (6)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:20

Generated On: 23 Jun 2014 15:19:04

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Time of Assessment

14:00
hour:min 24-hour clock

System

Lungs ☒

Outcome

Normal ☒

Abnormal, please specify: _____

Clinically significant

No ☐

Yes ☐

Not Done

False

Not Done; please specify the reason: _____

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Discharge

Form: Physical Examination (7)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:20

Generated On: 23 Jun 2014 15:19:04

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Time of Assessment

14:00
hour:min 24-hour clock

System

Gastrointestinal ☒

Outcome

Normal ☒

Abnormal, please specify: _____

Clinically significant

No ☐

Yes ☐

Not Done

False

Not Done; please specify the reason: _____

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Discharge

Form: Physical Examination (8)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:20

Generated On: 23 Jun 2014 15:19:04

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Time of Assessment

14:00
hour:min 24-hour clock

System

Cardiovascular System ☒

Outcome

Normal ☒

Abnormal, please specify: _____

Clinically significant

No ☐

Yes ☐

Not Done

False

Not Done; please specify the reason: _____

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Discharge

Form: Physical Examination (9)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:20

Generated On: 23 Jun 2014 15:19:04

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Time of Assessment

14:00
hour:min 24-hour clock

System

Neurologic ☒

Outcome

Normal ☒

Abnormal, please specify: _____

Clinically significant

No ☐

Yes ☐

Not Done

False

Not Done; please specify the reason: _____

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Discharge

Form: Physical Examination (10)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:20

Generated On: 23 Jun 2014 15:19:04

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Time of Assessment

14:00
hour:min 24-hour clock

System

Skin ☒

Outcome

Normal ☒

Abnormal, please specify: _____

Clinically significant

No ☐

Yes ☐

Not Done

False

Not Done; please specify the reason: _____

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Discharge

Form: Physical Examination (11)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:20

Generated On: 23 Jun 2014 15:19:04

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Time of Assessment

14:00
hour:min 24-hour clock

System

Back ☒

Outcome

Normal ☒

Abnormal, please specify: _____

Clinically significant

No ☐

Yes ☐

Not Done

False

Not Done; please specify the reason: _____

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Discharge

Form: Physical Examination (12)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:20

Generated On: 23 Jun 2014 15:19:04

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Time of Assessment

14:00
hour:min 24-hour clock

System

Musculoskeletal ☒

Outcome

Normal ☒

Abnormal, please specify: _____

Clinically significant

No ☐

Yes ☐

Not Done

False

Not Done; please specify the reason: _____

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Discharge

Form: Physical Examination (13)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:20

Generated On: 23 Jun 2014 15:19:04

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Time of Assessment

14:00
hour:min 24-hour clock

System

Abdomen ☒

Outcome

Normal ☒

Abnormal, please specify: _____

Clinically significant

No ☐

Yes ☐

Not Done

False

Not Done; please specify the reason: _____

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Discharge

Form: Physical Examination (14)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:20

Generated On: 23 Jun 2014 15:19:04

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Time of Assessment

14:00
hour:min 24-hour clock

System

Dentition ☒

Outcome

Normal ☒

Abnormal, please specify: _____

Clinically significant

No ☐

Yes ☐

Not Done

False

Not Done; please specify the reason: _____

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Discharge

Form: Physical Examination (15)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:20

Generated On: 23 Jun 2014 15:19:04

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Time of Assessment

14:00
hour:min 24-hour clock

System

Other ☒

Other, Specify _____

Outcome

Normal ☐
Abnormal ☐

Abnormal, please specify: _____

Clinically significant

No ☐
Yes ☐

Not Done

True

Not Done; please specify the reason: _____

NA

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Discharge

Form: Physical Examination (16)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:20

Generated On: 23 Jun 2014 15:19:04

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Time of Assessment

14:00
hour:min 24-hour clock

System

Other ☒

Other, Specify _____

Outcome

Normal ☐
Abnormal ☐

Abnormal, please specify: _____

Clinically significant

No ☐
Yes ☐

Not Done

True

Not Done; please specify the reason: _____

NA

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Discharge

Form: Physical Examination (17)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:20

Generated On: 23 Jun 2014 15:19:04

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Time of Assessment

14:00
hour:min 24-hour clock

System

Other ☒

Other, Specify _____

Outcome

Normal ☐
Abnormal ☐

Abnormal, please specify: _____

Clinically significant

No ☐
Yes ☐

Not Done

True

Not Done; please specify the reason: _____

NA

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Discharge

Form: Physical Examination (18)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:20

Generated On: 23 Jun 2014 15:19:04

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Time of Assessment

14:00
hour:min 24-hour clock

System

Other ☒

Other, Specify _____

Outcome

Normal ☐
Abnormal ☐

Abnormal, please specify: _____

Clinically significant

No ☐
Yes ☐

Not Done

True

Not Done; please specify the reason: _____

NA

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Discharge

Form: Physical Examination (19)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:20

Generated On: 23 Jun 2014 15:19:04

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Time of Assessment

14:00
hour:min 24-hour clock

System

Other ☒

Other, Specify _____

Outcome

Normal ☐
Abnormal ☐

Abnormal, please specify: _____

Clinically significant

No ☐
Yes ☐

Not Done

True

Not Done; please specify the reason: _____

NA

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Discharge

Form: Weight

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:28

Generated On: 23 Jun 2014 15:19:04

Measurement(s) assessed?

Yes ☒

If No, please specify the reason: _____

Time of assessment

13:20
hour:min 24-hour clock

Weight

56.6
kg

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Discharge

Form: Vital Signs

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:28

Generated On: 23 Jun 2014 15:19:04

Were vital signs assessed?

Yes ☒

If No, please specify the reason: _____

Has the subject smoked within 15 minutes prior to
assessment

No ☒

Time of assessment

13:15
hour:min 24-hour clock

Pulse rate

58
beats per minute

Respiratory rate

16
breaths per minute

Blood Pressure (systolic)

109
mmHg

Blood Pressure (diastolic)

64
mmHg

Vital Signs Position of Subject

Supine ☒

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Discharge

Form: Spirometry without a short-acting bronchodilator

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:29

Generated On: 23 Jun 2014 15:19:04

Was the spirometry performed? Yes ☒

If No, please specify the reason: _____

Category Without short-acting bronchodilator ☒

Date of assessment: 13 OCT 2013
DD/MMM/YYYY

Time of assessment: 13:40
hour:min 24-hour clock

Predicted FVC value 3.06
L

Best measured FVC value 4.16
L

Percent of predicted FVC value 135.9
%

Best measured FEV1 value 2.93
L

Predicted FEV1 value 2.57
L

Percent of predicted FEV1 value 114.0
%

Final 7.0 (Main CRF) (520)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Discharge

Form: Spirometry without a short-acting bronchodilator

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:29

Generated On: 23 Jun 2014 15:19:04

Interpretation

Normal ☒

If Abnormal, Clinical Significance

Not clinically significant ☐

Clinically significant ☐

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

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Discharge

Form: Haematology

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:29

Generated On: 23 Jun 2014 15:19:04

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-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Discharge

Form: Urine analysis

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:29

Generated On: 23 Jun 2014 15:19:04

Were samples collected?

Yes ☒

If No, please specify the reason:

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Discharge

Form: Clinical Chemistry

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:30

Generated On: 23 Jun 2014 15:19:04

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-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Discharge

Form: Urine Pregnancy Test

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:30

Generated On: 23 Jun 2014 15:19:04

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

If Not Done, specify reason

Specify result

Negative ☒

If unclear, please confirm with FSH test

Specify result of FSH test

< 20 IU/L ☐

>= 20 IU/L ☐

Time of Test

13:35

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Discharge

Form: CO Breath Test <NR/>

Generated On: 23 Jun 2014 15:19:04

Assessment not done

If not done, please specify the reason:

Actual Time of Assessment

Result

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Discharge

Form: Lab-BU BLOOD CHEMISTRY(2013/10/13)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:30

Generated On: 23 Jun 2014 15:19:04

Test Category

BLOOD CHEMISTRY

Date of Sample Collection

2013 OCT 13

Please document clinically relevant abnormalities in the AE form

Date (BU)

2013/10/13

Derived Form name

BLOOD
CHEMISTRY(2013/10/13)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Discharge

Form: Lab-BU BLOOD CHEMISTRY(2013/10/13)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:30

Generated On: 23 Jun 2014 15:19:04

Test Category	BLOOD CHEMISTRY
Date of Sample Collection	2013 OCT 13
Time of Blood Sample Collection	13:30
Time of Urine Sample Collection	13:35
Test Name	TOTAL PROTEIN
Result	6.7
Text Result	
Unit	G/DL
Lower limit	6.7
Upper limit	8.3
Flag	
Clinically Significant?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Comment	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Discharge

Form: Lab-BU BLOOD CHEMISTRY(2013/10/13)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:30

Generated On: 23 Jun 2014 15:19:04

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	
Specimen English Comment 2	
Result Supplementary Comment Code 1	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Discharge

Form: Lab-BU BLOOD CHEMISTRY(2013/10/13)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:30

Generated On: 23 Jun 2014 15:19:04

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004515382

Please document clinically relevant abnormalities in the AE form

Date (BU)

2013/10/13

Blood Sample time(BU)

1330

Urine Sample time(BU)

1335

Derived Form name

BLOOD
CHEMISTRY(2013/10/13)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Discharge

Form: Lab-BU (2)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:30

Generated On: 23 Jun 2014 15:19:04

Test Category	BLOOD CHEMISTRY
Date of Sample Collection	2013 OCT 13
Time of Blood Sample Collection	13:30
Time of Urine Sample Collection	13:35
Test Name	ALBUMIN
Result	4.3
Text Result	
Unit	G/DL
Lower limit	3.8
Upper limit	5.3
Flag	
Clinically Significant?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Comment	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Discharge

Form: Lab-BU (2)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:30

Generated On: 23 Jun 2014 15:19:04

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	
Specimen English Comment 2	
Result Supplementary Comment Code 1	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Discharge

Form: Lab-BU (2)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:30

Generated On: 23 Jun 2014 15:19:04

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004515382

Please document clinically relevant abnormalities in the AE form

Date (BU)

2013/10/13

Blood Sample time(BU)

1330

Urine Sample time(BU)

1335

Derived Form name

BLOOD
CHEMISTRY(2013/10/13)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Discharge

Form: Lab-BU (3)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:30

Generated On: 23 Jun 2014 15:19:04

Test Category	BLOOD CHEMISTRY
Date of Sample Collection	2013 OCT 13
Time of Blood Sample Collection	13:30
Time of Urine Sample Collection	13:35
Test Name	TOTAL BILIRUBIN
Result	1.0
Text Result	
Unit	MG/DL
Lower limit	0.2
Upper limit	1.2
Flag	
Clinically Significant?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Comment	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Discharge

Form: Lab-BU (3)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:30

Generated On: 23 Jun 2014 15:19:04

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	
Specimen English Comment 2	
Result Supplementary Comment Code 1	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Discharge

Form: Lab-BU (3)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:30

Generated On: 23 Jun 2014 15:19:04

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004515382

Please document clinically relevant abnormalities in the AE form

Date (BU)

2013/10/13

Blood Sample time(BU)

1330

Urine Sample time(BU)

1335

Derived Form name

BLOOD
CHEMISTRY(2013/10/13)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Discharge

Form: Lab-BU (4)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:30

Generated On: 23 Jun 2014 15:19:04

Test Category	BLOOD CHEMISTRY
Date of Sample Collection	2013 OCT 13
Time of Blood Sample Collection	13:30
Time of Urine Sample Collection	13:35
Test Name	DIRECT BILIRUBIN
Result	0.2
Text Result	
Unit	MG/DL
Lower limit	0.0
Upper limit	0.3
Flag	
Clinically Significant?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Comment	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Discharge

Form: Lab-BU (4)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:30

Generated On: 23 Jun 2014 15:19:04

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	
Specimen English Comment 2	
Result Supplementary Comment Code 1	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Discharge

Form: Lab-BU (4)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:30

Generated On: 23 Jun 2014 15:19:04

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004515382

Please document clinically relevant abnormalities in the AE form

Date (BU)

2013/10/13

Blood Sample time(BU)

1330

Urine Sample time(BU)

1335

Derived Form name

BLOOD
CHEMISTRY(2013/10/13)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Discharge

Form: Lab-BU (5)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:30

Generated On: 23 Jun 2014 15:19:04

Test Category	BLOOD CHEMISTRY
Date of Sample Collection	2013 OCT 13
Time of Blood Sample Collection	13:30
Time of Urine Sample Collection	13:35
Test Name	AST
Result	16
Text Result	
Unit	U/L
Lower limit	10
Upper limit	40
Flag	
Clinically Significant?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Comment	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Discharge

Form: Lab-BU (5)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:30

Generated On: 23 Jun 2014 15:19:04

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	
Specimen English Comment 2	
Result Supplementary Comment Code 1	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Discharge

Form: Lab-BU (5)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:30

Generated On: 23 Jun 2014 15:19:04

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004515382

Please document clinically relevant abnormalities in the AE form

Date (BU)

2013/10/13

Blood Sample time(BU)

1330

Urine Sample time(BU)

1335

Derived Form name

BLOOD
CHEMISTRY(2013/10/13)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Discharge

Form: Lab-BU (6)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:30

Generated On: 23 Jun 2014 15:19:04

Test Category	BLOOD CHEMISTRY
Date of Sample Collection	2013 OCT 13
Time of Blood Sample Collection	13:30
Time of Urine Sample Collection	13:35
Test Name	ALT
Result	12
Text Result	
Unit	U/L
Lower limit	5
Upper limit	45
Flag	
Clinically Significant?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Comment	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Discharge

Form: Lab-BU (6)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:30

Generated On: 23 Jun 2014 15:19:04

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	
Specimen English Comment 2	
Result Supplementary Comment Code 1	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Discharge

Form: Lab-BU (6)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:30

Generated On: 23 Jun 2014 15:19:04

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004515382

Please document clinically relevant abnormalities in the AE form

Date (BU)

2013/10/13

Blood Sample time(BU)

1330

Urine Sample time(BU)

1335

Derived Form name

BLOOD
CHEMISTRY(2013/10/13)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Discharge

Form: Lab-BU (7)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:30

Generated On: 23 Jun 2014 15:19:04

Test Category	BLOOD CHEMISTRY
Date of Sample Collection	2013 OCT 13
Time of Blood Sample Collection	13:30
Time of Urine Sample Collection	13:35
Test Name	LDH
Result	122
Text Result	
Unit	U/L
Lower limit	120
Upper limit	240
Flag	
Clinically Significant?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Comment	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Discharge

Form: Lab-BU (7)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:30

Generated On: 23 Jun 2014 15:19:04

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	
Specimen English Comment 2	
Result Supplementary Comment Code 1	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Discharge

Form: Lab-BU (7)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:30

Generated On: 23 Jun 2014 15:19:04

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004515382

Please document clinically relevant abnormalities in the AE form

Date (BU)

2013/10/13

Blood Sample time(BU)

1330

Urine Sample time(BU)

1335

Derived Form name

BLOOD
CHEMISTRY(2013/10/13)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Discharge

Form: Lab-BU (8)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:30

Generated On: 23 Jun 2014 15:19:04

Test Category	BLOOD CHEMISTRY
Date of Sample Collection	2013 OCT 13
Time of Blood Sample Collection	13:30
Time of Urine Sample Collection	13:35
Test Name	AP
Result	240
Text Result	
Unit	U/L
Lower limit	100
Upper limit	325
Flag	
Clinically Significant?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Comment	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Discharge

Form: Lab-BU (8)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:30

Generated On: 23 Jun 2014 15:19:04

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	
Specimen English Comment 2	
Result Supplementary Comment Code 1	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Discharge

Form: Lab-BU (8)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:30

Generated On: 23 Jun 2014 15:19:04

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004515382

Please document clinically relevant abnormalities in the AE form

Date (BU)

2013/10/13

Blood Sample time(BU)

1330

Urine Sample time(BU)

1335

Derived Form name

BLOOD
CHEMISTRY(2013/10/13)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Discharge

Form: Lab-BU (9)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:30

Generated On: 23 Jun 2014 15:19:04

Test Category	BLOOD CHEMISTRY
Date of Sample Collection	2013 OCT 13
Time of Blood Sample Collection	13:30
Time of Urine Sample Collection	13:35
Test Name	GGT
Result	15
Text Result	
Unit	U/L
Lower limit	
Upper limit	30
Flag	
Clinically Significant?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Comment	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Discharge

Form: Lab-BU (9)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:30

Generated On: 23 Jun 2014 15:19:04

Result Category	N
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Text Result Code	_____
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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	_____
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Specimen English Comment 1	_____
----------------------------	-------

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

Result Supplementary Comment Code 1	_____
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Final 7.0 (Main CRF) (520)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Discharge

Form: Lab-BU (9)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:30

Generated On: 23 Jun 2014 15:19:04

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004515382

Please document clinically relevant abnormalities in the AE form

Date (BU)

2013/10/13

Blood Sample time(BU)

1330

Urine Sample time(BU)

1335

Derived Form name

BLOOD
CHEMISTRY(2013/10/13)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Discharge

Form: Lab-BU (10)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:30

Generated On: 23 Jun 2014 15:19:04

Test Category	BLOOD CHEMISTRY
Date of Sample Collection	2013 OCT 13
Time of Blood Sample Collection	13:30
Time of Urine Sample Collection	13:35
Test Name	FASTING GLUCOSE
Result	80
Text Result	
Unit	MG/DL
Lower limit	70
Upper limit	109
Flag	
Clinically Significant?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Comment	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Discharge

Form: Lab-BU (10)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:30

Generated On: 23 Jun 2014 15:19:04

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	
Specimen English Comment 2	
Result Supplementary Comment Code 1	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Discharge

Form: Lab-BU (10)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:30

Generated On: 23 Jun 2014 15:19:04

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004515382

Please document clinically relevant abnormalities in the AE form

Date (BU)

2013/10/13

Blood Sample time(BU)

1330

Urine Sample time(BU)

1335

Derived Form name

BLOOD
CHEMISTRY(2013/10/13)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Discharge

Form: Lab-BU (11)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:30

Generated On: 23 Jun 2014 15:19:04

Test Category	BLOOD CHEMISTRY
Date of Sample Collection	2013 OCT 13
Time of Blood Sample Collection	13:30
Time of Urine Sample Collection	13:35
Test Name	CREATININE
Result	0.43
Text Result	
Unit	MG/DL
Lower limit	0.47
Upper limit	0.79
Flag	L
Clinically Significant?	No <input checked="" type="radio"/>
Comment	
Result Category	N

Final 7.0 (Main CRF) (520)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Discharge

Form: Lab-BU (11)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:30

Generated On: 23 Jun 2014 15:19:04

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

Specimen English Comment 2

Result Supplementary Comment Code 1

Result Supplementary English Comment Code 1

Final 7.0 (Main CRF) (520)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Discharge

Form: Lab-BU (11)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:30

Generated On: 23 Jun 2014 15:19:04

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004515382

Please document clinically relevant abnormalities in the AE form

Date (BU)

2013/10/13

Blood Sample time(BU)

1330

Urine Sample time(BU)

1335

Derived Form name

BLOOD
CHEMISTRY(2013/10/13)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Discharge

Form: Lab-BU (12)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:30

Generated On: 23 Jun 2014 15:19:04

Test Category	BLOOD CHEMISTRY
Date of Sample Collection	2013 OCT 13
Time of Blood Sample Collection	13:30
Time of Urine Sample Collection	13:35
Test Name	BUN
Result	9
Text Result	
Unit	MG/DL
Lower limit	8
Upper limit	23
Flag	
Clinically Significant?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Comment	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Discharge

Form: Lab-BU (12)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:30

Generated On: 23 Jun 2014 15:19:04

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	
Specimen English Comment 2	
Result Supplementary Comment Code 1	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Discharge

Form: Lab-BU (12)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:30

Generated On: 23 Jun 2014 15:19:04

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004515382

Please document clinically relevant abnormalities in the AE form

Date (BU)

2013/10/13

Blood Sample time(BU)

1330

Urine Sample time(BU)

1335

Derived Form name

BLOOD
CHEMISTRY(2013/10/13)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Discharge

Form: Lab-BU (13)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:30

Generated On: 23 Jun 2014 15:19:04

Test Category	BLOOD CHEMISTRY
Date of Sample Collection	2013 OCT 13
Time of Blood Sample Collection	13:30
Time of Urine Sample Collection	13:35
Test Name	TRIGLYCERIDES
Result	181
Text Result	
Unit	MG/DL
Lower limit	30
Upper limit	149
Flag	H
Clinically Significant?	No <input checked="" type="radio"/>
Comment	
Result Category	N

Final 7.0 (Main CRF) (520)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Discharge

Form: Lab-BU (13)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:30

Generated On: 23 Jun 2014 15:19:04

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

Specimen English Comment 2

Result Supplementary Comment Code 1

Result Supplementary English Comment Code 1

Final 7.0 (Main CRF) (520)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Discharge

Form: Lab-BU (13)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:30

Generated On: 23 Jun 2014 15:19:04

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004515382

Please document clinically relevant abnormalities in the AE form

Date (BU)

2013/10/13

Blood Sample time(BU)

1330

Urine Sample time(BU)

1335

Derived Form name

BLOOD
CHEMISTRY(2013/10/13)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Discharge

Form: Lab-BU (14)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:30

Generated On: 23 Jun 2014 15:19:04

Test Category	BLOOD CHEMISTRY
Date of Sample Collection	2013 OCT 13
Time of Blood Sample Collection	13:30
Time of Urine Sample Collection	13:35
Test Name	TOTAL CHOLESTEROL
Result	201
Text Result	
Unit	MG/DL
Lower limit	120
Upper limit	219
Flag	
Clinically Significant?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Comment	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Discharge

Form: Lab-BU (14)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:30

Generated On: 23 Jun 2014 15:19:04

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	
Specimen English Comment 2	
Result Supplementary Comment Code 1	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Discharge

Form: Lab-BU (14)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:30

Generated On: 23 Jun 2014 15:19:04

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004515382

Please document clinically relevant abnormalities in the AE form

Date (BU)

2013/10/13

Blood Sample time(BU)

1330

Urine Sample time(BU)

1335

Derived Form name

BLOOD
CHEMISTRY(2013/10/13)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Discharge

Form: Lab-BU (15)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:30

Generated On: 23 Jun 2014 15:19:04

Test Category	BLOOD CHEMISTRY
Date of Sample Collection	2013 OCT 13
Time of Blood Sample Collection	13:30
Time of Urine Sample Collection	13:35
Test Name	SODIUM
Result	140
Text Result	
Unit	MEQ/L
Lower limit	137
Upper limit	147
Flag	
Clinically Significant?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Comment	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Discharge

Form: Lab-BU (15)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:30

Generated On: 23 Jun 2014 15:19:04

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	
Specimen English Comment 2	
Result Supplementary Comment Code 1	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Discharge

Form: Lab-BU (15)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:30

Generated On: 23 Jun 2014 15:19:04

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004515382

Please document clinically relevant abnormalities in the AE form

Date (BU)

2013/10/13

Blood Sample time(BU)

1330

Urine Sample time(BU)

1335

Derived Form name

BLOOD
CHEMISTRY(2013/10/13)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Discharge

Form: Lab-BU (16)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:30

Generated On: 23 Jun 2014 15:19:04

Test Category	BLOOD CHEMISTRY
Date of Sample Collection	2013 OCT 13
Time of Blood Sample Collection	13:30
Time of Urine Sample Collection	13:35
Test Name	POTASSIUM
Result	4.0
Text Result	
Unit	MEQ/L
Lower limit	3.5
Upper limit	5.0
Flag	
Clinically Significant?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Comment	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Discharge

Form: Lab-BU (16)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:30

Generated On: 23 Jun 2014 15:19:04

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	
Specimen English Comment 2	
Result Supplementary Comment Code 1	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Discharge

Form: Lab-BU (16)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:30

Generated On: 23 Jun 2014 15:19:04

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004515382

Please document clinically relevant abnormalities in the AE form

Date (BU)

2013/10/13

Blood Sample time(BU)

1330

Urine Sample time(BU)

1335

Derived Form name

BLOOD
CHEMISTRY(2013/10/13)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Discharge

Form: Lab-BU HEMATOLOGY(2013/10/13)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:38

Generated On: 23 Jun 2014 15:19:04

Test Category

HEMATOLOGY

Date of Sample Collection

2013 OCT 13

Please document clinically relevant abnormalities in the AE form

Date (BU)

2013/10/13

Derived Form name

HEMATOLOGY(2013/10/13)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Discharge

Form: Lab-BU HEMATOLOGY(2013/10/13)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:38

Generated On: 23 Jun 2014 15:19:04

Test Category	HEMATOLOGY
Date of Sample Collection	2013 OCT 13
Time of Blood Sample Collection	13:30
Time of Urine Sample Collection	13:35
Test Name	WBC COUNT
Result	9200
Text Result	
Unit	/UL
Lower limit	3300
Upper limit	9000
Flag	H
Clinically Significant?	No <input checked="" type="radio"/>
Comment	
Result Category	N

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Discharge

Form: Lab-BU HEMATOLOGY(2013/10/13)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:38

Generated On: 23 Jun 2014 15:19:04

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

Specimen English Comment 2

Result Supplementary Comment Code 1

Result Supplementary English Comment Code 1

Final 7.0 (Main CRF) (520)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Discharge

Form: Lab-BU HEMATOLOGY(2013/10/13)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:38

Generated On: 23 Jun 2014 15:19:04

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004515382

Please document clinically relevant abnormalities in the AE form

Date (BU)

2013/10/13

Blood Sample time(BU)

1330

Urine Sample time(BU)

1335

Derived Form name

HEMATOLOGY(2013/10/13)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Discharge

Form: Lab-BU (2)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:38

Generated On: 23 Jun 2014 15:19:04

Test Category	HEMATOLOGY
Date of Sample Collection	2013 OCT 13
Time of Blood Sample Collection	13:30
Time of Urine Sample Collection	13:35
Test Name	RBC COUNT
Result	410
Text Result	
Unit	10 ⁴ /UL
Lower limit	380
Upper limit	500
Flag	
Clinically Significant?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Comment	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Discharge

Form: Lab-BU (2)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:38

Generated On: 23 Jun 2014 15:19:04

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	
Specimen English Comment 2	
Result Supplementary Comment Code 1	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Discharge

Form: Lab-BU (2)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:38

Generated On: 23 Jun 2014 15:19:04

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004515382

Please document clinically relevant abnormalities in the AE form

Date (BU)

2013/10/13

Blood Sample time(BU)

1330

Urine Sample time(BU)

1335

Derived Form name

HEMATOLOGY(2013/10/13)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Discharge

Form: Lab-BU (3)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:38

Generated On: 23 Jun 2014 15:19:04

Test Category	HEMATOLOGY
Date of Sample Collection	2013 OCT 13
Time of Blood Sample Collection	13:30
Time of Urine Sample Collection	13:35
Test Name	HEMOGLOBIN
Result	12.6
Text Result	
Unit	G/DL
Lower limit	11.5
Upper limit	15.0
Flag	
Clinically Significant?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Comment	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Discharge

Form: Lab-BU (3)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:38

Generated On: 23 Jun 2014 15:19:04

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	
Specimen English Comment 2	
Result Supplementary Comment Code 1	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Discharge

Form: Lab-BU (3)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:38

Generated On: 23 Jun 2014 15:19:04

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004515382

Please document clinically relevant abnormalities in the AE form

Date (BU)

2013/10/13

Blood Sample time(BU)

1330

Urine Sample time(BU)

1335

Derived Form name

HEMATOLOGY(2013/10/13)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Discharge

Form: Lab-BU (4)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:38

Generated On: 23 Jun 2014 15:19:04

Test Category	HEMATOLOGY
Date of Sample Collection	2013 OCT 13
Time of Blood Sample Collection	13:30
Time of Urine Sample Collection	13:35
Test Name	HEMATOCRIT
Result	36.6
Text Result	
Unit	%
Lower limit	34.8
Upper limit	45.0
Flag	
Clinically Significant?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Comment	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Discharge

Form: Lab-BU (4)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:38

Generated On: 23 Jun 2014 15:19:04

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	
Specimen English Comment 2	
Result Supplementary Comment Code 1	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Discharge

Form: Lab-BU (4)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:38

Generated On: 23 Jun 2014 15:19:04

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004515382

Please document clinically relevant abnormalities in the AE form

Date (BU)

2013/10/13

Blood Sample time(BU)

1330

Urine Sample time(BU)

1335

Derived Form name

HEMATOLOGY(2013/10/13)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Discharge

Form: Lab-BU (5)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:38

Generated On: 23 Jun 2014 15:19:04

Test Category	HEMATOLOGY
Date of Sample Collection	2013 OCT 13
Time of Blood Sample Collection	13:30
Time of Urine Sample Collection	13:35
Test Name	MCV
Result	89
Text Result	
Unit	FL
Lower limit	85
Upper limit	102
Flag	
Clinically Significant?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Comment	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Discharge

Form: Lab-BU (5)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:38

Generated On: 23 Jun 2014 15:19:04

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	
Specimen English Comment 2	
Result Supplementary Comment Code 1	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Discharge

Form: Lab-BU (5)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:38

Generated On: 23 Jun 2014 15:19:04

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004515382

Please document clinically relevant abnormalities in the AE form

Date (BU)

2013/10/13

Blood Sample time(BU)

1330

Urine Sample time(BU)

1335

Derived Form name

HEMATOLOGY(2013/10/13)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Discharge

Form: Lab-BU (6)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:38

Generated On: 23 Jun 2014 15:19:04

Test Category	HEMATOLOGY
Date of Sample Collection	2013 OCT 13
Time of Blood Sample Collection	13:30
Time of Urine Sample Collection	13:35
Test Name	MCH
Result	30.7
Text Result	
Unit	PG
Lower limit	28.0
Upper limit	34.0
Flag	
Clinically Significant?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Comment	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Discharge

Form: Lab-BU (6)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:38

Generated On: 23 Jun 2014 15:19:04

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	
Specimen English Comment 2	
Result Supplementary Comment Code 1	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Discharge

Form: Lab-BU (6)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:38

Generated On: 23 Jun 2014 15:19:04

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004515382

Please document clinically relevant abnormalities in the AE form

Date (BU)

2013/10/13

Blood Sample time(BU)

1330

Urine Sample time(BU)

1335

Derived Form name

HEMATOLOGY(2013/10/13)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Discharge

Form: Lab-BU (7)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:38

Generated On: 23 Jun 2014 15:19:04

Test Category	HEMATOLOGY
Date of Sample Collection	2013 OCT 13
Time of Blood Sample Collection	13:30
Time of Urine Sample Collection	13:35
Test Name	MCHC
Result	34.4
Text Result	
Unit	%
Lower limit	30.2
Upper limit	35.1
Flag	
Clinically Significant?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Comment	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Discharge

Form: Lab-BU (7)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:38

Generated On: 23 Jun 2014 15:19:04

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	
Specimen English Comment 2	
Result Supplementary Comment Code 1	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Discharge

Form: Lab-BU (7)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:38

Generated On: 23 Jun 2014 15:19:04

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004515382

Please document clinically relevant abnormalities in the AE form

Date (BU)

2013/10/13

Blood Sample time(BU)

1330

Urine Sample time(BU)

1335

Derived Form name

HEMATOLOGY(2013/10/13)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Discharge

Form: Lab-BU (8)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:38

Generated On: 23 Jun 2014 15:19:04

Test Category	HEMATOLOGY
Date of Sample Collection	2013 OCT 13
Time of Blood Sample Collection	13:30
Time of Urine Sample Collection	13:35
Test Name	PLATELET COUNT
Result	26.0
Text Result	
Unit	10 ⁴ /UL
Lower limit	14.0
Upper limit	34.0
Flag	
Clinically Significant?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Comment	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Discharge

Form: Lab-BU (8)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:38

Generated On: 23 Jun 2014 15:19:04

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	
Specimen English Comment 2	
Result Supplementary Comment Code 1	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Discharge

Form: Lab-BU (8)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:38

Generated On: 23 Jun 2014 15:19:04

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004515382

Please document clinically relevant abnormalities in the AE form

Date (BU)

2013/10/13

Blood Sample time(BU)

1330

Urine Sample time(BU)

1335

Derived Form name

HEMATOLOGY(2013/10/13)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Discharge

Form: Lab-BU (9)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:38

Generated On: 23 Jun 2014 15:19:04

Test Category	HEMATOLOGY
Date of Sample Collection	2013 OCT 13
Time of Blood Sample Collection	13:30
Time of Urine Sample Collection	13:35
Test Name	DIFFERENTIAL WBC
Result	
Text Result	
Unit	
Lower limit	
Upper limit	
Flag	
Clinically Significant?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Comment	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Discharge

Form: Lab-BU (9)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:38

Generated On: 23 Jun 2014 15:19:04

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

Specimen English Comment 2

Result Supplementary Comment Code 1

Final 7.0 (Main CRF) (520)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Discharge

Form: Lab-BU (9)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:38

Generated On: 23 Jun 2014 15:19:04

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004515382

Please document clinically relevant abnormalities in the AE form

Date (BU)

2013/10/13

Blood Sample time(BU)

1330

Urine Sample time(BU)

1335

Derived Form name

HEMATOLOGY(2013/10/13)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Discharge

Form: Lab-BU (10)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:38

Generated On: 23 Jun 2014 15:19:04

Test Category	HEMATOLOGY
Date of Sample Collection	2013 OCT 13
Time of Blood Sample Collection	13:30
Time of Urine Sample Collection	13:35
Test Name	NEUTROPHILS (REL)
Result	75.0
Text Result	
Unit	%
Lower limit	40.0
Upper limit	75.0
Flag	
Clinically Significant?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Comment	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Discharge

Form: Lab-BU (10)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:38

Generated On: 23 Jun 2014 15:19:04

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	
Specimen English Comment 2	
Result Supplementary Comment Code 1	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Discharge

Form: Lab-BU (10)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:38

Generated On: 23 Jun 2014 15:19:04

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004515382

Please document clinically relevant abnormalities in the AE form

Date (BU)

2013/10/13

Blood Sample time(BU)

1330

Urine Sample time(BU)

1335

Derived Form name

HEMATOLOGY(2013/10/13)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Discharge

Form: Lab-BU (11)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:38

Generated On: 23 Jun 2014 15:19:04

Test Category	HEMATOLOGY
Date of Sample Collection	2013 OCT 13
Time of Blood Sample Collection	13:30
Time of Urine Sample Collection	13:35
Test Name	LYMPHOCYTES (REL)
Result	19.0
Text Result	
Unit	%
Lower limit	18.0
Upper limit	49.0
Flag	
Clinically Significant?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Comment	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Discharge

Form: Lab-BU (11)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:38

Generated On: 23 Jun 2014 15:19:04

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	
Specimen English Comment 2	
Result Supplementary Comment Code 1	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Discharge

Form: Lab-BU (11)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:38

Generated On: 23 Jun 2014 15:19:04

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004515382

Please document clinically relevant abnormalities in the AE form

Date (BU)

2013/10/13

Blood Sample time(BU)

1330

Urine Sample time(BU)

1335

Derived Form name

HEMATOLOGY(2013/10/13)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Discharge

Form: Lab-BU (12)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:38

Generated On: 23 Jun 2014 15:19:04

Test Category	HEMATOLOGY
Date of Sample Collection	2013 OCT 13
Time of Blood Sample Collection	13:30
Time of Urine Sample Collection	13:35
Test Name	MONOCYTES (REL)
Result	5.0
Text Result	
Unit	%
Lower limit	2.0
Upper limit	10.0
Flag	
Clinically Significant?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Comment	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Discharge

Form: Lab-BU (12)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:38

Generated On: 23 Jun 2014 15:19:04

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	
Specimen English Comment 2	
Result Supplementary Comment Code 1	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Discharge

Form: Lab-BU (12)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:38

Generated On: 23 Jun 2014 15:19:04

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004515382

Please document clinically relevant abnormalities in the AE form

Date (BU)

2013/10/13

Blood Sample time(BU)

1330

Urine Sample time(BU)

1335

Derived Form name

HEMATOLOGY(2013/10/13)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Discharge

Form: Lab-BU (13)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:38

Generated On: 23 Jun 2014 15:19:04

Test Category	HEMATOLOGY
Date of Sample Collection	2013 OCT 13
Time of Blood Sample Collection	13:30
Time of Urine Sample Collection	13:35
Test Name	EOSINOPHILS (REL)
Result	0.0
Text Result	
Unit	%
Lower limit	0.0
Upper limit	8.0
Flag	
Clinically Significant?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Comment	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Discharge

Form: Lab-BU (13)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:38

Generated On: 23 Jun 2014 15:19:04

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	
Specimen English Comment 2	
Result Supplementary Comment Code 1	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Discharge

Form: Lab-BU (13)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:38

Generated On: 23 Jun 2014 15:19:04

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004515382

Please document clinically relevant abnormalities in the AE form

Date (BU)

2013/10/13

Blood Sample time(BU)

1330

Urine Sample time(BU)

1335

Derived Form name

HEMATOLOGY(2013/10/13)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Discharge

Form: Lab-BU (14)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:38

Generated On: 23 Jun 2014 15:19:04

Test Category	HEMATOLOGY
Date of Sample Collection	2013 OCT 13
Time of Blood Sample Collection	13:30
Time of Urine Sample Collection	13:35
Test Name	BASOPHILS (REL)
Result	1.0
Text Result	
Unit	%
Lower limit	0.0
Upper limit	2.0
Flag	
Clinically Significant?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Comment	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Discharge

Form: Lab-BU (14)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:38

Generated On: 23 Jun 2014 15:19:04

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	
Specimen English Comment 2	
Result Supplementary Comment Code 1	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Discharge

Form: Lab-BU (14)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:38

Generated On: 23 Jun 2014 15:19:04

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004515382

Please document clinically relevant abnormalities in the AE form

Date (BU)

2013/10/13

Blood Sample time(BU)

1330

Urine Sample time(BU)

1335

Derived Form name

HEMATOLOGY(2013/10/13)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Discharge

Form: Lab-BU (15)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:38

Generated On: 23 Jun 2014 15:19:04

Test Category	HEMATOLOGY
Date of Sample Collection	2013 OCT 13
Time of Blood Sample Collection	13:30
Time of Urine Sample Collection	13:35
Test Name	NEUTROPHILS (ABS)
Result	6900
Text Result	
Unit	/UL
Lower limit	
Upper limit	
Flag	
Clinically Significant?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Comment	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Discharge

Form: Lab-BU (15)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:38

Generated On: 23 Jun 2014 15:19:04

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	
Specimen English Comment 2	
Result Supplementary Comment Code 1	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Discharge

Form: Lab-BU (15)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:38

Generated On: 23 Jun 2014 15:19:04

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004515382

Please document clinically relevant abnormalities in the AE form

Date (BU)

2013/10/13

Blood Sample time(BU)

1330

Urine Sample time(BU)

1335

Derived Form name

HEMATOLOGY(2013/10/13)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Discharge

Form: Lab-BU (16)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:38

Generated On: 23 Jun 2014 15:19:04

Test Category	HEMATOLOGY
Date of Sample Collection	2013 OCT 13
Time of Blood Sample Collection	13:30
Time of Urine Sample Collection	13:35
Test Name	LYMPHOCYTES (ABS)
Result	1700
Text Result	
Unit	/UL
Lower limit	
Upper limit	
Flag	
Clinically Significant?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Comment	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Discharge

Form: Lab-BU (16)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:38

Generated On: 23 Jun 2014 15:19:04

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	
Specimen English Comment 2	
Result Supplementary Comment Code 1	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Discharge

Form: Lab-BU (16)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:38

Generated On: 23 Jun 2014 15:19:04

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004515382

Please document clinically relevant abnormalities in the AE form

Date (BU)

2013/10/13

Blood Sample time(BU)

1330

Urine Sample time(BU)

1335

Derived Form name

HEMATOLOGY(2013/10/13)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Discharge

Form: Lab-BU (17)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:38

Generated On: 23 Jun 2014 15:19:04

Test Category	HEMATOLOGY
Date of Sample Collection	2013 OCT 13
Time of Blood Sample Collection	13:30
Time of Urine Sample Collection	13:35
Test Name	MONOCYTES (ABS)
Result	460
Text Result	
Unit	/UL
Lower limit	
Upper limit	
Flag	
Clinically Significant?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Comment	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Discharge

Form: Lab-BU (17)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:38

Generated On: 23 Jun 2014 15:19:04

Result Category	N
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Text Result Code	_____
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Reference Value Category	_____
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Timepoint(COHB)	_____
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Material Code	BLOOD
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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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Specimen English Comment 2	_____
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Result Supplementary Comment Code 1	_____
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Final 7.0 (Main CRF) (520)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Discharge

Form: Lab-BU (17)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:38

Generated On: 23 Jun 2014 15:19:04

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004515382

Please document clinically relevant abnormalities in the AE form

Date (BU)

2013/10/13

Blood Sample time(BU)

1330

Urine Sample time(BU)

1335

Derived Form name

HEMATOLOGY(2013/10/13)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Discharge

Form: Lab-BU (18)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:38

Generated On: 23 Jun 2014 15:19:04

Test Category	HEMATOLOGY
Date of Sample Collection	2013 OCT 13
Time of Blood Sample Collection	13:30
Time of Urine Sample Collection	13:35
Test Name	EOSINOPHILS (ABS)
Result	0
Text Result	
Unit	/UL
Lower limit	
Upper limit	
Flag	
Clinically Significant?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Comment	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Discharge

Form: Lab-BU (18)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:38

Generated On: 23 Jun 2014 15:19:04

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	
Specimen English Comment 2	
Result Supplementary Comment Code 1	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Discharge

Form: Lab-BU (18)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:38

Generated On: 23 Jun 2014 15:19:04

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004515382

Please document clinically relevant abnormalities in the AE form

Date (BU)

2013/10/13

Blood Sample time(BU)

1330

Urine Sample time(BU)

1335

Derived Form name

HEMATOLOGY(2013/10/13)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Discharge

Form: Lab-BU (19)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:38

Generated On: 23 Jun 2014 15:19:04

Test Category	HEMATOLOGY
Date of Sample Collection	2013 OCT 13
Time of Blood Sample Collection	13:30
Time of Urine Sample Collection	13:35
Test Name	BASOPHILS (ABS)
Result	92
Text Result	
Unit	/UL
Lower limit	
Upper limit	
Flag	
Clinically Significant?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Comment	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Discharge

Form: Lab-BU (19)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:38

Generated On: 23 Jun 2014 15:19:04

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	
Specimen English Comment 2	
Result Supplementary Comment Code 1	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Discharge

Form: Lab-BU (19)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:38

Generated On: 23 Jun 2014 15:19:04

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004515382

Please document clinically relevant abnormalities in the AE form

Date (BU)

2013/10/13

Blood Sample time(BU)

1330

Urine Sample time(BU)

1335

Derived Form name

HEMATOLOGY(2013/10/13)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Discharge

Form: Lab-BU URINALYSIS(2013/10/13)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:45

Generated On: 23 Jun 2014 15:19:04

Test Category

URINALYSIS

Date of Sample Collection

2013 OCT 13

Please document clinically relevant abnormalities in the AE form

Date (BU)

2013/10/13

Derived Form name

URINALYSIS(2013/10/13)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Discharge

Form: Lab-BU URINALYSIS(2013/10/13)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:45

Generated On: 23 Jun 2014 15:19:04

Test Category	URINALYSIS
Date of Sample Collection	2013 OCT 13
Time of Blood Sample Collection	13:30
Time of Urine Sample Collection	13:35
Test Name	SPECIFIC GRAVITY
Result	1.015
Text Result	
Unit	
Lower limit	1.002
Upper limit	1.030
Flag	
Clinically Significant?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Comment	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Discharge

Form: Lab-BU URINALYSIS(2013/10/13)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:45

Generated On: 23 Jun 2014 15:19:04

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	_____
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Specimen English Comment 1	_____
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Specimen Comment Code 2	_____
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Specimen English Comment 2	_____
----------------------------	-------

Result Supplementary Comment Code 1	_____
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Final 7.0 (Main CRF) (520)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Discharge

Form: Lab-BU URINALYSIS(2013/10/13)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:45

Generated On: 23 Jun 2014 15:19:04

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004515382

Please document clinically relevant abnormalities in the AE form

Date (BU)

2013/10/13

Blood Sample time(BU)

1330

Urine Sample time(BU)

1335

Derived Form name

URINALYSIS(2013/10/13)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Discharge

Form: Lab-BU (2)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:45

Generated On: 23 Jun 2014 15:19:04

Test Category	URINALYSIS
Date of Sample Collection	2013 OCT 13
Time of Blood Sample Collection	13:30
Time of Urine Sample Collection	13:35
Test Name	PH
Result	7.0
Text Result	
Unit	
Lower limit	5.0
Upper limit	8.0
Flag	
Clinically Significant?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Comment	

Final 7.0 (Main CRF) (520)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Discharge

Form: Lab-BU (2)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:45

Generated On: 23 Jun 2014 15:19:04

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	
Specimen English Comment 2	
Result Supplementary Comment Code 1	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Discharge

Form: Lab-BU (2)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:45

Generated On: 23 Jun 2014 15:19:04

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004515382

Please document clinically relevant abnormalities in the AE form

Date (BU)

2013/10/13

Blood Sample time(BU)

1330

Urine Sample time(BU)

1335

Derived Form name

URINALYSIS(2013/10/13)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Discharge

Form: Lab-BU (3)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:45

Generated On: 23 Jun 2014 15:19:04

Test Category	URINALYSIS
Date of Sample Collection	2013 OCT 13
Time of Blood Sample Collection	13:30
Time of Urine Sample Collection	13:35
Test Name	GLUCOSE
Result	
Text Result	-
Unit	
Lower limit	
Upper limit	-
Flag	
Clinically Significant?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Comment	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Discharge

Form: Lab-BU (3)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:45

Generated On: 23 Jun 2014 15:19:04

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	
Specimen English Comment 2	
Result Supplementary Comment Code 1	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Discharge

Form: Lab-BU (3)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:45

Generated On: 23 Jun 2014 15:19:04

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004515382

Please document clinically relevant abnormalities in the AE form

Date (BU)

2013/10/13

Blood Sample time(BU)

1330

Urine Sample time(BU)

1335

Derived Form name

URINALYSIS(2013/10/13)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Discharge

Form: Lab-BU (4)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:45

Generated On: 23 Jun 2014 15:19:04

Test Category	URINALYSIS
Date of Sample Collection	2013 OCT 13
Time of Blood Sample Collection	13:30
Time of Urine Sample Collection	13:35
Test Name	PROTEIN
Result	
Text Result	-
Unit	
Lower limit	
Upper limit	-
Flag	
Clinically Significant?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Comment	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Discharge

Form: Lab-BU (4)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:45

Generated On: 23 Jun 2014 15:19:04

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	
Specimen English Comment 2	
Result Supplementary Comment Code 1	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Discharge

Form: Lab-BU (4)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:45

Generated On: 23 Jun 2014 15:19:04

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004515382

Please document clinically relevant abnormalities in the AE form

Date (BU)

2013/10/13

Blood Sample time(BU)

1330

Urine Sample time(BU)

1335

Derived Form name

URINALYSIS(2013/10/13)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Discharge

Form: Lab-BU (5)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:45

Generated On: 23 Jun 2014 15:19:04

Test Category	URINALYSIS
Date of Sample Collection	2013 OCT 13
Time of Blood Sample Collection	13:30
Time of Urine Sample Collection	13:35
Test Name	BILIRUBIN
Result	
Text Result	-
Unit	
Lower limit	
Upper limit	-
Flag	
Clinically Significant?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Comment	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Discharge

Form: Lab-BU (5)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:45

Generated On: 23 Jun 2014 15:19:04

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	
Specimen English Comment 2	
Result Supplementary Comment Code 1	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Discharge

Form: Lab-BU (5)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:45

Generated On: 23 Jun 2014 15:19:04

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004515382

Please document clinically relevant abnormalities in the AE form

Date (BU)

2013/10/13

Blood Sample time(BU)

1330

Urine Sample time(BU)

1335

Derived Form name

URINALYSIS(2013/10/13)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Discharge

Form: Lab-BU (6)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:45

Generated On: 23 Jun 2014 15:19:04

Test Category	URINALYSIS
Date of Sample Collection	2013 OCT 13
Time of Blood Sample Collection	13:30
Time of Urine Sample Collection	13:35
Test Name	NITRITE
Result	
Text Result	-
Unit	
Lower limit	
Upper limit	-
Flag	
Clinically Significant?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Comment	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Discharge

Form: Lab-BU (6)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:45

Generated On: 23 Jun 2014 15:19:04

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	
Specimen English Comment 2	
Result Supplementary Comment Code 1	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Discharge

Form: Lab-BU (6)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:45

Generated On: 23 Jun 2014 15:19:04

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004515382

Please document clinically relevant abnormalities in the AE form

Date (BU)

2013/10/13

Blood Sample time(BU)

1330

Urine Sample time(BU)

1335

Derived Form name

URINALYSIS(2013/10/13)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Discharge

Form: Lab-BU (7)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:45

Generated On: 23 Jun 2014 15:19:04

Test Category	URINALYSIS
Date of Sample Collection	2013 OCT 13
Time of Blood Sample Collection	13:30
Time of Urine Sample Collection	13:35
Test Name	OCCULT BLOOD
Result	
Text Result	2+
Unit	
Lower limit	
Upper limit	-
Flag	!
Clinically Significant?	No <input checked="" type="radio"/>
Comment	
Result Category	S

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Discharge

Form: Lab-BU (7)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:45

Generated On: 23 Jun 2014 15:19:04

Text Result Code	069
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	
Specimen English Comment 2	
Result Supplementary Comment Code 1	
Result Supplementary English Comment Code 1	

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Discharge

Form: Lab-BU (7)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:45

Generated On: 23 Jun 2014 15:19:04

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004515382

Please document clinically relevant abnormalities in the AE form

Date (BU)

2013/10/13

Blood Sample time(BU)

1330

Urine Sample time(BU)

1335

Derived Form name

URINALYSIS(2013/10/13)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Adverse Events

Form: Adverse Events Y/N

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:48

Generated On: 23 Jun 2014 15:19:04

Was there any Adverse Event for this subject?

No ☒

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Concomitant Medications

Form: Previous and Concomitant Medication Y/N

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:48

Generated On: 23 Jun 2014 15:19:04

Has the subject taken previous or concomitant
medication?

No ☒

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Device Events (1)

Form: Device report - THS 2.2 Menthol Cigarette Holder

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:48

Generated On: 23 Jun 2014 15:19:04

Were there any events with the device?

No ☒

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Device Events (1)

Form: Device report - THS 2.2 Menthol Cigarette Holder (1)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:48

Generated On: 23 Jun 2014 15:19:04

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

- CH stops heating before ☐
end of smoking experience
- CH does not charge when ☐
inserted into the Mobil unit
- CH heater broken (LED ☐
blinking red)
- Smoking experience does ☐
not start when pressing the
button
- Electronic malfunction ☐
during
the smoking experience
- Other ☐

Other Describe

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Device Events (1)

Form: Device report - THS 2.2 Menthol Cigarette Holder (1)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:48

Generated On: 23 Jun 2014 15:19:04

Severity of Event

Minor (can be resolved easily) ☐

Major (cannot be resolved. Device needs to be exchanged) ☐

Adverse Event Relationship

Is related to AE ☐

Is not related to AE ☐

If Related to AE, AE Number

Solution Proposed:

Device Replaced ☐

Device Recharged ☐

Device Withdrawn ☐

If replaced, new device serial number:

Date of Device Event Closure:
DD/MMM/YYYY

Time of Device Event Closure:
hour:min 24-hour clock

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Device Events (1)

Form: Device report - THS 2.2 Menthol Charging Unit

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:49

Generated On: 23 Jun 2014 15:19:04

Were there any events with the device?

No ☒

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Device Events (1)

Form: Device report - THS 2.2 Menthol Charging Unit (1)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:49

Generated On: 23 Jun 2014 15:19:04

Were there any events with the device?

No ☒

Event Log Number

Date of
Device Event
DD/MMM/YYYY

Time of
Device Event
hour:min 24-hour clock

Event Relates to
Device Type:

THS 2.2 CHARGING UNIT

Unique Device Identifier Serial Number

Event Description

Battery Malfunction ☐

Device Discharged ☐

Other ☐

Other Describe

Severity of Event

Minor (can be resolved easily) ☐

Major (cannot be resolved. Device needs to be exchanged) ☐

Final 7.0 (Main CRF) (520)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Device Events (1)

Form: Device report - THS 2.2 Menthol Charging Unit (1)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:49

Generated On: 23 Jun 2014 15:19:04

Adverse Event
Relationship

Is related to AE ☐
Is not related to AE ☐

Solution Proposed:

Device Replaced ☐
Device Recharged ☐
Device Withdrawn ☐

If replaced, new device serial number: _____

Date of Device Event Closure:
DD/MMM/YYYY _____

Time of Device Event Closure:
DD/MMM/YYYY _____

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Device Inventory (1)

Form: Device Inventory - THS 2.2 Menthol Cigarette Holder (1)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:49

Generated On: 23 Jun 2014 15:19:04

Device Inventory Log Number	1
--------------------------------	---

Visit	-1
-------	----

Date of Device Distribution DD/MMM/YYYY	11 OCT 2013
---	-------------

Time of Device Distribution hour:min 24-hour clock	14:15
--	-------

Device Type	THS 2.2 CIGARETTE HOLDER
-------------	--------------------------

Device Serial Number	1245506
----------------------	---------

Date of Device Collection DD/MMM/YYYY	11 OCT 2013
---	-------------

Time of Device Collection hour:min 24-hour clock	14:21
--	-------

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Device Inventory (1)

Form: Device Inventory - THS 2.2 Menthol Cigarette Holder (2)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:49

Generated On: 23 Jun 2014 15:19:04

Device Inventory Log Number	2
--------------------------------	---

Visit	1
-------	---

Date of Device Distribution DD/MMM/YYYY	13 Oct 2013
---	-------------

Time of Device Distribution hour:min 24-hour clock	07:55
--	-------

Device Type	THS 2.2 CIGARETTE HOLDER
-------------	--------------------------

Device Serial Number	1245506
----------------------	---------

Date of Device Collection DD/MMM/YYYY	13 Oct 2013
---	-------------

Time of Device Collection hour:min 24-hour clock	07:59
--	-------

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Device Inventory (1)

Form: Device Inventory - THS 2.2 Menthol Charging Unit (1)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:50

Generated On: 23 Jun 2014 15:19:04

Device Inventory Log Number	1
--------------------------------	---

Visit	-1
-------	----

Date of Device Distribution DD/MMM/YYYY	11 OCT 2013
---	-------------

Time of Device Distribution hour:min 24-hour clock	14:15
--	-------

Device Type	THS 2.2 CHARGING UNIT
-------------	-----------------------

Device Serial Number	1316858
----------------------	---------

Date of Device Collection DD/MMM/YYYY	11 OCT 2013
---	-------------

Time of Device Collection hour:min 24-hour clock	14:21
--	-------

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Device Inventory (1)

Form: Device Inventory - THS 2.2 Menthol Charging Unit (2)

Data signed: (FumimasaNobuoka) 14 May 2014 06:18:50

Generated On: 23 Jun 2014 15:19:04

Device Inventory Log Number	2
--------------------------------	---

Visit	1
-------	---

Date of Device Distribution DD/MMM/YYYY	13 Oct 2013
---	-------------

Time of Device Distribution hour:min 24-hour clock	07:55
--	-------

Device Type	THS 2.2 CHARGING UNIT
-------------	-----------------------

Device Serial Number	1316858
----------------------	---------

Date of Device Collection DD/MMM/YYYY	13 Oct 2013
---	-------------

Time of Device Collection hour:min 24-hour clock	07:59
--	-------

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Unscheduled Visit >> Unscheduled Laboratory Assessments

Form: Lab-BU BLOOD CHEMISTRY(2013/10/13)

Generated On: 23 Jun 2014 15:19:04

Test Category

~~BLOOD-CHEMISTRY~~

Date of Sample Collection

~~2013-OCT-13~~

Please document clinically relevant abnormalities in the AE form

Date (BU)

~~2013/10/13~~

Derived Form name

~~BLOOD
CHEMISTRY(2013/10/13)~~

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Unscheduled Visit >> Unscheduled Laboratory Assessments

Form: Lab-BU BLOOD CHEMISTRY(2013/10/13)

Generated On: 23 Jun 2014 15:19:04

Test Category	BLOOD-CHEMISTRY
---------------	-----------------

Date of Sample Collection	2013-OCT-13
---------------------------	-------------

Time of Blood Sample Collection	13:30
---------------------------------	-------

Time of Urine Sample Collection	13:35
---------------------------------	-------

Test Name	TOTAL PROTEIN
-----------	---------------

Result	6.7
--------	-----

Text Result	
-------------	--

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

Lower limit	6.7
-------------	-----

Upper limit	8.3
-------------	-----

Flag	
------	--

Clinically Significant?	No <input type="checkbox"/>
	Yes <input type="checkbox"/>

Comment	
---------	--

Result Category	N
-----------------	---

Final 7.0 (Main CRF) (520)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Unscheduled Visit >> Unscheduled Laboratory Assessments

Form: Lab-BU BLOOD CHEMISTRY(2013/10/13)

Generated On: 23 Jun 2014 15:19:04

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

Specimen English Comment 2

Result Supplementary Comment Code 1

Result Supplementary English Comment Code 1

Final 7.0 (Main CRF) (520)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Unscheduled Visit >> Unscheduled Laboratory Assessments

Form: Lab-BU BLOOD CHEMISTRY(2013/10/13)

Generated On: 23 Jun 2014 15:19:04

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004515382

Please document clinically relevant abnormalities in the AE form

Date (BU)

2013/10/13

Blood Sample time(BU)

1330

Urine Sample time(BU)

1335

Derived Form name

BLOOD
CHEMISTRY(2013/10/13)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Unscheduled Visit >> Unscheduled Laboratory Assessments

Form: Lab-BU BLOOD CHEMISTRY(2013/10/13)

Generated On: 23 Jun 2014 15:19:04

Test Category	BLOOD-CHEMISTRY
---------------	-----------------

Date of Sample Collection	2013-OCT-13
---------------------------	-------------

Time of Blood Sample Collection	13:30
---------------------------------	-------

Time of Urine Sample Collection	13:35
---------------------------------	-------

Test Name	ALBUMIN
-----------	---------

Result	4.3
--------	-----

Text Result	
-------------	--

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

Lower limit	3.8
-------------	-----

Upper limit	5.3
-------------	-----

Flag	
------	--

Clinically Significant?	No <input type="checkbox"/>
	Yes <input type="checkbox"/>

Comment	
---------	--

Result Category	N
-----------------	---

Final 7.0 (Main CRF) (520)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Unscheduled Visit >> Unscheduled Laboratory Assessments

Form: Lab-BU BLOOD CHEMISTRY(2013/10/13)

Generated On: 23 Jun 2014 15:19:04

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

Specimen English Comment 2

Result Supplementary Comment Code 1

Result Supplementary English Comment Code 1

Final 7.0 (Main CRF) (520)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Unscheduled Visit >> Unscheduled Laboratory Assessments

Form: Lab-BU BLOOD CHEMISTRY(2013/10/13)

Generated On: 23 Jun 2014 15:19:04

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004515382

Please document clinically relevant abnormalities in the AE form

Date (BU)

2013/10/13

Blood Sample time(BU)

1330

Urine Sample time(BU)

1335

Derived Form name

BLOOD
CHEMISTRY(2013/10/13)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Unscheduled Visit >> Unscheduled Laboratory Assessments

Form: Lab-BU BLOOD CHEMISTRY(2013/10/13)

Generated On: 23 Jun 2014 15:19:04

Test Category	BLOOD-CHEMISTRY
---------------	-----------------

Date of Sample Collection	2013-OCT-13
---------------------------	-------------

Time of Blood Sample Collection	13:30
---------------------------------	-------

Time of Urine Sample Collection	13:35
---------------------------------	-------

Test Name	TOTAL-BILIRUBIN
-----------	-----------------

Result	1.0
--------	-----

Text Result	
-------------	--

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

Lower limit	0.2
-------------	-----

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

Flag	
------	--

Clinically Significant?	No <input type="checkbox"/>
	Yes <input type="checkbox"/>

Comment	
---------	--

Result Category	N
-----------------	---

Final 7.0 (Main CRF) (520)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Unscheduled Visit >> Unscheduled Laboratory Assessments

Form: Lab-BU BLOOD CHEMISTRY(2013/10/13)

Generated On: 23 Jun 2014 15:19:04

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

Specimen English Comment 2

Result Supplementary Comment Code 1

Result Supplementary English Comment Code 1

Final 7.0 (Main CRF) (520)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Unscheduled Visit >> Unscheduled Laboratory Assessments

Form: Lab-BU BLOOD CHEMISTRY(2013/10/13)

Generated On: 23 Jun 2014 15:19:04

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004515382

Please document clinically relevant abnormalities in the AE form

Date (BU)

2013/10/13

Blood Sample time(BU)

1330

Urine Sample time(BU)

1335

Derived Form name

BLOOD
CHEMISTRY(2013/10/13)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Unscheduled Visit >> Unscheduled Laboratory Assessments

Form: Lab-BU BLOOD CHEMISTRY(2013/10/13)

Generated On: 23 Jun 2014 15:19:04

Test Category	BLOOD CHEMISTRY
---------------	-----------------

Date of Sample Collection	2013 OCT 13
---------------------------	-------------

Time of Blood Sample Collection	13:30
---------------------------------	-------

Time of Urine Sample Collection	13:35
---------------------------------	-------

Test Name	DIRECT BILIRUBIN
-----------	------------------

Result	0.2
--------	-----

Text Result	
-------------	--

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

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

Upper limit	0.3
-------------	-----

Flag	
------	--

Clinically Significant?	No <input type="checkbox"/>
	Yes <input type="checkbox"/>

Comment	
---------	--

Result Category	N
-----------------	---

Final 7.0 (Main CRF) (520)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Unscheduled Visit >> Unscheduled Laboratory Assessments

Form: Lab-BU BLOOD CHEMISTRY(2013/10/13)

Generated On: 23 Jun 2014 15:19:04

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

Specimen English Comment 2

Result Supplementary Comment Code 1

Result Supplementary English Comment Code 1

Final 7.0 (Main CRF) (520)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Unscheduled Visit >> Unscheduled Laboratory Assessments

Form: Lab-BU BLOOD CHEMISTRY(2013/10/13)

Generated On: 23 Jun 2014 15:19:04

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004515382

Please document clinically relevant abnormalities in the AE form

Date (BU)

2013/10/13

Blood Sample time(BU)

1330

Urine Sample time(BU)

1335

Derived Form name

BLOOD
CHEMISTRY(2013/10/13)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Unscheduled Visit >> Unscheduled Laboratory Assessments

Form: Lab-BU BLOOD CHEMISTRY(2013/10/13)

Generated On: 23 Jun 2014 15:19:04

Test Category	BLOOD CHEMISTRY
---------------	-----------------

Date of Sample Collection	2013-OCT-13
---------------------------	-------------

Time of Blood Sample Collection	13:30
---------------------------------	-------

Time of Urine Sample Collection	13:35
---------------------------------	-------

Test Name	AST
-----------	-----

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

Text Result	
-------------	--

Unit	U/L
------	-----

Lower limit	10
-------------	----

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

Flag	
------	--

Clinically Significant?	No <input type="checkbox"/>
	Yes <input type="checkbox"/>

Comment	
---------	--

Result Category	N
-----------------	---

Final 7.0 (Main CRF) (520)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Unscheduled Visit >> Unscheduled Laboratory Assessments

Form: Lab-BU BLOOD CHEMISTRY(2013/10/13)

Generated On: 23 Jun 2014 15:19:04

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

Specimen English Comment 2

Result Supplementary Comment Code 1

Result Supplementary English Comment Code 1

Final 7.0 (Main CRF) (520)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Unscheduled Visit >> Unscheduled Laboratory Assessments

Form: Lab-BU BLOOD CHEMISTRY(2013/10/13)

Generated On: 23 Jun 2014 15:19:04

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004515382

Please document clinically relevant abnormalities in the AE form

Date (BU)

2013/10/13

Blood Sample time(BU)

1330

Urine Sample time(BU)

1335

Derived Form name

BLOOD
CHEMISTRY(2013/10/13)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Unscheduled Visit >> Unscheduled Laboratory Assessments

Form: Lab-BU BLOOD CHEMISTRY(2013/10/13)

Generated On: 23 Jun 2014 15:19:04

Test Category	BLOOD-CHEMISTRY
---------------	-----------------

Date of Sample Collection	2013-OCT-13
---------------------------	-------------

Time of Blood Sample Collection	13:30
---------------------------------	-------

Time of Urine Sample Collection	13:35
---------------------------------	-------

Test Name	ALT
-----------	-----

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

Text Result	
-------------	--

Unit	U/L
------	-----

Lower limit	5
-------------	---

Upper limit	45
-------------	----

Flag	
------	--

Clinically Significant?	No <input type="checkbox"/>
	Yes <input type="checkbox"/>

Comment	
---------	--

Result Category	N
-----------------	---

Final 7.0 (Main CRF) (520)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Unscheduled Visit >> Unscheduled Laboratory Assessments

Form: Lab-BU BLOOD CHEMISTRY(2013/10/13)

Generated On: 23 Jun 2014 15:19:04

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

Specimen English Comment 2

Result Supplementary Comment Code 1

Result Supplementary English Comment Code 1

Final 7.0 (Main CRF) (520)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Unscheduled Visit >> Unscheduled Laboratory Assessments

Form: Lab-BU BLOOD CHEMISTRY(2013/10/13)

Generated On: 23 Jun 2014 15:19:04

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004515382

Please document clinically relevant abnormalities in the AE form

Date (BU)

2013/10/13

Blood Sample time(BU)

1330

Urine Sample time(BU)

1335

Derived Form name

BLOOD
CHEMISTRY(2013/10/13)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Unscheduled Visit >> Unscheduled Laboratory Assessments

Form: Lab-BU BLOOD CHEMISTRY(2013/10/13)

Generated On: 23 Jun 2014 15:19:04

Test Category	BLOOD-CHEMISTRY
---------------	-----------------

Date of Sample Collection	2013-OCT-13
---------------------------	-------------

Time of Blood Sample Collection	13:30
---------------------------------	-------

Time of Urine Sample Collection	13:35
---------------------------------	-------

Test Name	LDH
-----------	-----

Result	122
--------	-----

Text Result	
-------------	--

Unit	U/L
------	-----

Lower limit	120
-------------	-----

Upper limit	240
-------------	-----

Flag	
------	--

Clinically Significant?	No <input type="checkbox"/>
	Yes <input type="checkbox"/>

Comment	
---------	--

Result Category	N
-----------------	---

Final 7.0 (Main CRF) (520)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Unscheduled Visit >> Unscheduled Laboratory Assessments

Form: Lab-BU BLOOD CHEMISTRY(2013/10/13)

Generated On: 23 Jun 2014 15:19:04

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

Specimen English Comment 2

Result Supplementary Comment Code 1

Result Supplementary English Comment Code 1

Final 7.0 (Main CRF) (520)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Unscheduled Visit >> Unscheduled Laboratory Assessments

Form: Lab-BU BLOOD CHEMISTRY(2013/10/13)

Generated On: 23 Jun 2014 15:19:04

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004515382

Please document clinically relevant abnormalities in the AE form

Date (BU)

2013/10/13

Blood Sample time(BU)

1330

Urine Sample time(BU)

1335

Derived Form name

BLOOD
CHEMISTRY(2013/10/13)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Unscheduled Visit >> Unscheduled Laboratory Assessments

Form: Lab-BU BLOOD CHEMISTRY(2013/10/13)

Generated On: 23 Jun 2014 15:19:04

Test Category	BLOOD-CHEMISTRY
---------------	-----------------

Date of Sample Collection	2013-OCT-13
---------------------------	-------------

Time of Blood Sample Collection	13:30
---------------------------------	-------

Time of Urine Sample Collection	13:35
---------------------------------	-------

Test Name	AP
-----------	----

Result	240
--------	-----

Text Result	
-------------	--

Unit	U/L
------	-----

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

Upper limit	325
-------------	-----

Flag	
------	--

Clinically Significant?	No <input type="checkbox"/>
	Yes <input type="checkbox"/>

Comment	
---------	--

Result Category	N
-----------------	---

Final 7.0 (Main CRF) (520)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Unscheduled Visit >> Unscheduled Laboratory Assessments

Form: Lab-BU BLOOD CHEMISTRY(2013/10/13)

Generated On: 23 Jun 2014 15:19:04

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

Specimen English Comment 2

Result Supplementary Comment Code 1

Result Supplementary English Comment Code 1

Final 7.0 (Main CRF) (520)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Unscheduled Visit >> Unscheduled Laboratory Assessments

Form: Lab-BU BLOOD CHEMISTRY(2013/10/13)

Generated On: 23 Jun 2014 15:19:04

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004515382

Please document clinically relevant abnormalities in the AE form

Date (BU)

2013/10/13

Blood Sample time(BU)

1330

Urine Sample time(BU)

1335

Derived Form name

BLOOD
CHEMISTRY(2013/10/13)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Unscheduled Visit >> Unscheduled Laboratory Assessments

Form: Lab-BU BLOOD CHEMISTRY(2013/10/13)

Generated On: 23 Jun 2014 15:19:04

Test Category	BLOOD-CHEMISTRY
---------------	-----------------

Date of Sample Collection	2013-OCT-13
---------------------------	-------------

Time of Blood Sample Collection	13:30
---------------------------------	-------

Time of Urine Sample Collection	13:35
---------------------------------	-------

Test Name	GGT
-----------	-----

Result	15
--------	----

Text Result	
-------------	--

Unit	U/L
------	-----

Lower limit	
-------------	--

Upper limit	30
-------------	----

Flag	
------	--

Clinically Significant?	No <input type="checkbox"/>
	Yes <input type="checkbox"/>

Comment	
---------	--

Result Category	N
-----------------	---

Final 7.0 (Main CRF) (520)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Unscheduled Visit >> Unscheduled Laboratory Assessments

Form: Lab-BU BLOOD CHEMISTRY(2013/10/13)

Generated On: 23 Jun 2014 15:19:04

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

Specimen English Comment 2

Result Supplementary Comment Code 1

Result Supplementary English Comment Code 1

Final 7.0 (Main CRF) (520)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Unscheduled Visit >> Unscheduled Laboratory Assessments

Form: Lab-BU BLOOD CHEMISTRY(2013/10/13)

Generated On: 23 Jun 2014 15:19:04

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004515382

Please document clinically relevant abnormalities in the AE form

Date (BU)

2013/10/13

Blood Sample time(BU)

1330

Urine Sample time(BU)

1335

Derived Form name

BLOOD
CHEMISTRY(2013/10/13)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Unscheduled Visit >> Unscheduled Laboratory Assessments

Form: Lab-BU BLOOD CHEMISTRY(2013/10/13)

Generated On: 23 Jun 2014 15:19:04

Test Category	BLOOD-CHEMISTRY
---------------	-----------------

Date of Sample Collection	2013-OCT-13
---------------------------	-------------

Time of Blood Sample Collection	13:30
---------------------------------	-------

Time of Urine Sample Collection	13:35
---------------------------------	-------

Test Name	FASTING-GLUCOSE
-----------	-----------------

Result	80
--------	----

Text Result	
-------------	--

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

Lower limit	70
-------------	----

Upper limit	109
-------------	-----

Flag	
------	--

Clinically Significant?	No <input type="checkbox"/>
	Yes <input type="checkbox"/>

Comment	
---------	--

Result Category	N
-----------------	---

Final 7.0 (Main CRF) (520)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Unscheduled Visit >> Unscheduled Laboratory Assessments

Form: Lab-BU BLOOD CHEMISTRY(2013/10/13)

Generated On: 23 Jun 2014 15:19:04

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

Specimen English Comment 2

Result Supplementary Comment Code 1

Result Supplementary English Comment Code 1

Final 7.0 (Main CRF) (520)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Unscheduled Visit >> Unscheduled Laboratory Assessments

Form: Lab-BU BLOOD CHEMISTRY(2013/10/13)

Generated On: 23 Jun 2014 15:19:04

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004515382

Please document clinically relevant abnormalities in the AE form

Date (BU)

2013/10/13

Blood Sample time(BU)

1330

Urine Sample time(BU)

1335

Derived Form name

BLOOD
CHEMISTRY(2013/10/13)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Unscheduled Visit >> Unscheduled Laboratory Assessments

Form: Lab-BU BLOOD CHEMISTRY(2013/10/13)

Generated On: 23 Jun 2014 15:19:04

Test Category	BLOOD-CHEMISTRY
---------------	-----------------

Date of Sample Collection	2013-OCT-13
---------------------------	-------------

Time of Blood Sample Collection	13:30
---------------------------------	-------

Time of Urine Sample Collection	13:35
---------------------------------	-------

Test Name	CREATININE
-----------	------------

Result	0.43
--------	------

Text Result	
-------------	--

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

Lower limit	0.47
-------------	------

Upper limit	0.79
-------------	------

Flag	L
------	---

Clinically Significant?	No <input checked="" type="radio"/>
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Comment	
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Result Category	N
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Final 7.0 (Main CRF) (520)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Unscheduled Visit >> Unscheduled Laboratory Assessments

Form: Lab-BU BLOOD CHEMISTRY(2013/10/13)

Generated On: 23 Jun 2014 15:19:04

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

Specimen English Comment 2

Result Supplementary Comment Code 1

Result Supplementary English Comment Code 1

Final 7.0 (Main CRF) (520)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Unscheduled Visit >> Unscheduled Laboratory Assessments

Form: Lab-BU BLOOD CHEMISTRY(2013/10/13)

Generated On: 23 Jun 2014 15:19:04

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004515382

Please document clinically relevant abnormalities in the AE form

Date (BU)

2013/10/13

Blood Sample time(BU)

1330

Urine Sample time(BU)

1335

Derived Form name

BLOOD
CHEMISTRY(2013/10/13)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Unscheduled Visit >> Unscheduled Laboratory Assessments

Form: Lab-BU BLOOD CHEMISTRY(2013/10/13)

Generated On: 23 Jun 2014 15:19:04

Test Category	BLOOD-CHEMISTRY
---------------	-----------------

Date of Sample Collection	2013-OCT-13
---------------------------	-------------

Time of Blood Sample Collection	13:30
---------------------------------	-------

Time of Urine Sample Collection	13:35
---------------------------------	-------

Test Name	BUN
-----------	-----

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

Text Result	
-------------	--

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

Lower limit	8
-------------	---

Upper limit	23
-------------	----

Flag	
------	--

Clinically Significant?	No <input type="checkbox"/>
	Yes <input type="checkbox"/>

Comment	
---------	--

Result Category	N
-----------------	---

Final 7.0 (Main CRF) (520)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Unscheduled Visit >> Unscheduled Laboratory Assessments

Form: Lab-BU BLOOD CHEMISTRY(2013/10/13)

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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

Specimen English Comment 2

Result Supplementary Comment Code 1

Result Supplementary English Comment Code 1

Final 7.0 (Main CRF) (520)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Unscheduled Visit >> Unscheduled Laboratory Assessments

Form: Lab-BU BLOOD CHEMISTRY(2013/10/13)

Generated On: 23 Jun 2014 15:19:04

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004515382

Please document clinically relevant abnormalities in the AE form

Date (BU)

2013/10/13

Blood Sample time(BU)

1330

Urine Sample time(BU)

1335

Derived Form name

BLOOD
CHEMISTRY(2013/10/13)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Unscheduled Visit >> Unscheduled Laboratory Assessments

Form: Lab-BU BLOOD CHEMISTRY(2013/10/13)

Generated On: 23 Jun 2014 15:19:04

Test Category	BLOOD-CHEMISTRY
---------------	-----------------

Date of Sample Collection	2013-OCT-13
---------------------------	-------------

Time of Blood Sample Collection	13:30
---------------------------------	-------

Time of Urine Sample Collection	13:35
---------------------------------	-------

Test Name	TRIGLYCERIDES
-----------	---------------

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

Text Result	
-------------	--

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

Lower limit	30
-------------	----

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

Flag	H
------	---

Clinically Significant?	No <input checked="" type="radio"/>
-------------------------	-------------------------------------

Comment	
---------	--

Result Category	N
-----------------	---

Final 7.0 (Main CRF) (520)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Unscheduled Visit >> Unscheduled Laboratory Assessments

Form: Lab-BU BLOOD CHEMISTRY(2013/10/13)

Generated On: 23 Jun 2014 15:19:04

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

Specimen English Comment 2

Result Supplementary Comment Code 1

Result Supplementary English Comment Code 1

Final 7.0 (Main CRF) (520)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Unscheduled Visit >> Unscheduled Laboratory Assessments

Form: Lab-BU BLOOD CHEMISTRY(2013/10/13)

Generated On: 23 Jun 2014 15:19:04

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004515382

Please document clinically relevant abnormalities in the AE form

Date (BU)

2013/10/13

Blood Sample time(BU)

1330

Urine Sample time(BU)

1335

Derived Form name

BLOOD
CHEMISTRY(2013/10/13)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Unscheduled Visit >> Unscheduled Laboratory Assessments

Form: Lab-BU BLOOD CHEMISTRY(2013/10/13)

Generated On: 23 Jun 2014 15:19:04

Test Category	BLOOD-CHEMISTRY
---------------	-----------------

Date of Sample Collection	2013-OCT-13
---------------------------	-------------

Time of Blood Sample Collection	13:30
---------------------------------	-------

Time of Urine Sample Collection	13:35
---------------------------------	-------

Test Name	TOTAL-CHOLESTEROL
-----------	-------------------

Result	201
--------	-----

Text Result	
-------------	--

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

Lower limit	120
-------------	-----

Upper limit	219
-------------	-----

Flag	
------	--

Clinically Significant?	No <input type="checkbox"/>
	Yes <input type="checkbox"/>

Comment	
---------	--

Result Category	N
-----------------	---

Final 7.0 (Main CRF) (520)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Unscheduled Visit >> Unscheduled Laboratory Assessments

Form: Lab-BU BLOOD CHEMISTRY(2013/10/13)

Generated On: 23 Jun 2014 15:19:04

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

Specimen English Comment 2

Result Supplementary Comment Code 1

Result Supplementary English Comment Code 1

Final 7.0 (Main CRF) (520)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Unscheduled Visit >> Unscheduled Laboratory Assessments

Form: Lab-BU BLOOD CHEMISTRY(2013/10/13)

Generated On: 23 Jun 2014 15:19:04

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004515382

Please document clinically relevant abnormalities in the AE form

Date (BU)

2013/10/13

Blood Sample time(BU)

1330

Urine Sample time(BU)

1335

Derived Form name

BLOOD
CHEMISTRY(2013/10/13)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Unscheduled Visit >> Unscheduled Laboratory Assessments

Form: Lab-BU BLOOD CHEMISTRY(2013/10/13)

Generated On: 23 Jun 2014 15:19:04

Test Category	BLOOD-CHEMISTRY
---------------	-----------------

Date of Sample Collection	2013-OCT-13
---------------------------	-------------

Time of Blood Sample Collection	13:30
---------------------------------	-------

Time of Urine Sample Collection	13:35
---------------------------------	-------

Test Name	SODIUM
-----------	--------

Result	140
--------	-----

Text Result	
-------------	--

Unit	MEQ/L
------	-------

Lower limit	137
-------------	-----

Upper limit	147
-------------	-----

Flag	
------	--

Clinically Significant?	No <input type="checkbox"/>
	Yes <input type="checkbox"/>

Comment	
---------	--

Result Category	N
-----------------	---

Final 7.0 (Main CRF) (520)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Unscheduled Visit >> Unscheduled Laboratory Assessments

Form: Lab-BU BLOOD CHEMISTRY(2013/10/13)

Generated On: 23 Jun 2014 15:19:04

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

Specimen English Comment 2

Result Supplementary Comment Code 1

Result Supplementary English Comment Code 1

Final 7.0 (Main CRF) (520)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Unscheduled Visit >> Unscheduled Laboratory Assessments

Form: Lab-BU BLOOD CHEMISTRY(2013/10/13)

Generated On: 23 Jun 2014 15:19:04

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004515382

Please document clinically relevant abnormalities in the AE form

Date (BU)

2013/10/13

Blood Sample time(BU)

1330

Urine Sample time(BU)

1335

Derived Form name

BLOOD
CHEMISTRY(2013/10/13)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Unscheduled Visit >> Unscheduled Laboratory Assessments

Form: Lab-BU BLOOD CHEMISTRY(2013/10/13)

Generated On: 23 Jun 2014 15:19:04

Test Category	BLOOD-CHEMISTRY
---------------	-----------------

Date of Sample Collection	2013-OCT-13
---------------------------	-------------

Time of Blood Sample Collection	13:30
---------------------------------	-------

Time of Urine Sample Collection	13:35
---------------------------------	-------

Test Name	POTASSIUM
-----------	-----------

Result	4.0
--------	-----

Text Result	
-------------	--

Unit	MEQ/L
------	-------

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

Upper limit	5.0
-------------	-----

Flag	
------	--

Clinically Significant?	No <input type="checkbox"/>
	Yes <input type="checkbox"/>

Comment	
---------	--

Result Category	N
-----------------	---

Final 7.0 (Main CRF) (520)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Unscheduled Visit >> Unscheduled Laboratory Assessments

Form: Lab-BU BLOOD CHEMISTRY(2013/10/13)

Generated On: 23 Jun 2014 15:19:04

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

Specimen English Comment 2

Result Supplementary Comment Code 1

Result Supplementary English Comment Code 1

Final 7.0 (Main CRF) (520)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Unscheduled Visit >> Unscheduled Laboratory Assessments

Form: Lab-BU BLOOD CHEMISTRY(2013/10/13)

Generated On: 23 Jun 2014 15:19:04

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004515382

Please document clinically relevant abnormalities in the AE form

Date (BU)

2013/10/13

Blood Sample time(BU)

1330

Urine Sample time(BU)

1335

Derived Form name

BLOOD
CHEMISTRY(2013/10/13)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Unscheduled Visit >> Unscheduled Laboratory Assessments

Form: Lab-BU HEMATOLOGY(2013/10/13)

Generated On: 23 Jun 2014 15:19:04

Test Category

HEMATOLOGY

Date of Sample Collection

~~2013-OCT-13~~

Please document clinically relevant abnormalities in the AE form

Date (BU)

2013/10/13

Derived Form name

HEMATOLOGY(2013/10/13)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Unscheduled Visit >> Unscheduled Laboratory Assessments

Form: Lab-BU HEMATOLOGY(2013/10/13)

Generated On: 23 Jun 2014 15:19:04

Test Category	HEMATOLOGY
---------------	------------

Date of Sample Collection	2013-OCT-13
---------------------------	-------------

Time of Blood Sample Collection	13:30
---------------------------------	-------

Time of Urine Sample Collection	13:35
---------------------------------	-------

Test Name	WBC COUNT
-----------	-----------

Result	9200
--------	------

Text Result	
-------------	--

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

Lower limit	3300
-------------	------

Upper limit	9000
-------------	------

Flag	H
------	---

Clinically Significant?	No <input checked="" type="radio"/>
-------------------------	-------------------------------------

Comment	
---------	--

Result Category	N
-----------------	---

Final 7.0 (Main CRF) (520)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Unscheduled Visit >> Unscheduled Laboratory Assessments

Form: Lab-BU HEMATOLOGY(2013/10/13)

Generated On: 23 Jun 2014 15:19:04

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

Specimen English Comment 2

Result Supplementary Comment Code 1

Result Supplementary English Comment Code 1

Final 7.0 (Main CRF) (520)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Unscheduled Visit >> Unscheduled Laboratory Assessments

Form: Lab-BU HEMATOLOGY(2013/10/13)

Generated On: 23 Jun 2014 15:19:04

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004515382

Please document clinically relevant abnormalities in the AE form

Date (BU)

2013/10/13

Blood Sample time(BU)

1330

Urine Sample time(BU)

1335

Derived Form name

HEMATOLOGY(2013/10/13)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Unscheduled Visit >> Unscheduled Laboratory Assessments

Form: Lab-BU HEMATOLOGY(2013/10/13)

Generated On: 23 Jun 2014 15:19:04

Test Category	HEMATOLOGY
---------------	------------

Date of Sample Collection	2013-OCT-13
---------------------------	-------------

Time of Blood Sample Collection	13:30
---------------------------------	-------

Time of Urine Sample Collection	13:35
---------------------------------	-------

Test Name	RBC COUNT
-----------	-----------

Result	410
--------	-----

Text Result	
-------------	--

Unit	10 ⁴ /UL
------	---------------------

Lower limit	380
-------------	-----

Upper limit	500
-------------	-----

Flag	
------	--

Clinically Significant?	No <input type="checkbox"/>
	Yes <input type="checkbox"/>

Comment	
---------	--

Result Category	N
-----------------	---

Final 7.0 (Main CRF) (520)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Unscheduled Visit >> Unscheduled Laboratory Assessments

Form: Lab-BU HEMATOLOGY(2013/10/13)

Generated On: 23 Jun 2014 15:19:04

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

Specimen English Comment 2

Result Supplementary Comment Code 1

Result Supplementary English Comment Code 1

Final 7.0 (Main CRF) (520)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Unscheduled Visit >> Unscheduled Laboratory Assessments

Form: Lab-BU HEMATOLOGY(2013/10/13)

Generated On: 23 Jun 2014 15:19:04

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004515382

Please document clinically relevant abnormalities in the AE form

Date (BU)

2013/10/13

Blood Sample time(BU)

1330

Urine Sample time(BU)

1335

Derived Form name

HEMATOLOGY(2013/10/13)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Unscheduled Visit >> Unscheduled Laboratory Assessments

Form: Lab-BU HEMATOLOGY(2013/10/13)

Generated On: 23 Jun 2014 15:19:04

Test Category	HEMATOLOGY
---------------	------------

Date of Sample Collection	2013-OCT-13
---------------------------	-------------

Time of Blood Sample Collection	13:30
---------------------------------	-------

Time of Urine Sample Collection	13:35
---------------------------------	-------

Test Name	HEMOGLOBIN
-----------	------------

Result	12.6
--------	------

Text Result	
-------------	--

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

Lower limit	11.5
-------------	------

Upper limit	15.0
-------------	------

Flag	
------	--

Clinically Significant?	No <input type="checkbox"/>
	Yes <input type="checkbox"/>

Comment	
---------	--

Result Category	N
-----------------	---

Final 7.0 (Main CRF) (520)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Unscheduled Visit >> Unscheduled Laboratory Assessments

Form: Lab-BU HEMATOLOGY(2013/10/13)

Generated On: 23 Jun 2014 15:19:04

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

Specimen English Comment 2

Result Supplementary Comment Code 1

Result Supplementary English Comment Code 1

Final 7.0 (Main CRF) (520)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Unscheduled Visit >> Unscheduled Laboratory Assessments

Form: Lab-BU HEMATOLOGY(2013/10/13)

Generated On: 23 Jun 2014 15:19:04

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004515382

Please document clinically relevant abnormalities in the AE form

Date (BU)

2013/10/13

Blood Sample time(BU)

1330

Urine Sample time(BU)

1335

Derived Form name

HEMATOLOGY(2013/10/13)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Unscheduled Visit >> Unscheduled Laboratory Assessments

Form: Lab-BU HEMATOLOGY(2013/10/13)

Generated On: 23 Jun 2014 15:19:04

Test Category	HEMATOLOGY
---------------	------------

Date of Sample Collection	2013-OCT-13
---------------------------	-------------

Time of Blood Sample Collection	13:30
---------------------------------	-------

Time of Urine Sample Collection	13:35
---------------------------------	-------

Test Name	HEMATOCRIT
-----------	------------

Result	36.6
--------	------

Text Result	
-------------	--

Unit	%
------	---

Lower limit	34.8
-------------	------

Upper limit	45.0
-------------	------

Flag	
------	--

Clinically Significant?	No <input type="checkbox"/>
	Yes <input type="checkbox"/>

Comment	
---------	--

Result Category	N
-----------------	---

Final 7.0 (Main CRF) (520)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Unscheduled Visit >> Unscheduled Laboratory Assessments

Form: Lab-BU HEMATOLOGY(2013/10/13)

Generated On: 23 Jun 2014 15:19:04

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

Specimen English Comment 2

Result Supplementary Comment Code 1

Result Supplementary English Comment Code 1

Final 7.0 (Main CRF) (520)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Unscheduled Visit >> Unscheduled Laboratory Assessments

Form: Lab-BU HEMATOLOGY(2013/10/13)

Generated On: 23 Jun 2014 15:19:04

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004515382

Please document clinically relevant abnormalities in the AE form

Date (BU)

2013/10/13

Blood Sample time(BU)

1330

Urine Sample time(BU)

1335

Derived Form name

HEMATOLOGY(2013/10/13)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Unscheduled Visit >> Unscheduled Laboratory Assessments

Form: Lab-BU HEMATOLOGY(2013/10/13)

Generated On: 23 Jun 2014 15:19:04

Test Category	HEMATOLOGY
Date of Sample Collection	2013-OCT-13
Time of Blood Sample Collection	13:30
Time of Urine Sample Collection	13:35
Test Name	MCV
Result	89
Text Result	
Unit	FL
Lower limit	85
Upper limit	102
Flag	
Clinically Significant?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Comment	
Result Category	N

Final 7.0 (Main CRF) (520)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Unscheduled Visit >> Unscheduled Laboratory Assessments

Form: Lab-BU HEMATOLOGY(2013/10/13)

Generated On: 23 Jun 2014 15:19:04

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

Specimen English Comment 2

Result Supplementary Comment Code 1

Result Supplementary English Comment Code 1

Final 7.0 (Main CRF) (520)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Unscheduled Visit >> Unscheduled Laboratory Assessments

Form: Lab-BU HEMATOLOGY(2013/10/13)

Generated On: 23 Jun 2014 15:19:04

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004515382

Please document clinically relevant abnormalities in the AE form

Date (BU)

2013/10/13

Blood Sample time(BU)

1330

Urine Sample time(BU)

1335

Derived Form name

HEMATOLOGY(2013/10/13)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Unscheduled Visit >> Unscheduled Laboratory Assessments

Form: Lab-BU HEMATOLOGY(2013/10/13)

Generated On: 23 Jun 2014 15:19:04

Test Category	HEMATOLOGY
Date of Sample Collection	2013-OCT-13
Time of Blood Sample Collection	13:30
Time of Urine Sample Collection	13:35
Test Name	MCH
Result	30.7
Text Result	
Unit	PG
Lower limit	28.0
Upper limit	34.0
Flag	
Clinically Significant?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Comment	
Result Category	N

Final 7.0 (Main CRF) (520)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Unscheduled Visit >> Unscheduled Laboratory Assessments

Form: Lab-BU HEMATOLOGY(2013/10/13)

Generated On: 23 Jun 2014 15:19:04

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

Specimen English Comment 2

Result Supplementary Comment Code 1

Result Supplementary English Comment Code 1

Final 7.0 (Main CRF) (520)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Unscheduled Visit >> Unscheduled Laboratory Assessments

Form: Lab-BU HEMATOLOGY(2013/10/13)

Generated On: 23 Jun 2014 15:19:04

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004515382

Please document clinically relevant abnormalities in the AE form

Date (BU)

2013/10/13

Blood Sample time(BU)

1330

Urine Sample time(BU)

1335

Derived Form name

HEMATOLOGY(2013/10/13)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Unscheduled Visit >> Unscheduled Laboratory Assessments

Form: Lab-BU HEMATOLOGY(2013/10/13)

Generated On: 23 Jun 2014 15:19:04

Test Category	HEMATOLOGY
---------------	------------

Date of Sample Collection	2013-OCT-13
---------------------------	-------------

Time of Blood Sample Collection	13:30
---------------------------------	-------

Time of Urine Sample Collection	13:35
---------------------------------	-------

Test Name	MCHC
-----------	------

Result	34.4
--------	------

Text Result	
-------------	--

Unit	%
------	---

Lower limit	30.2
-------------	------

Upper limit	35.1
-------------	------

Flag	
------	--

Clinically Significant?	No <input type="checkbox"/>
	Yes <input type="checkbox"/>

Comment	
---------	--

Result Category	N
-----------------	---

Final 7.0 (Main CRF) (520)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Unscheduled Visit >> Unscheduled Laboratory Assessments

Form: Lab-BU HEMATOLOGY(2013/10/13)

Generated On: 23 Jun 2014 15:19:04

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

Specimen English Comment 2

Result Supplementary Comment Code 1

Result Supplementary English Comment Code 1

Final 7.0 (Main CRF) (520)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Unscheduled Visit >> Unscheduled Laboratory Assessments

Form: Lab-BU HEMATOLOGY(2013/10/13)

Generated On: 23 Jun 2014 15:19:04

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004515382

Please document clinically relevant abnormalities in the AE form

Date (BU)

2013/10/13

Blood Sample time(BU)

1330

Urine Sample time(BU)

1335

Derived Form name

HEMATOLOGY(2013/10/13)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Unscheduled Visit >> Unscheduled Laboratory Assessments

Form: Lab-BU HEMATOLOGY(2013/10/13)

Generated On: 23 Jun 2014 15:19:04

Test Category	HEMATOLOGY
---------------	------------

Date of Sample Collection	2013-OCT-13
---------------------------	-------------

Time of Blood Sample Collection	13:30
---------------------------------	-------

Time of Urine Sample Collection	13:35
---------------------------------	-------

Test Name	PLATELET COUNT
-----------	----------------

Result	26.0
--------	------

Text Result	
-------------	--

Unit	10 ⁴ /UL
------	---------------------

Lower limit	14.0
-------------	------

Upper limit	34.0
-------------	------

Flag	
------	--

Clinically Significant?	No <input type="checkbox"/>
	Yes <input type="checkbox"/>

Comment	
---------	--

Result Category	N
-----------------	---

Final 7.0 (Main CRF) (520)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Unscheduled Visit >> Unscheduled Laboratory Assessments

Form: Lab-BU HEMATOLOGY(2013/10/13)

Generated On: 23 Jun 2014 15:19:04

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

Specimen English Comment 2

Result Supplementary Comment Code 1

Result Supplementary English Comment Code 1

Final 7.0 (Main CRF) (520)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Unscheduled Visit >> Unscheduled Laboratory Assessments

Form: Lab-BU HEMATOLOGY(2013/10/13)

Generated On: 23 Jun 2014 15:19:04

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004515382

Please document clinically relevant abnormalities in the AE form

Date (BU)

2013/10/13

Blood Sample time(BU)

1330

Urine Sample time(BU)

1335

Derived Form name

HEMATOLOGY(2013/10/13)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Unscheduled Visit >> Unscheduled Laboratory Assessments

Form: Lab-BU HEMATOLOGY(2013/10/13)

Generated On: 23 Jun 2014 15:19:04

Test Category	HEMATOLOGY
---------------	------------

Date of Sample Collection	2013-OCT-13
---------------------------	-------------

Time of Blood Sample Collection	13:30
---------------------------------	-------

Time of Urine Sample Collection	13:35
---------------------------------	-------

Test Name	DIFFERENTIAL WBC
-----------	------------------

Result	
--------	--

Text Result	
-------------	--

Unit	
------	--

Lower limit	
-------------	--

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

Flag	
------	--

Clinically Significant?	No <input type="checkbox"/>
	Yes <input type="checkbox"/>

Comment	
---------	--

Result Category	
-----------------	--

Final 7.0 (Main CRF) (520)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Unscheduled Visit >> Unscheduled Laboratory Assessments

Form: Lab-BU HEMATOLOGY(2013/10/13)

Generated On: 23 Jun 2014 15:19:04

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

Specimen English Comment 2

Result Supplementary Comment Code 1

Result Supplementary English Comment Code 1

Final 7.0 (Main CRF) (520)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Unscheduled Visit >> Unscheduled Laboratory Assessments

Form: Lab-BU HEMATOLOGY(2013/10/13)

Generated On: 23 Jun 2014 15:19:04

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004515382

Please document clinically relevant abnormalities in the AE form

Date (BU)

2013/10/13

Blood Sample time(BU)

1330

Urine Sample time(BU)

1335

Derived Form name

HEMATOLOGY(2013/10/13)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Unscheduled Visit >> Unscheduled Laboratory Assessments

Form: Lab-BU HEMATOLOGY(2013/10/13)

Generated On: 23 Jun 2014 15:19:04

Test Category	HEMATOLOGY
---------------	------------

Date of Sample Collection	2013-OCT-13
---------------------------	-------------

Time of Blood Sample Collection	13:30
---------------------------------	-------

Time of Urine Sample Collection	13:35
---------------------------------	-------

Test Name	NEUTROPHILS (REL)
-----------	-------------------

Result	75.0
--------	------

Text Result	
-------------	--

Unit	%
------	---

Lower limit	40.0
-------------	------

Upper limit	75.0
-------------	------

Flag	
------	--

Clinically Significant?	No <input type="checkbox"/>
	Yes <input type="checkbox"/>

Comment	
---------	--

Result Category	N
-----------------	---

Final 7.0 (Main CRF) (520)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Unscheduled Visit >> Unscheduled Laboratory Assessments

Form: Lab-BU HEMATOLOGY(2013/10/13)

Generated On: 23 Jun 2014 15:19:04

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

Specimen English Comment 2

Result Supplementary Comment Code 1

Result Supplementary English Comment Code 1

Final 7.0 (Main CRF) (520)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Unscheduled Visit >> Unscheduled Laboratory Assessments

Form: Lab-BU HEMATOLOGY(2013/10/13)

Generated On: 23 Jun 2014 15:19:04

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004515382

Please document clinically relevant abnormalities in the AE form

Date (BU)

2013/10/13

Blood Sample time(BU)

1330

Urine Sample time(BU)

1335

Derived Form name

HEMATOLOGY(2013/10/13)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Unscheduled Visit >> Unscheduled Laboratory Assessments

Form: Lab-BU HEMATOLOGY(2013/10/13)

Generated On: 23 Jun 2014 15:19:04

Test Category	HEMATOLOGY
---------------	------------

Date of Sample Collection	2013-OCT-13
---------------------------	-------------

Time of Blood Sample Collection	13:30
---------------------------------	-------

Time of Urine Sample Collection	13:35
---------------------------------	-------

Test Name	LYMPHOCYTES (REL)
-----------	-------------------

Result	19.0
--------	------

Text Result	
-------------	--

Unit	%
------	---

Lower limit	18.0
-------------	------

Upper limit	49.0
-------------	------

Flag	
------	--

Clinically Significant?	No <input type="checkbox"/>
	Yes <input type="checkbox"/>

Comment	
---------	--

Result Category	N
-----------------	---

Final 7.0 (Main CRF) (520)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Unscheduled Visit >> Unscheduled Laboratory Assessments

Form: Lab-BU HEMATOLOGY(2013/10/13)

Generated On: 23 Jun 2014 15:19:04

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

Specimen English Comment 2

Result Supplementary Comment Code 1

Result Supplementary English Comment Code 1

Final 7.0 (Main CRF) (520)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Unscheduled Visit >> Unscheduled Laboratory Assessments

Form: Lab-BU HEMATOLOGY(2013/10/13)

Generated On: 23 Jun 2014 15:19:04

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004515382

Please document clinically relevant abnormalities in the AE form

Date (BU)

2013/10/13

Blood Sample time(BU)

1330

Urine Sample time(BU)

1335

Derived Form name

HEMATOLOGY(2013/10/13)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Unscheduled Visit >> Unscheduled Laboratory Assessments

Form: Lab-BU HEMATOLOGY(2013/10/13)

Generated On: 23 Jun 2014 15:19:04

Test Category	HEMATOLOGY
---------------	------------

Date of Sample Collection	2013-OCT-13
---------------------------	-------------

Time of Blood Sample Collection	13:30
---------------------------------	-------

Time of Urine Sample Collection	13:35
---------------------------------	-------

Test Name	MONOCYTES (REL)
-----------	-----------------

Result	5.0
--------	-----

Text Result	
-------------	--

Unit	%
------	---

Lower limit	2.0
-------------	-----

Upper limit	10.0
-------------	------

Flag	
------	--

Clinically Significant?	No <input type="checkbox"/>
	Yes <input type="checkbox"/>

Comment	
---------	--

Result Category	N
-----------------	---

Final 7.0 (Main CRF) (520)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Unscheduled Visit >> Unscheduled Laboratory Assessments

Form: Lab-BU HEMATOLOGY(2013/10/13)

Generated On: 23 Jun 2014 15:19:04

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

Specimen English Comment 2

Result Supplementary Comment Code 1

Result Supplementary English Comment Code 1

Final 7.0 (Main CRF) (520)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Unscheduled Visit >> Unscheduled Laboratory Assessments

Form: Lab-BU HEMATOLOGY(2013/10/13)

Generated On: 23 Jun 2014 15:19:04

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004515382

Please document clinically relevant abnormalities in the AE form

Date (BU)

2013/10/13

Blood Sample time(BU)

1330

Urine Sample time(BU)

1335

Derived Form name

HEMATOLOGY(2013/10/13)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Unscheduled Visit >> Unscheduled Laboratory Assessments

Form: Lab-BU HEMATOLOGY(2013/10/13)

Generated On: 23 Jun 2014 15:19:04

Test Category	HEMATOLOGY
---------------	------------

Date of Sample Collection	2013-OCT-13
---------------------------	-------------

Time of Blood Sample Collection	13:30
---------------------------------	-------

Time of Urine Sample Collection	13:35
---------------------------------	-------

Test Name	EOSINOPHILS (REL)
-----------	-------------------

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

Text Result	
-------------	--

Unit	%
------	---

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

Upper limit	8.0
-------------	-----

Flag	
------	--

Clinically Significant?	No <input type="checkbox"/>
	Yes <input type="checkbox"/>

Comment	
---------	--

Result Category	N
-----------------	---

Final 7.0 (Main CRF) (520)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Unscheduled Visit >> Unscheduled Laboratory Assessments

Form: Lab-BU HEMATOLOGY(2013/10/13)

Generated On: 23 Jun 2014 15:19:04

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

Specimen English Comment 2

Result Supplementary Comment Code 1

Result Supplementary English Comment Code 1

Final 7.0 (Main CRF) (520)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Unscheduled Visit >> Unscheduled Laboratory Assessments

Form: Lab-BU HEMATOLOGY(2013/10/13)

Generated On: 23 Jun 2014 15:19:04

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004515382

Please document clinically relevant abnormalities in the AE form

Date (BU)

2013/10/13

Blood Sample time(BU)

1330

Urine Sample time(BU)

1335

Derived Form name

HEMATOLOGY(2013/10/13)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Unscheduled Visit >> Unscheduled Laboratory Assessments

Form: Lab-BU HEMATOLOGY(2013/10/13)

Generated On: 23 Jun 2014 15:19:04

Test Category	HEMATOLOGY
---------------	------------

Date of Sample Collection	2013-OCT-13
---------------------------	-------------

Time of Blood Sample Collection	13:30
---------------------------------	-------

Time of Urine Sample Collection	13:35
---------------------------------	-------

Test Name	BASOPHILS (REL)
-----------	-----------------

Result	1.0
--------	-----

Text Result	
-------------	--

Unit	%
------	---

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

Upper limit	2.0
-------------	-----

Flag	
------	--

Clinically Significant?	No <input type="checkbox"/>
	Yes <input type="checkbox"/>

Comment	
---------	--

Result Category	N
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Final 7.0 (Main CRF) (520)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Unscheduled Visit >> Unscheduled Laboratory Assessments

Form: Lab-BU HEMATOLOGY(2013/10/13)

Generated On: 23 Jun 2014 15:19:04

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

Specimen English Comment 2

Result Supplementary Comment Code 1

Result Supplementary English Comment Code 1

Final 7.0 (Main CRF) (520)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Unscheduled Visit >> Unscheduled Laboratory Assessments

Form: Lab-BU HEMATOLOGY(2013/10/13)

Generated On: 23 Jun 2014 15:19:04

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004515382

Please document clinically relevant abnormalities in the AE form

Date (BU)

2013/10/13

Blood Sample time(BU)

1330

Urine Sample time(BU)

1335

Derived Form name

HEMATOLOGY(2013/10/13)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Unscheduled Visit >> Unscheduled Laboratory Assessments

Form: Lab-BU HEMATOLOGY(2013/10/13)

Generated On: 23 Jun 2014 15:19:04

Test Category	HEMATOLOGY
---------------	------------

Date of Sample Collection	2013-OCT-13
---------------------------	-------------

Time of Blood Sample Collection	13:30
---------------------------------	-------

Time of Urine Sample Collection	13:35
---------------------------------	-------

Test Name	NEUTROPHILS (ABS)
-----------	-------------------

Result	6900
--------	------

Text Result	
-------------	--

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

Lower limit	
-------------	--

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

Flag	
------	--

Clinically Significant?	No <input type="checkbox"/>
	Yes <input type="checkbox"/>

Comment	
---------	--

Result Category	N
-----------------	---

Final 7.0 (Main CRF) (520)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Unscheduled Visit >> Unscheduled Laboratory Assessments

Form: Lab-BU HEMATOLOGY(2013/10/13)

Generated On: 23 Jun 2014 15:19:04

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

Specimen English Comment 2

Result Supplementary Comment Code 1

Result Supplementary English Comment Code 1

Final 7.0 (Main CRF) (520)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Unscheduled Visit >> Unscheduled Laboratory Assessments

Form: Lab-BU HEMATOLOGY(2013/10/13)

Generated On: 23 Jun 2014 15:19:04

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004515382

Please document clinically relevant abnormalities in the AE form

Date (BU)

2013/10/13

Blood Sample time(BU)

1330

Urine Sample time(BU)

1335

Derived Form name

HEMATOLOGY(2013/10/13)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Unscheduled Visit >> Unscheduled Laboratory Assessments

Form: Lab-BU HEMATOLOGY(2013/10/13)

Generated On: 23 Jun 2014 15:19:04

Test Category	HEMATOLOGY
---------------	------------

Date of Sample Collection	2013-OCT-13
---------------------------	-------------

Time of Blood Sample Collection	13:30
---------------------------------	-------

Time of Urine Sample Collection	13:35
---------------------------------	-------

Test Name	LYMPHOCYTES (ABS)
-----------	-------------------

Result	1700
--------	------

Text Result	
-------------	--

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

Lower limit	
-------------	--

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

Flag	
------	--

Clinically Significant?	No <input type="checkbox"/>
	Yes <input type="checkbox"/>

Comment	
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Result Category	N
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Final 7.0 (Main CRF) (520)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Unscheduled Visit >> Unscheduled Laboratory Assessments

Form: Lab-BU HEMATOLOGY(2013/10/13)

Generated On: 23 Jun 2014 15:19:04

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

Specimen English Comment 2

Result Supplementary Comment Code 1

Result Supplementary English Comment Code 1

Final 7.0 (Main CRF) (520)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Unscheduled Visit >> Unscheduled Laboratory Assessments

Form: Lab-BU HEMATOLOGY(2013/10/13)

Generated On: 23 Jun 2014 15:19:04

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004515382

Please document clinically relevant abnormalities in the AE form

Date (BU)

2013/10/13

Blood Sample time(BU)

1330

Urine Sample time(BU)

1335

Derived Form name

HEMATOLOGY(2013/10/13)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Unscheduled Visit >> Unscheduled Laboratory Assessments

Form: Lab-BU HEMATOLOGY(2013/10/13)

Generated On: 23 Jun 2014 15:19:04

Test Category	HEMATOLOGY
---------------	------------

Date of Sample Collection	2013-OCT-13
---------------------------	-------------

Time of Blood Sample Collection	13:30
---------------------------------	-------

Time of Urine Sample Collection	13:35
---------------------------------	-------

Test Name	MONOCYTES (ABS)
-----------	-----------------

Result	460
--------	-----

Text Result	
-------------	--

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

Lower limit	
-------------	--

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

Flag	
------	--

Clinically Significant?	No <input type="checkbox"/>
	Yes <input type="checkbox"/>

Comment	
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Result Category	N
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Final 7.0 (Main CRF) (520)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Unscheduled Visit >> Unscheduled Laboratory Assessments

Form: Lab-BU HEMATOLOGY(2013/10/13)

Generated On: 23 Jun 2014 15:19:04

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

Specimen English Comment 2

Result Supplementary Comment Code 1

Result Supplementary English Comment Code 1

Final 7.0 (Main CRF) (520)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Unscheduled Visit >> Unscheduled Laboratory Assessments

Form: Lab-BU HEMATOLOGY(2013/10/13)

Generated On: 23 Jun 2014 15:19:04

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004515382

Please document clinically relevant abnormalities in the AE form

Date (BU)

2013/10/13

Blood Sample time(BU)

1330

Urine Sample time(BU)

1335

Derived Form name

HEMATOLOGY(2013/10/13)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Unscheduled Visit >> Unscheduled Laboratory Assessments

Form: Lab-BU HEMATOLOGY(2013/10/13)

Generated On: 23 Jun 2014 15:19:04

Test Category	HEMATOLOGY
---------------	------------

Date of Sample Collection	2013-OCT-13
---------------------------	-------------

Time of Blood Sample Collection	13:30
---------------------------------	-------

Time of Urine Sample Collection	13:35
---------------------------------	-------

Test Name	EOSINOPHILS (ABS)
-----------	-------------------

Result	0
--------	---

Text Result	
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Unit	/UL
------	-----

Lower limit	
-------------	--

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

Flag	
------	--

Clinically Significant?	No <input type="checkbox"/>
	Yes <input type="checkbox"/>

Comment	
---------	--

Result Category	N
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Final 7.0 (Main CRF) (520)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Unscheduled Visit >> Unscheduled Laboratory Assessments

Form: Lab-BU HEMATOLOGY(2013/10/13)

Generated On: 23 Jun 2014 15:19:04

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

Specimen English Comment 2

Result Supplementary Comment Code 1

Result Supplementary English Comment Code 1

Final 7.0 (Main CRF) (520)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Unscheduled Visit >> Unscheduled Laboratory Assessments

Form: Lab-BU HEMATOLOGY(2013/10/13)

Generated On: 23 Jun 2014 15:19:04

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004515382

Please document clinically relevant abnormalities in the AE form

Date (BU)

2013/10/13

Blood Sample time(BU)

1330

Urine Sample time(BU)

1335

Derived Form name

HEMATOLOGY(2013/10/13)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Unscheduled Visit >> Unscheduled Laboratory Assessments

Form: Lab-BU HEMATOLOGY(2013/10/13)

Generated On: 23 Jun 2014 15:19:04

Test Category	HEMATOLOGY
---------------	------------

Date of Sample Collection	2013-OCT-13
---------------------------	-------------

Time of Blood Sample Collection	13:30
---------------------------------	-------

Time of Urine Sample Collection	13:35
---------------------------------	-------

Test Name	BASOPHILS (ABS)
-----------	-----------------

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

Text Result	
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Unit	/UL
------	-----

Lower limit	
-------------	--

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

Flag	
------	--

Clinically Significant?	No <input type="checkbox"/>
	Yes <input type="checkbox"/>

Comment	
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Result Category	N
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Final 7.0 (Main CRF) (520)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Unscheduled Visit >> Unscheduled Laboratory Assessments

Form: Lab-BU HEMATOLOGY(2013/10/13)

Generated On: 23 Jun 2014 15:19:04

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

Specimen English Comment 2

Result Supplementary Comment Code 1

Result Supplementary English Comment Code 1

Final 7.0 (Main CRF) (520)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Unscheduled Visit >> Unscheduled Laboratory Assessments

Form: Lab-BU HEMATOLOGY(2013/10/13)

Generated On: 23 Jun 2014 15:19:04

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004515382

Please document clinically relevant abnormalities in the AE form

Date (BU)

2013/10/13

Blood Sample time(BU)

1330

Urine Sample time(BU)

1335

Derived Form name

HEMATOLOGY(2013/10/13)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Unscheduled Visit >> Unscheduled Laboratory Assessments

Form: Lab-BU URINALYSIS(2013/10/13)

Generated On: 23 Jun 2014 15:19:04

Test Category

URINALYSIS

Date of Sample Collection

~~2013-OCT-13~~

Please document clinically relevant abnormalities in the AE form

Date (BU)

2013/10/13

Derived Form name

URINALYSIS(2013/10/13)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Unscheduled Visit >> Unscheduled Laboratory Assessments

Form: Lab-BU URINALYSIS(2013/10/13)

Generated On: 23 Jun 2014 15:19:04

Test Category	URINALYSIS
---------------	------------

Date of Sample Collection	2013-OCT-13
---------------------------	-------------

Time of Blood Sample Collection	13:30
---------------------------------	-------

Time of Urine Sample Collection	13:35
---------------------------------	-------

Test Name	SPECIFIC GRAVITY
-----------	------------------

Result	1.015
--------	-------

Text Result	
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Unit	
------	--

Lower limit	1.002
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Upper limit	1.030
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Flag	
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Clinically Significant?	No <input type="checkbox"/>
	Yes <input type="checkbox"/>

Comment	
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Result Category	N
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Final 7.0 (Main CRF) (520)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Unscheduled Visit >> Unscheduled Laboratory Assessments

Form: Lab-BU URINALYSIS(2013/10/13)

Generated On: 23 Jun 2014 15:19:04

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

Specimen English Comment 2

Result Supplementary Comment Code 1

Result Supplementary English Comment Code 1

Final 7.0 (Main CRF) (520)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Unscheduled Visit >> Unscheduled Laboratory Assessments

Form: Lab-BU URINALYSIS(2013/10/13)

Generated On: 23 Jun 2014 15:19:04

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004515382

Please document clinically relevant abnormalities in the AE form

Date (BU)

2013/10/13

Blood Sample time(BU)

1330

Urine Sample time(BU)

1335

Derived Form name

URINALYSIS(2013/10/13)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Unscheduled Visit >> Unscheduled Laboratory Assessments

Form: Lab-BU URINALYSIS(2013/10/13)

Generated On: 23 Jun 2014 15:19:04

Test Category	URINALYSIS
---------------	------------

Date of Sample Collection	2013-OCT-13
---------------------------	-------------

Time of Blood Sample Collection	13:30
---------------------------------	-------

Time of Urine Sample Collection	13:35
---------------------------------	-------

Test Name	PH
-----------	----

Result	7.0
--------	-----

Text Result	
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Unit	
------	--

Lower limit	5.0
-------------	-----

Upper limit	8.0
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Flag	
------	--

Clinically Significant?	No <input type="checkbox"/>
	Yes <input type="checkbox"/>

Comment	
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Result Category	N
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Final 7.0 (Main CRF) (520)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Unscheduled Visit >> Unscheduled Laboratory Assessments

Form: Lab-BU URINALYSIS(2013/10/13)

Generated On: 23 Jun 2014 15:19:04

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

Specimen English Comment 2

Result Supplementary Comment Code 1

Result Supplementary English Comment Code 1

Final 7.0 (Main CRF) (520)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Unscheduled Visit >> Unscheduled Laboratory Assessments

Form: Lab-BU URINALYSIS(2013/10/13)

Generated On: 23 Jun 2014 15:19:04

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004515382

Please document clinically relevant abnormalities in the AE form

Date (BU)

2013/10/13

Blood Sample time(BU)

1330

Urine Sample time(BU)

1335

Derived Form name

URINALYSIS(2013/10/13)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Unscheduled Visit >> Unscheduled Laboratory Assessments

Form: Lab-BU URINALYSIS(2013/10/13)

Generated On: 23 Jun 2014 15:19:04

Test Category	URINALYSIS
---------------	------------

Date of Sample Collection	2013-OCT-13
---------------------------	-------------

Time of Blood Sample Collection	13:30
---------------------------------	-------

Time of Urine Sample Collection	13:35
---------------------------------	-------

Test Name	GLUCOSE
-----------	---------

Result	
--------	--

Text Result	-
-------------	---

Unit	
------	--

Lower limit	
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Upper limit	-
-------------	---

Flag	
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Clinically Significant?	No <input type="checkbox"/>
	Yes <input type="checkbox"/>

Comment	
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Result Category	S
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Final 7.0 (Main CRF) (520)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Unscheduled Visit >> Unscheduled Laboratory Assessments

Form: Lab-BU URINALYSIS(2013/10/13)

Generated On: 23 Jun 2014 15:19:04

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

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

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

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

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

Specimen English Comment 2	
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Result Supplementary Comment Code 1	
-------------------------------------	--

Result Supplementary English Comment Code 1	
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Final 7.0 (Main CRF) (520)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Unscheduled Visit >> Unscheduled Laboratory Assessments

Form: Lab-BU URINALYSIS(2013/10/13)

Generated On: 23 Jun 2014 15:19:04

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004515382

Please document clinically relevant abnormalities in the AE form

Date (BU)

2013/10/13

Blood Sample time(BU)

1330

Urine Sample time(BU)

1335

Derived Form name

URINALYSIS(2013/10/13)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Unscheduled Visit >> Unscheduled Laboratory Assessments

Form: Lab-BU URINALYSIS(2013/10/13)

Generated On: 23 Jun 2014 15:19:04

Test Category	URINALYSIS
---------------	------------

Date of Sample Collection	2013-OCT-13
---------------------------	-------------

Time of Blood Sample Collection	13:30
---------------------------------	-------

Time of Urine Sample Collection	13:35
---------------------------------	-------

Test Name	PROTEIN
-----------	---------

Result	
--------	--

Text Result	-
-------------	---

Unit	
------	--

Lower limit	
-------------	--

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

Flag	
------	--

Clinically Significant?	No <input type="checkbox"/>
	Yes <input type="checkbox"/>

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

Final 7.0 (Main CRF) (520)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Unscheduled Visit >> Unscheduled Laboratory Assessments

Form: Lab-BU URINALYSIS(2013/10/13)

Generated On: 23 Jun 2014 15:19:04

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

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

Specimen English Comment 2	
----------------------------	--

Result Supplementary Comment Code 1	
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Result Supplementary English Comment Code 1	
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Final 7.0 (Main CRF) (520)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Unscheduled Visit >> Unscheduled Laboratory Assessments

Form: Lab-BU URINALYSIS(2013/10/13)

Generated On: 23 Jun 2014 15:19:04

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004515382

Please document clinically relevant abnormalities in the AE form

Date (BU)

2013/10/13

Blood Sample time(BU)

1330

Urine Sample time(BU)

1335

Derived Form name

URINALYSIS(2013/10/13)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Unscheduled Visit >> Unscheduled Laboratory Assessments

Form: Lab-BU URINALYSIS(2013/10/13)

Generated On: 23 Jun 2014 15:19:04

Test Category	URINALYSIS
---------------	------------

Date of Sample Collection	2013-OCT-13
---------------------------	-------------

Time of Blood Sample Collection	13:30
---------------------------------	-------

Time of Urine Sample Collection	13:35
---------------------------------	-------

Test Name	BILIRUBIN
-----------	-----------

Result	
--------	--

Text Result	-
-------------	---

Unit	
------	--

Lower limit	
-------------	--

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

Flag	
------	--

Clinically Significant?	No <input type="checkbox"/>
	Yes <input type="checkbox"/>

Comment	
---------	--

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

Final 7.0 (Main CRF) (520)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Unscheduled Visit >> Unscheduled Laboratory Assessments

Form: Lab-BU URINALYSIS(2013/10/13)

Generated On: 23 Jun 2014 15:19:04

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

Specimen English Comment 2	
----------------------------	--

Result Supplementary Comment Code 1	
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Result Supplementary English Comment Code 1	
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Final 7.0 (Main CRF) (520)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Unscheduled Visit >> Unscheduled Laboratory Assessments

Form: Lab-BU URINALYSIS(2013/10/13)

Generated On: 23 Jun 2014 15:19:04

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004515382

Please document clinically relevant abnormalities in the AE form

Date (BU)

2013/10/13

Blood Sample time(BU)

1330

Urine Sample time(BU)

1335

Derived Form name

URINALYSIS(2013/10/13)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Unscheduled Visit >> Unscheduled Laboratory Assessments

Form: Lab-BU URINALYSIS(2013/10/13)

Generated On: 23 Jun 2014 15:19:04

Test Category	URINALYSIS
---------------	------------

Date of Sample Collection	2013-OCT-13
---------------------------	-------------

Time of Blood Sample Collection	13:30
---------------------------------	-------

Time of Urine Sample Collection	13:35
---------------------------------	-------

Test Name	NITRITE
-----------	---------

Result	
--------	--

Text Result	-
-------------	---

Unit	
------	--

Lower limit	
-------------	--

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

Flag	
------	--

Clinically Significant?	No <input type="checkbox"/>
	Yes <input type="checkbox"/>

Comment	
---------	--

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

Final 7.0 (Main CRF) (520)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Unscheduled Visit >> Unscheduled Laboratory Assessments

Form: Lab-BU URINALYSIS(2013/10/13)

Generated On: 23 Jun 2014 15:19:04

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

Specimen English Comment 2	
----------------------------	--

Result Supplementary Comment Code 1	
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Result Supplementary English Comment Code 1	
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Final 7.0 (Main CRF) (520)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Unscheduled Visit >> Unscheduled Laboratory Assessments

Form: Lab-BU URINALYSIS(2013/10/13)

Generated On: 23 Jun 2014 15:19:04

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004515382

Please document clinically relevant abnormalities in the AE form

Date (BU)

2013/10/13

Blood Sample time(BU)

1330

Urine Sample time(BU)

1335

Derived Form name

URINALYSIS(2013/10/13)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Unscheduled Visit >> Unscheduled Laboratory Assessments

Form: Lab-BU URINALYSIS(2013/10/13)

Generated On: 23 Jun 2014 15:19:04

Test Category	URINALYSIS
---------------	------------

Date of Sample Collection	2013-OCT-13
---------------------------	-------------

Time of Blood Sample Collection	13:30
---------------------------------	-------

Time of Urine Sample Collection	13:35
---------------------------------	-------

Test Name	OCCULT BLOOD
-----------	--------------

Result	
--------	--

Text Result	2+
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Unit	
------	--

Lower limit	
-------------	--

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

Flag	!
------	---

Clinically Significant?	No <input checked="" type="radio"/>
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Comment	
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Result Category	S
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Final 7.0 (Main CRF) (520)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Unscheduled Visit >> Unscheduled Laboratory Assessments

Form: Lab-BU URINALYSIS(2013/10/13)

Generated On: 23 Jun 2014 15:19:04

Text Result Code	069
------------------	-----

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

Specimen English Comment 2	
----------------------------	--

Result Supplementary Comment Code 1	
-------------------------------------	--

Result Supplementary English Comment Code 1	
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Final 7.0 (Main CRF) (520)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Unscheduled Visit >> Unscheduled Laboratory Assessments

Form: Lab-BU URINALYSIS(2013/10/13)

Generated On: 23 Jun 2014 15:19:04

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

000004515382

Please document clinically relevant abnormalities in the AE form

Date (BU)

2013/10/13

Blood Sample time(BU)

1330

Urine Sample time(BU)

1335

Derived Form name

URINALYSIS(2013/10/13)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Unscheduled Visit (1)

Form: Vital Signs <Unscheduled />

Generated On: 23 Jun 2014 15:19:04

Date of assessment DD/MMM/YYYY	Time of assessment hour:min 24-hour clock	Has the subject smoked within 15 minutes prior to assessm ent	Pulse rate beats per minute	Respiratory rate breaths per minute	Blood Pressure (systolic) mmHg	Blood Pressure (diastolic) mmHg	Vital Signs Position of Subject
13-OCT-2013	13:15	No	58	16	109	64	Supine

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Unscheduled Visit (1)

Form: Spirometry <Unscheduled /> (1)

Generated On: 23 Jun 2014 15:19:04

Category	Without short-acting bronchodilator <input checked="" type="radio"/>
----------	---

Date of assessment: DD/MMM/YYYY	13-OCT-2013
------------------------------------	-------------

Time of assessment: hour:min 24-hour clock	13:40
---	-------

Name of bronchodilator	
------------------------	--

Dose	
------	--

Predicted FVC value L	3.06
--------------------------	------

Best measured FVC value L	4.16
------------------------------	------

Percent of predicted FVC value %	135
-------------------------------------	-----

Best measured FEV1 value L	2.93
-------------------------------	------

Predicted FEV1 value L	2.57
---------------------------	------

Percent of predicted FEV1 value %	114
--------------------------------------	-----

Final 7.0 (Main CRF) (520)

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107
Folder: Unscheduled Visit (1)
Form: Spirometry <Unscheduled /> (1)
Generated On: 23 Jun 2014 15:19:04

Interpretation

Normal ☒

If Abnormal, Clinical Significance

Not clinically significant ☐

Clinically significant ☐

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

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Unscheduled Visit (1)

Form: Physical Examination <Unscheduled /> 13 October 2013

Generated On: 23 Jun 2014 15:19:04

Date of assessment

~~13-OCT-2013~~
~~DD/MMM/YYYY~~

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Unscheduled Visit (1)

Form: Physical Examination <Unscheduled /> 13 October 2013

Generated On: 23 Jun 2014 15:19:04

Date of assessment

~~13 OCT 2013~~
DD/MMM/YYYY

System

General Appearance ☒

Outcome

Normal ☒

Abnormal, please specify: _____

Clinically significant

No ☐

Yes ☐

Not Done

False

Not Done; please specify the reason: _____

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Unscheduled Visit (1)

Form: Physical Examination <Unscheduled /> 13 October 2013

Generated On: 23 Jun 2014 15:19:04

Date of assessment

~~13 OCT 2013~~
DD/MMM/YYYY

System

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

Outcome

Normal ☒

Abnormal, please specify: _____

Clinically significant

No ☐
Yes ☐

Not Done

False

Not Done; please specify the reason: _____

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Unscheduled Visit (1)

Form: Physical Examination <Unscheduled /> 13 October 2013

Generated On: 23 Jun 2014 15:19:04

Date of assessment

~~13 OCT 2013~~
DD/MMM/YYYY

System

Thyroid Gland ☒

Outcome

Normal ☒

Abnormal, please specify: _____

Clinically significant

No ☐

Yes ☐

Not Done

False

Not Done; please specify the reason: _____

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Unscheduled Visit (1)

Form: Physical Examination <Unscheduled /> 13 October 2013

Generated On: 23 Jun 2014 15:19:04

Date of assessment

~~13 OCT 2013~~
DD/MMM/YYYY

System

Heart ☒

Outcome

Normal ☒

Abnormal, please specify: _____

Clinically significant

No ☐

Yes ☐

Not Done

False

Not Done; please specify the reason: _____

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Unscheduled Visit (1)

Form: Physical Examination <Unscheduled /> 13 October 2013

Generated On: 23 Jun 2014 15:19:04

Date of assessment

~~13 OCT 2013~~
DD/MMM/YYYY

System

Chest ☒

Outcome

Normal ☒

Abnormal, please specify: _____

Clinically significant

No ☐

Yes ☐

Not Done

False

Not Done; please specify the reason: _____

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Unscheduled Visit (1)

Form: Physical Examination <Unscheduled /> 13 October 2013

Generated On: 23 Jun 2014 15:19:04

Date of assessment

~~13 OCT 2013~~
DD/MMM/YYYY

System

Lungs ☒

Outcome

Normal ☒

Abnormal, please specify: _____

Clinically significant

No ☐

Yes ☐

Not Done

False

Not Done; please specify the reason: _____

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Unscheduled Visit (1)

Form: Physical Examination <Unscheduled /> 13 October 2013

Generated On: 23 Jun 2014 15:19:04

Date of assessment

~~13 OCT 2013~~
DD/MMM/YYYY

System

Gastrointestinal ☒

Outcome

Normal ☒

Abnormal, please specify: _____

Clinically significant

No ☐

Yes ☐

Not Done

False

Not Done; please specify the reason: _____

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Unscheduled Visit (1)

Form: Physical Examination <Unscheduled /> 13 October 2013

Generated On: 23 Jun 2014 15:19:04

Date of assessment

~~13 OCT 2013~~
DD/MMM/YYYY

System

Cardiovascular System ☒

Outcome

Normal ☒

Abnormal, please specify: _____

Clinically significant

No ☐

Yes ☐

Not Done

False

Not Done; please specify the reason: _____

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Unscheduled Visit (1)

Form: Physical Examination <Unscheduled /> 13 October 2013

Generated On: 23 Jun 2014 15:19:04

Date of assessment	13 OCT 2013 DD/MMM/YYYY
--------------------	---------------------------------------

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

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

Abnormal, please specify:	<hr/>
---------------------------	-------

Clinically significant	No <input type="radio"/>
	Yes <input type="radio"/>

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

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

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Unscheduled Visit (1)

Form: Physical Examination <Unscheduled /> 13 October 2013

Generated On: 23 Jun 2014 15:19:04

Date of assessment

~~13 OCT 2013~~
DD/MMM/YYYY

System

Skin ☒

Outcome

Normal ☒

Abnormal, please specify: _____

Clinically significant

No ☐

Yes ☐

Not Done

False

Not Done; please specify the reason: _____

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Unscheduled Visit (1)

Form: Physical Examination <Unscheduled /> 13 October 2013

Generated On: 23 Jun 2014 15:19:04

Date of assessment

~~13 OCT 2013~~
DD/MMM/YYYY

System

Back ☒

Outcome

Normal ☒

Abnormal, please specify: _____

Clinically significant

No ☐

Yes ☐

Not Done

False

Not Done; please specify the reason: _____

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Unscheduled Visit (1)

Form: Physical Examination <Unscheduled /> 13 October 2013

Generated On: 23 Jun 2014 15:19:04

Date of assessment

~~13 OCT 2013~~
DD/MMM/YYYY

System

Musculoskeletal ☒

Outcome

Normal ☒

Abnormal, please specify: _____

Clinically significant

No ☐

Yes ☐

Not Done

False

Not Done; please specify the reason: _____

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Unscheduled Visit (1)

Form: Physical Examination <Unscheduled /> 13 October 2013

Generated On: 23 Jun 2014 15:19:04

Date of assessment

~~13 OCT 2013~~
DD/MMM/YYYY

System

Abdomen ☒

Outcome

Normal ☒

Abnormal, please specify: _____

Clinically significant

No ☐

Yes ☐

Not Done

False

Not Done; please specify the reason: _____

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Unscheduled Visit (1)

Form: Physical Examination <Unscheduled /> 13 October 2013

Generated On: 23 Jun 2014 15:19:04

Date of assessment

~~13 OCT 2013~~
DD/MMM/YYYY

System

Dentition ☒

Outcome

Normal ☒

Abnormal, please specify: _____

Clinically significant

No ☐

Yes ☐

Not Done

False

Not Done; please specify the reason: _____

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Unscheduled Visit (1)

Form: Physical Examination <Unscheduled /> 13 October 2013

Generated On: 23 Jun 2014 15:19:04

Date of assessment

~~13 OCT 2013~~
DD/MMM/YYYY

System

Other ☒

Other, Specify

Outcome

Normal ☐
Abnormal ☐

Abnormal, please specify:

Clinically significant

No ☐
Yes ☐

Not Done

True

Not Done; please specify the reason:

NA

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Unscheduled Visit (1)

Form: Physical Examination <Unscheduled /> 13 October 2013

Generated On: 23 Jun 2014 15:19:04

Date of assessment

~~13 OCT 2013~~
DD/MMM/YYYY

System

Other ☒

Other, Specify

Outcome

Normal ☐
Abnormal ☐

Abnormal, please specify:

Clinically significant

No ☐
Yes ☐

Not Done

True

Not Done; please specify the reason:

NA

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Unscheduled Visit (1)

Form: Physical Examination <Unscheduled /> 13 October 2013

Generated On: 23 Jun 2014 15:19:04

Date of assessment

~~13 OCT 2013~~
DD/MMM/YYYY

System

Other ☒

Other, Specify

Outcome

Normal ☐
Abnormal ☐

Abnormal, please specify:

Clinically significant

No ☐
Yes ☐

Not Done

True

Not Done; please specify the reason:

NA

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Unscheduled Visit (1)

Form: Physical Examination <Unscheduled /> 13 October 2013

Generated On: 23 Jun 2014 15:19:04

Date of assessment

~~13 OCT 2013~~
DD/MMM/YYYY

System

Other ☒

Other, Specify

Outcome

Normal ☐
Abnormal ☐

Abnormal, please specify:

Clinically significant

No ☐
Yes ☐

Not Done

True

Not Done; please specify the reason:

NA

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Unscheduled Visit (1)

Form: Physical Examination <Unscheduled /> 13 October 2013

Generated On: 23 Jun 2014 15:19:04

Date of assessment

~~13 OCT 2013~~
DD/MMM/YYYY

System

Other ☒

Other, Specify

Outcome

Normal ☐
Abnormal ☐

Abnormal, please specify:

Clinically significant

No ☐
Yes ☐

Not Done

True

Not Done; please specify the reason:

NA

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Folder: Unscheduled Visit (1)

Form: Weight <Unscheduled />

Generated On: 23 Jun 2014 15:19:04

Date of assessment DD/MMM/YYYY	Time of assessment hour:min 24-hour clock	Weight
13 -OCT-2013	13 :20	56.6 kg

ZRHM-PK-05-JP: Ageo Medical Clinic: 0107

Form: End of study

Data signed: (FumimasaNobuoka) 14 May 2014 06:16:57

Generated On: 23 Jun 2014 15:19:04

End of study date

20 OCT 2013
DD/MMM/YYYY

Has the subject completed the study ?

No ☒

If No, please specify the reason:

Withdrawal by Subject ☒

Details:
