



PMI RESEARCH & DEVELOPMENT

Study ZRHM-REXA-07-JP

Clinical Study Report Appendix 16.1.9

Bioanalytical Documentation

| | |
|---|--|
| Study Title: | A randomized, controlled, open-label, 3-arm parallel group, multi-center study to demonstrate reductions in exposure to selected smoke constituents in healthy smokers switching to the Tobacco Heating System 2.2 Menthol (THS 2.2 Menthol) or observing smoking abstinence, compared to continuing to use menthol conventional cigarettes, for 5 days in confinement and prolonged by 85 days in an ambulatory setting |
| Study Number: | ZRHM-REXA-07-JP |
| Product Name: | Tobacco Heating System 2.2 Menthol (THS 2.2 Menthol) |
| Study Initiated (first subject screened): | 01 August 2013 |
| Study Completed (last subject last visit): | 03 July 2014 |
| Principal Investigator and Affiliation: | Mamoru Oki, MD, PhD, Seishukai Clinic 3-18-5, Matsugaya, Taitou-ku Tokyo 111-0036, Japan Professor Masahiro Endo, MD, Tokyo Heart Center, 5-4-12, Kita-Shinagawa, Shinagawa-ku, Tokyo 141-0001, Japan |
| Sponsor: | Philip Morris Products S.A. PMI Research & Development Quai Jeanrenaud 5 2000 Neuchâtel, Switzerland |
| Sponsor Signatories: | Christelle Haziza, PhD, Manager P1 Clinical Program, Clinical Scientist Nicola Lama, PhD, Biostatistician Andrea Donelli, Clinical Scientist Patrick Picavet, MD, Medical Safety Officer |
| Version: | 1.0 |
| Date: | 24 February 2016 |

This study was conducted in accordance with Good Clinical Practice.

Confidentiality Statement

This document is confidential. Disclosure of any of its contents to third parties is not permitted except by the prior written consent of Philip Morris Products S.A.



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16.1.9 Bioanalytical Documentation

16.1.9.1 Standardization and Laboratory Reference Ranges



| Categories | Analyte Name | Testing Lab | Apply to Panic Alert * | Analyte Code | Method | Reference Ranges | Unit |
|--------------------|-------------------|-------------|------------------------|--------------|---|------------------------------|-----------------------------|
| Hematology | Hematocrit | 02 | | 83094 | Electrical Resistivity Method | M:39.7~62.4 F:34.8~45.0 | % |
| | Hemoglobin | 02 | * | 83093 | Spectrophotometry (Based on Cyanmethemoglobin Method) | M:13.5~17.5 F:11.5~15.0 | g/dL |
| | MCH | 02 | | 83096 | Calculation | 28.0~34.0 | pg |
| | MCHC | 02 | | 83097 | Calculation | 30.2~35.1 | g/dL |
| | MCV | 02 | | 83095 | Calculation | 85~105 | fL |
| | Platelet count | 02 | * | 83098 | Electrical Resistivity Method | 14.0~34.0 | $\times 10^9 / \mu\text{L}$ |
| | RBC count | 02 | | 83092 | Electrical Resistivity Method | M:430~670 F:380~500 | $\times 10^9 / \mu\text{L}$ |
| | WBC count | 02 | * | 83091 | Electrical Resistivity Method | 5500~8000 | $/ \mu\text{L}$ |
| | Differential WBC | 02 | * | 83200 | | | |
| | Neutrophils (rel) | 02 | | 83201 | | 40.0~75.0 | % |
| | Lymphocytes (rel) | 02 | | 83204 | VCS Flow Cytometry | 18.0~49.0 | % |
| | Monocytes (rel) | 02 | | 83205 | Blood Film Slides:Visual Inspection | 2.0~10.0 | % |
| | Eosinophils (rel) | 02 | | 83206 | | 0.0~8.0 | % |
| | Basophils (rel) | 02 | | 83207 | | 0.0~2.0 | % |
| | Neutrophils (abs) | 02 | | 83251 | Calculation | — | $/ \mu\text{L}$ |
| | Lymphocytes (abs) | 02 | | 83254 | Calculation | — | $/ \mu\text{L}$ |
| | Monocytes (abs) | 02 | | 83255 | Calculation | — | $/ \mu\text{L}$ |
| Clinical Chemistry | Eosinophils (abs) | 02 | | 83256 | Calculation | — | $/ \mu\text{L}$ |
| | Basophils (abs) | 02 | | 83257 | Calculation | — | $/ \mu\text{L}$ |
| | Albumin | 02 | | 81002 | BCG Method | 3.8~5.3 | g/dL |
| | Total protein | 02 | * | 81001 | Biuret Method | 6.7~8.3 | g/dL |
| | AP | 02 | * | 81034 | JSCC Standardization Method | 100~225 | U/L |
| | ALT | 02 | * | 81022 | UV Method(JSCC Standardization Method) | 5~45 | U/L |
| | AST | 02 | * | 81021 | UV Method(JSCC Standardization Method) | 10~40 | U/L |
| | BUN | 02 | * | 81044 | Urease-UV Method(Enzymatic Assay) | 8~25 | mg/dL |
| | Creatinine | 02 | * | 81041 | Enzymatic Assay | M:0.61~1.04 F:0.47~0.79 | mg/dL |
| | GCT | 02 | | 81025 | JSCC Standardization Method | M: ≤ 80 F: ≤ 90 | U/L |
| | Fasting Glucose | 02 | | 81031 | HK/G6PDH Method | 70~109 | mg/dL |
| | LDH | 02 | * | 81023 | UV Method(JSCC Standardization Method) | 120~240 | U/L |
| | Potassium | 02 | * | 81077 | ISE Method | 3.5~5.0 | mEq/L |
| | Sodium | 02 | * | 81076 | ISE Method | 137~147 | mEq/L |
| Urine analysis | Total bilirubin | 02 | * | 81011 | Bilirubinase | 0.2~1.4 | mg/dL |
| | Direct bilirubin | 02 | * | 81013 | Bilirubinase | 0.0~0.5 | mg/dL |
| | Total cholesterol | 02 | | 81053 | Cholesterol Oxidase Method | 120~219 | mg/dL |
| | Triglycerides | 02 | | 81052 | Free Cholesterol Elimination Enzymatic Assay | 30~149 | mg/dL |
| | pH | 02 | | 84002 | Test Strip Method | 5.0~8.0 | — |
| | Bilirubin | 02 | | 84006 | Test Strip Method | (-) | — |
| | Glucose | 02 | | 84003 | Test Strip Method | (-) | — |
| | Nitrite | 02 | | 84007 | Test Strip Method | (-) | — |
| | Ocalt blood | 02 | | 84006 | Test Strip Method | (-) | — |
| | Protein | 02 | | 84004 | Test Strip Method | (-) | — |
| Biomarker | Specific gravity | 02 | | 84001 | Refractive Index method | 1.006~1.030 | — |
| | COHb | 01 | | 00379 | Spectrophotometric Method | — | % |
| Serology | HIV antigen | 01 | | 30006 | | — | — |
| | Pos/Neg | 01 | | 30007 | CLIA | (-) | — |
| | Concentration | 01 | | 30008 | | < 0.06 | RU/mL |
| | Confirmatory test | 01 | | 30005 | CLIA | — | — |
| | Hepatitis C virus | 01 | | 2491 | | — | — |
| | Pos/Neg | 01 | | 2492 | CLIA | Negative | — |
| | S/CO value | 01 | | 2493 | | 1.00 | S/CO |
| | HIV antigen | 01 | | 4455 | CLIA | Negative (-) | — |
| HIV antigen | HIV antigen | 01 | | 4699 | Western Blot Method | Negative (-) | — |

01:Main Reference Laboratory (COHb test will be performed at Tokios Chemical Industries Co.Ltd.,)

02:Clinical Testing Center



16.1.9.2 Laboratory Certificates



B4: Withheld one page, vendor information



B4: Withheld one page, vendor information



Advancing Excellence

Accredited
Laboratory



The College of American Pathologists

certifies that the laboratory named below

Celerion Inc
Clinical Laboratory
Lincoln, Nebraska
Gregory R. Post, PhD

LAP Number: 2542201
AU-ID: 1188932
CLIA Number: 28D0652627

*has met all applicable standards for accreditation and
is hereby accredited by the College of American Pathologists'
Laboratory Accreditation Program. Reinspection should occur prior
to November 4, 2014 to maintain accreditation.*

Accreditation does not automatically survive a change in director, ownership,
or location and assumes that all interim requirements are met.

Fronde R Rudy

Chair, Commission on Laboratory Accreditation

Stanley A. Rothman

President, College of American Pathologists



The Swiss GLP Monitoring Authorities



Schweizerische Eidgenossenschaft
Confédération suisse
Confederazione Svizzera
Confederaziun svizra

Swiss Confederation

Federal Department of Home Affairs DHA
Federal Office of Public Health FOPH

Federal Department of the Environment,
Transport, Energy and Communications DETEC
Federal Office for the Environment FOEN

**SWISSmedic**

Swiss Agency for Therapeutic Products

Statement of GLP Compliance

According to Article 14 paragraph 3 Ordinance on Good Laboratory Practice [OGLP, SR 813.112.1]

The notification authority for chemicals confirms that the following test facility was inspected with respect to the compliance with the Swiss Ordinance on Good Laboratory Practice, adopted on 18th May 2005 [OGLP, SR 813.112.1]. This Ordinance is based on the OECD Principles of Good Laboratory Practice, as revised in 1997 and adopted on 26th November 1997 by decision of the OECD Council [C(97)186/Final].

Unequivocal name and address
of the test facility:

Area of expertise according to
article 3 paragraph 1 letter d OGLP:

Celerion Switzerland Ltd
Allmendstrasse 32
8320 Fehraltorf, Switzerland

8. analytic and clinical chemistry testing.

Inspection authority: Swiss Agency for Therapeutic Products (Swissmedic)

Date of inspection: 13 to 14 May 2013

Date of decision: 27 June 2013

Based on the above mentioned decision it can be confirmed that the above mentioned test facility is able to conduct studies according to the aforementioned area of expertise in compliance with the principles of GLP. The above mentioned test facility is listed in the register and GLP list according to the Article 14 OGLP and is inspected on a regular basis according to Article 6 paragraph 2 OGLP.

Swiss Federal Office of Public Health
Consumer protection directorate
Notification authority for chemicals
CH-3003 Bern



Bern, 14 August 2013, The Head, Dr. Dag Kappel.

The notification authority for chemicals is the coordination and decision authority for the good laboratory practice (GLP) for the FOEN, the FOPH and Swissmedic.

Swiss Federal Office of Public Health, Consumer protection directorate, Notification authority for chemicals, CH-3003 Bern.

www.rlp.admin.ch Phone: +41 (0)31 322 73 05, Fax: +41 (0)31 323 54 86



LAP #: 2542201
AU ID: 1188932
November 7, 2014

Gregory R. Post, PhD
Celerion Inc
Clinical Laboratory
PO Box 80837
Lincoln, NE 68501-0837

Dear Dr. Post:

Celerion Inc Clinical Laboratory, in Lincoln, Nebraska under the direction of Gregory R. Post, PhD is accredited by the College of American Pathologists' CAP Accreditation Program.

Accreditation is a continual process. A laboratory remains accredited until otherwise notified. Accreditation does not necessarily terminate on the expiration date of the Accreditation certificate.

If you have any questions regarding this matter, please call 800-323-4040.

Sincerely,

CAP Accreditation Programs
College of American Pathologists

STILACCRED



| Run: 11-Jun-13 11:58 PM | | Reference Range Report (Clinical) Reported in: Conventional Units Group: FIBRINOGEN | | | | Page: 1 Project: 800225 | |
|--------------------------------------|--------|---|---------|---------------|-------------|----------------------------|----------------|
| Test | Ethnic | Sex | Age | Range | Alert Flags | | Effective Date |
| Fibrinogen (DOT285) | | Both | 0Y-150Y | 200-400 mg/dL | L <200 | H >400 | 01-Mar-2007 |
| Key: Alert flags: H High L Low | | | | | | | |

(b) (4)

| Run: 11-Jun-13 11:58 PM | | Reference Range Report (Clinical) Reported in: Conventional Units Group: HOMOCYSTEINE | | | | Page: 1 Project: 800225 | |
|--------------------------------------|--------|---|--------------------|--|-------------|----------------------------|----------------|
| Test | Ethnic | Sex | Age | Range | Alert Flags | | Effective Date |
| HCY (ONT145) | | Both | 0Y-10Y 18Y-150Y | µmol/L No Ref Rng 3.70-13.90 µmol/L | L <3.70 | H >13.90 | 21-Apr-2009 |
| Key: Alert flags: H High L Low | | | | | | | |

(b) (4)



| Run: 11-Jun-13 11:58 PM | | Reference Range Report (Clinical) Reported in: Conventional Units Group: HBA10 | | | | Page: 1 Project: 800225 |
|----------------------------|--------|--|---------|-------|----------------|----------------------------|
| Test | Ethnic | Sex | Age | Range | Alert Flag | Effective Date |
| Hgb A1c (HMT370) | | Both | 01-150Y | <6.5% | H >6.495855 | 17-Nov-2010 |
| Key: Alert flag: H High | | | | | | |

(b) (4)

| Run: 11-Jun-13 11:58 PM | | Reference Range Report (Clinical) Reported in: Conventional Units Group: WBC MORPHOLOGY | | | | Page: 1 Project: 800225 |
|---|--------|---|---------|-----------|-------------|----------------------------|
| Test | Ethnic | Sex | Age | Range | Alert Flag | Effective Date |
| Blasts (WTS4) | | Both | 01-150Y | 0 x10E3/L | HT >0.00 | 19-Jul-1994 |
| Key: Alert flag: HT High - Telephone | | | | | | |

(b) (4)



| Run: 11-Jun-13 11:58 PM | | Reference Range Report (Clinical) Reported in: Conventional Units Group: WBC MORPHOLOGY | | | | Page: 1 Project: 800225 |
|--|--------|---|---------|------------|-------------|----------------------------|
| Test | Ethnic | Sex | Age | Range | Alert Flags | Effective Date |
| ProTymph (HIT81) | | Both | 0Y-150Y | D x10E3/uL | H >0 | 19-Jul-1994 |
| Ly,Immunob (HIT83) | | Both | 0Y-150Y | D x10E3/uL | H >0 | 19-Jul-1994 |
| Ly,Plasency (HIT84) | | Both | 0Y-150Y | D x10E3/uL | H >0 | 19-Jul-1994 |
| Lymph,Recd (HIT85) | | Both | 0Y-150Y | D x10E3/uL | H >0 | 19-Jul-1994 |
| Lymphoblas (HIT86) | | Both | 0Y-150Y | D x10E3/uL | HT >0.00 | 19-Jul-1994 |
| Atyp Lymph (HIT89) | | Both | 0Y-150Y | D x10E3/uL | H >0 | 19-Jul-1994 |
| Lymphoma C (HIT88) | | Both | 0Y-150Y | D x10E3/uL | HT >0.00 | 19-Jul-1994 |
| Serum, Abs (HIT72) | | Both | 0Y-150Y | D x10E3/uL | H >0 | 19-Jul-1994 |
| Key: Alert flags: H - High HT - High - Telephone | | | | | | |
| (b) (4) | | | | | | |

| Run: 11-Jun-13 11:58 PM | | Reference Range Report (Clinical) Reported in: Conventional Units Group: WBC MORPHOLOGY | | | | Page: 1 Project: 800225 |
|--|--------|---|---------|------------|-------------|----------------------------|
| Test | Ethnic | Sex | Age | Range | Alert Flags | Effective Date |
| Proendocyt (HIT97) | | Both | 0Y-150Y | D x10E3/uL | H >0 | 19-Jul-1994 |
| Hemo,Isast (HIT99) | | Both | 0Y-150Y | D x10E3/uL | H >0 | 19-Jul-1994 |
| Hemoblast (HIT88) | | Both | 0Y-150Y | D x10E3/uL | HT >0.00 | 19-Jul-1994 |
| Key: Alert flags: H - High HT - High - Telephone | | | | | | |
| (b) (4) | | | | | | |



| | | | | | | | | |
|-----------------------------|--------|------|---------|---|-------|-------|----------------------------|--|
| Run: 11-Jun-13 11:58 PM | | | | Reference Range Report (Clinical) Reported in: Conventional Units Group: WBC MORPHOLOGY | | | Page: 1 Project: 800225 | |
| Test | Ethnic | Sex | Age | Range | Alert | Flags | Effective Date | |
| Eos, Leuk (HMT75) | | Both | 0Y-150Y | 0 x 10E3/uL | H | >0 | 31-Mar-2011 | |
| Key: Alert flags: H High | | | | | | | | |

(b) (4)

| Run: 11-Jun-13 11:58 PM | | Reference Range Report (Clinical) Reported in: Conventional Units Group: WBC MORPHOLOGY | | | | Page: 1 Project: 800225 |
|--|--------|---|---------|------------|-------------|----------------------------|
| Test | Ethnic | Sex | Age | Range | Alert Flags | Effective Date |
| Baso,Least (HMT74) | | Both | 0Y-150Y | 0 x10E3/uL | H >0 | 19-Jul-1994 |
| Platelet Pct (HMT77) | | Both | 0Y-150Y | 0 x10E3/uL | H >0 | 19-Jul-1994 |
| Platelet Inc (HMT78) | | Both | 0Y-150Y | 0 x10E3/uL | H >0 | 19-Jul-1994 |
| Platelet Cal (HMT79) | | Both | 0Y-150Y | 0 x10E3/uL | H >0 | 19-Jul-1994 |
| Maligr,WBC (HMT76) | | Both | 0Y-150Y | 0 x10E3/uL | H >0 | 19-Jul-1994 |
| Hairy Cell (HMT92) | | Both | 0Y-150Y | 0 x10E3/uL | HT >0.00 | 19-Jul-1994 |
| NRBC (HMT95) | | Both | 0Y-150Y | DE | H >0.00 | 19-Jul-1994 |
| CBC Count: (HMT98) | | Both | 0Y-150Y | | | 09-Dec-1992 |
| Key: Alert flags: H High HT High - Telephone | | | | | | |

(b) (4)



| Run: 11-Jun-13 11:58 PM | | Reference Range Report (Clinical) Reported in: Conventional Units Group: HEPATOLOGY/DIFFERENTIAL PANEL | | | | Page: 1 Project: BD0225 | | | | | | | | |
|----------------------------|------------------|--|------------|------------------|-------------|----------------------------|------------------|----------------|-------|-------------|-------------|----|----|-------------|
| Test | Ethnic | Sex | Age | Range | Alert Flags | | | Effective Date | | | | | | |
| HGB (HPT40) | Female | | 0Y-10 | 13.5-22.0 g/dL | LP | LT | L | H | HT | HP | 23-Oct-2000 | | | |
| | | | 10-60 | 13.5-22.0 g/dL | <8.0 | <10.0 | <13.5 | >22.0 | | | | | | |
| | | | 60-150 | 12.5-21.0 g/dL | <8.0 | <10.0 | <12.5 | >21.0 | | | | | | |
| | | | 150-310 | 10.0-20.0 g/dL | <8.0 | | <10.0 | >20.0 | | | | | | |
| | | | 310-4M | 10.0-14.0 g/dL | <8.0 | | <10.0 | >14.0 | | | | | | |
| | | | 4Y-7M | 10.0-14.0 g/dL | <8.0 | | <10.0 | >14.0 | | | | | | |
| | | | 7M-2Y | 10.5-13.5 g/dL | <8.0 | | <10.5 | >13.5 | | | | | | |
| | | | 2Y-3Y | 11.0-14.0 g/dL | <8.0 | | <11.0 | >14.0 | | | | | | |
| | | | 3Y-6Y | 11.0-14.7 g/dL | <8.0 | | <11.0 | >14.7 | | | | | | |
| | | | 6Y-12Y | 11.2-15.5 g/dL | <8.0 | <8.0 | <11.2 | >15.5 | >19.0 | >21.0 | | | | |
| | | | 12Y-59Y | 11.5-15.8 g/dL | <8.0 | <10.0 | <11.5 | >15.8 | >19.0 | >23.0 | | | | |
| | | | 59Y-150Y | 11.5-15.0 g/dL | <8.0 | <10.0 | <11.5 | >15.0 | >19.0 | >23.0 | | | | |
| | Male | | 0Y-10 | 13.5-22.0 g/dL | <8.0 | <10.0 | <13.5 | >22.0 | | | | | | |
| | | | 10-60 | 13.5-22.0 g/dL | <8.0 | <10.0 | <13.5 | >22.0 | | | | | | |
| | | | 60-150 | 12.5-21.0 g/dL | <8.0 | <10.0 | <12.5 | >21.0 | | | | | | |
| | | | 150-310 | 10.0-20.0 g/dL | <8.0 | | <10.0 | >20.0 | | | | | | |
| | | | 310-4M | 10.0-14.0 g/dL | <8.0 | | <10.0 | >14.0 | | | | | | |
| | | | 4Y-7M | 10.0-14.0 g/dL | <8.0 | | <10.0 | >14.0 | | | | | | |
| | | | 7M-2Y | 10.5-13.5 g/dL | <8.0 | | <10.5 | >13.5 | | | | | | |
| | | | 2Y-3Y | 11.0-14.0 g/dL | <8.0 | | <11.0 | >14.0 | | | | | | |
| | | | 3Y-6Y | 11.0-14.5 g/dL | <8.0 | | <11.0 | >14.5 | | | | | | |
| | | | 6Y-12Y | 11.2-15.5 g/dL | <8.0 | <8.0 | <11.2 | >15.5 | >19.0 | >21.0 | | | | |
| | | | 12Y-59Y | 12.2-16.1 g/dL | <8.0 | <10.0 | <12.2 | >16.1 | >19.0 | >23.0 | | | | |
| | | | 59Y-150Y | 12.5-17.0 g/dL | <8.0 | <10.0 | <12.5 | >17.0 | >19.0 | >23.0 | | | | |
| HCT (HPT2) | Female | | 0Y-10 | 42-60 % | LP | LT | L | H | HT | HP | 16-Oct-2000 | | | |
| | | | 10-60 | 42-60 % | <24 | <30 | <42 | >60 | >65 | | | | | |
| | | | 60-150 | 39-60 % | <24 | <30 | <39 | >60 | >65 | | | | | |
| | | | 150-310 | 31-55 % | <20 | <24 | <31 | >55 | >60 | | | | | |
| | | | 310-4M | 28-42 % | <20 | <24 | <28 | >42 | >55 | | | | | |
| | | | 4Y-7M | 28-42 % | <20 | <24 | <28 | >42 | >55 | | | | | |
| | | | 7M-2Y | 33-40 % | <20 | <24 | <33 | >40 | >50 | | | | | |
| | | | 2Y-3Y | 33-42 % | <24 | <28 | <33 | >42 | >50 | | | | | |
| | | | 3Y-6Y | 35-44 % | <26 | <35 | <42 | >44 | >50 | | | | | |
| | | | 6Y-12Y | 34-44 % | <28 | <34 | <34 | >44 | >50 | | | | | |
| | | | 12Y-59Y | 34-48 % | <28 | <34 | <34 | >48 | >50 | | | | | |
| | | | 59Y-150Y | 34-48 % | <28 | <34 | <34 | >48 | >50 | | | | | |
| | Male | | 0Y-10 | 42-60 % | <24 | <30 | <42 | >60 | >65 | | | | | |
| | | | 10-60 | 42-60 % | <24 | <30 | <42 | >60 | >65 | | | | | |
| | | | 60-150 | 39-60 % | <24 | <30 | <39 | >60 | >65 | | | | | |
| | | | 150-310 | 31-55 % | <20 | <24 | <31 | >55 | >60 | | | | | |
| | | | 310-4M | 28-42 % | <20 | <24 | <28 | >42 | >55 | | | | | |
| | | | 4Y-7M | 28-42 % | <20 | <24 | <28 | >42 | >55 | | | | | |
| | | | RBC (HPT3) | Female | | 0Y-10 | 3.9-5.5 x10E6/uL | LP | LT | L | H | HT | HP | 02-Jun-1999 |
| | | | | | | 10-60 | 3.9-5.5 x10E6/uL | <3.0 | <3.9 | >5.5 | | | | |
| | | | | | | 60-150 | 3.6-5.0 x10E6/uL | <3.0 | <3.6 | >5.0 | | | | |
| | | | | | | 150-310 | 3.0-5.5 x10E6/uL | <2.0 | <3.0 | >5.5 | | | | |
| | | | | | | 310-4M | 2.7-5.5 x10E6/uL | <2.0 | <2.7 | >5.5 | | | | |
| | | | | | | 4Y-7M | 3.1-4.5 x10E6/uL | <2.0 | <3.1 | >4.5 | | | | |
| 7M-2Y | 3.7-5.0 x10E6/uL | <2.0 | | | | <3.7 | >5.0 | | | | | | | |
| 2Y-3Y | 4.4-5.0 x10E6/uL | <3.0 | | | | <4.4 | >5.0 | | | | | | | |
| 3Y-6Y | 4.1-5.2 x10E6/uL | <3.0 | | | | <4.1 | >5.2 | | | | | | | |
| 6Y-12Y | 3.7-5.0 x10E6/uL | <3.0 | | | | <3.7 | >5.0 | | | | | | | |
| 12Y-59Y | 4.1-5.5 x10E6/uL | <3.0 | | | | <4.1 | >5.5 | | | | | | | |
| 59Y-150Y | 3.9-5.5 x10E6/uL | <3.0 | | | | <3.9 | >5.5 | | | | | | | |
| Male | | 0Y-10 | | 3.9-5.5 x10E6/uL | <3.0 | <3.9 | >5.5 | | | | | | | |
| | | 10-60 | | 3.9-5.5 x10E6/uL | <3.0 | <3.9 | >5.5 | | | | | | | |
| | | 60-150 | | 3.6-5.0 x10E6/uL | <3.0 | <3.6 | >5.0 | | | | | | | |
| | | 150-310 | | 3.0-5.5 x10E6/uL | <2.0 | <3.0 | >5.5 | | | | | | | |
| | | 310-4M | | 2.7-5.5 x10E6/uL | <2.0 | <2.7 | >5.5 | | | | | | | |
| | | 4Y-7M | | 3.1-4.5 x10E6/uL | <2.0 | <3.1 | >4.5 | | | | | | | |
| | | 7M-2Y | | 3.7-5.0 x10E6/uL | <2.0 | <3.7 | >5.0 | | | | | | | |
| | | 2Y-3Y | | 4.1-5.2 x10E6/uL | <3.0 | <4.1 | >5.2 | | | | | | | |
| | | 3Y-6Y | | 4.1-5.2 x10E6/uL | <3.0 | <4.1 | >5.2 | | | | | | | |
| | | 6Y-12Y | | 3.7-5.0 x10E6/uL | <3.0 | <3.7 | >5.0 | | | | | | | |
| | | 12Y-59Y | | 4.5-5.4 x10E6/uL | <3.0 | <4.5 | >5.4 | | | | | | | |
| | | 59Y-150Y | | 4.0-5.5 x10E6/uL | <3.0 | <4.0 | >5.5 | | | | | | | |
| MCV (HPT4) | Female | | 0Y-10 | 88-120 fL | L | H | | | | 20-Oct-1999 | | | | |
| | | | 10-60 | 88-120 fL | <88 | >120 | | | | | | | | |
| | | | 60-150 | 86-120 fL | <86 | >120 | | | | | | | | |
| | | | 150-310 | 85-110 fL | <85 | >110 | | | | | | | | |
| | | | 310-4M | 77-110 fL | <77 | >110 | | | | | | | | |
| | | | 4Y-7M | 74-108 fL | <74 | >108 | | | | | | | | |
| | | | 7M-2Y | 70-90 fL | <70 | >90 | | | | | | | | |
| | | | 2Y-3Y | 75-88 fL | <75 | >88 | | | | | | | | |
| | | | 3Y-6Y | 74-89 fL | <74 | >89 | | | | | | | | |
| | | | 6Y-12Y | 74-89 fL | <74 | >89 | | | | | | | | |
| | | | 12Y-59Y | 74-89 fL | <74 | >89 | | | | | | | | |
| | | | 59Y-150Y | 74-89 fL | <74 | >89 | | | | | | | | |



| Run: 11-Jun-13 11:58 PM | | Reference Range Report (Clinical) Reported in: Conventional Units Group: HEMATOLOGY/DIFFERENTIAL PANEL | | | | Page: 5 Project: B00225 | | | | |
|--------------------------------|--------------------|--|----------|---------------------|-------------|----------------------------|--------|----------------|--------|-------------|
| Test | Ethnic | Sex | Age | Range | Alert Flags | | | Effective Date | | |
| Continued Neutrophil (Ht9) | | Male | 7N-2Y | 1.50-9.40 x10E3/uL | LP | LT | L | H | HT | 26-Dec-2000 |
| | | | 2Y-3Y | 1.35-8.85 x10E3/uL | <0.50 | <1.00 | <1.50 | >9.40 | >12.00 | |
| | | | 3N-6Y | 1.35-8.85 x10E3/uL | <0.50 | <1.00 | <1.35 | >8.85 | >11.00 | |
| | | | 6Y-12Y | 1.35-8.15 x10E3/uL | <0.50 | <1.00 | <1.35 | >8.15 | >11.00 | |
| | | | 12Y-18Y | 1.65-8.15 x10E3/uL | <0.50 | <1.00 | <1.65 | >8.15 | >11.00 | |
| | | | 18Y-60Y | 1.96-7.23 x10E3/uL | <0.50 | <1.00 | <1.96 | >7.23 | >11.00 | |
| | | | 60Y-150Y | 1.96-7.23 x10E3/uL | <0.50 | <1.00 | <1.96 | >7.23 | >11.00 | |
| | | | | | LT | L | H | HT | | |
| | | | | | | | | | | |
| | | | | | | | | | | |
| Lymphocyte (Ht9) | Female | | 00-10 | 2.00-11.00 x10E3/uL | <0.50 | <2.00 | >11.00 | >25.00 | | 26-Dec-2000 |
| | | | 10-60 | 2.00-17.00 x10E3/uL | <0.50 | <2.00 | >17.00 | >25.00 | | |
| | | | 60-100 | 2.00-17.00 x10E3/uL | <0.50 | <2.00 | >17.00 | >25.00 | | |
| | | | 150-310 | 2.50-17.00 x10E3/uL | <0.50 | <2.50 | >17.00 | >25.00 | | |
| | | | 310-4M | 2.50-16.00 x10E3/uL | <0.50 | <2.50 | >16.00 | >25.00 | | |
| | | | 4M-7M | 3.00-16.00 x10E3/uL | <0.50 | <3.00 | >16.00 | >25.00 | | |
| | | | 7N-2Y | 1.70-6.70 x10E3/uL | <1.30 | <1.70 | >6.70 | >10.00 | | |
| | | | 2Y-3Y | 1.50-10.00 x10E3/uL | <1.00 | <1.50 | >10.00 | >25.00 | | |
| | | | 3N-6Y | 1.50-8.00 x10E3/uL | <1.00 | <1.50 | >8.00 | >25.00 | | |
| | | | 6Y-12Y | 1.15-6.65 x10E3/uL | | <1.15 | >6.65 | | | |
| | Male | | 12Y-18Y | 0.95-5.25 x10E3/uL | | <0.95 | >5.25 | | | |
| | | | 18Y-60Y | 0.91-4.20 x10E3/uL | | <0.91 | >4.20 | | | |
| | | | 60Y-150Y | 0.80-3.00 x10E3/uL | | <0.80 | >3.00 | | | |
| | | | 00-10 | 2.00-11.00 x10E3/uL | <0.50 | <2.00 | >11.00 | >25.00 | | |
| | | | 10-60 | 2.00-17.00 x10E3/uL | <0.50 | <2.00 | >17.00 | >25.00 | | |
| | | | 60-100 | 2.00-17.00 x10E3/uL | <0.50 | <2.00 | >17.00 | >25.00 | | |
| | | | 150-310 | 2.50-17.00 x10E3/uL | <0.50 | <2.50 | >17.00 | >25.00 | | |
| | | | 310-4M | 2.50-16.00 x10E3/uL | <0.50 | <2.50 | >16.00 | >25.00 | | |
| | | | 4M-7M | 3.00-16.00 x10E3/uL | <0.50 | <3.00 | >16.00 | >25.00 | | |
| | | | 7N-2Y | 1.70-6.50 x10E3/uL | <1.30 | <1.70 | >6.50 | >10.00 | | |
| | | | 2Y-3Y | 1.50-10.00 x10E3/uL | <1.00 | <1.50 | >10.00 | >25.00 | | |
| | | | 3N-6Y | 1.50-8.00 x10E3/uL | <1.00 | <1.50 | >8.00 | >25.00 | | |
| | | | 6Y-12Y | 1.15-6.65 x10E3/uL | | <1.15 | >6.65 | | | |
| | | | 12Y-18Y | 0.95-5.25 x10E3/uL | | <0.95 | >5.25 | | | |
| | | | 18Y-60Y | 0.91-4.20 x10E3/uL | | <0.91 | >4.20 | | | |
| | | | 60Y-150Y | 0.80-3.00 x10E3/uL | | <0.80 | >3.00 | | | |
| Monocytes (Ht10) | Female | | 00-40 | 0.20-2.20 x10E3/uL | <0.20 | >2.20 | | | | 13-Jul-2008 |
| | | | 40-80 | 0.20-2.20 x10E3/uL | <0.20 | >2.20 | | | | |
| | | | 80-150 | 0.10-2.80 x10E3/uL | <0.10 | >2.80 | | | | |
| | | | 150-310 | 0.20-5.00 x10E3/uL | <0.20 | >5.00 | | | | |
| | | | 310-610 | 0.20-2.10 x10E3/uL | <0.20 | >2.10 | | | | |
| | | | 610-1800 | 0.60-1.80 x10E3/uL | <0.60 | >1.80 | | | | |
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| | | | | | | | | | | |
| Continued Monocytes (Ht10) | | Female | 1800-2Y | 0.30-1.50 x10E3/uL | <0.30 | >1.50 | | | | 13-Jul-2008 |
| | | | 2Y-6Y | 0.50-1.10 x10E3/uL | <0.50 | >1.10 | | | | |
| | | | 6Y-12Y | 0.40-0.90 x10E3/uL | <0.40 | >0.90 | | | | |
| | | | 12Y-18Y | 0.40-0.90 x10E3/uL | <0.40 | >0.90 | | | | |
| | | | 18Y-150Y | 0.12-0.92 x10E3/uL | <0.12 | >0.92 | | | | |
| | Male | | 00-40 | 0.20-1.80 x10E3/uL | <0.20 | >1.80 | | | | |
| | | | 40-80 | 0.20-2.20 x10E3/uL | <0.20 | >2.20 | | | | |
| | | | 80-150 | 0.30-3.00 x10E3/uL | <0.30 | >3.00 | | | | |
| | | | 150-310 | 0.20-5.00 x10E3/uL | <0.20 | >5.00 | | | | |
| | | | 310-610 | 0.30-2.70 x10E3/uL | <0.30 | >2.70 | | | | |
| | | | 610-1800 | 0.50-1.90 x10E3/uL | <0.50 | >1.90 | | | | |
| | | | 1800-2Y | 0.40-2.00 x10E3/uL | <0.40 | >2.00 | | | | |
| | | | 2Y-6Y | 0.30-1.20 x10E3/uL | <0.30 | >1.20 | | | | |
| | | | 6Y-12Y | 0.30-0.90 x10E3/uL | <0.30 | >0.90 | | | | |
| | | | 12Y-18Y | 0.40-1.30 x10E3/uL | <0.40 | >1.30 | | | | |
| 18Y-150Y | 0.12-0.92 x10E3/uL | <0.12 | >0.92 | | | | | | | |
| Continued Eosinophil (Ht11) | | Female | 00-40 | 0.00-0.20 x10E3/uL | >0.20 | | | | | 13-Jul-2008 |
| | | | 40-60 | 0.00-0.50 x10E3/uL | >0.50 | | | | | |
| | | | 60-150 | 0.00-0.50 x10E3/uL | >0.50 | | | | | |
| | | | 150-310 | 0.00-0.50 x10E3/uL | >0.50 | | | | | |
| | | | 310-610 | 0.00-0.20 x10E3/uL | >0.20 | | | | | |
| | | | 610-1800 | 0.00-0.10 x10E3/uL | >0.10 | | | | | |
| | | | 1800-2Y | 0.00-0.20 x10E3/uL | >0.20 | | | | | |
| | | | 2Y-6Y | 0.00-0.20 x10E3/uL | >0.20 | | | | | |
| | | | 6Y-12Y | 0.00-0.20 x10E3/uL | >0.20 | | | | | |
| | | | 12Y-18Y | 0.00-0.20 x10E3/uL | >0.20 | | | | | |
| Continued Basophils (Ht12) | | Male | 18Y-150Y | 0.00-0.57 x10E3/uL | >0.57 | | | | | 29-Sep-1993 |
| | | | 00-40 | 0.00-0.30 x10E3/uL | >0.30 | | | | | |
| | | | 40-60 | 0.00-0.80 x10E3/uL | >0.80 | | | | | |
| | | | 60-150 | 0.00-0.60 x10E3/uL | >0.60 | | | | | |
| | | | 150-310 | 0.00-0.90 x10E3/uL | >0.90 | | | | | |
| | | | 310-610 | 0.00-0.50 x10E3/uL | >0.50 | | | | | |
| | | | 610-1800 | 0.00-0.40 x10E3/uL | >0.40 | | | | | |
| | | | 1800-2Y | 0.00-0.30 x10E3/uL | >0.30 | | | | | |
| | | | 2Y-6Y | 0.00-0.20 x10E3/uL | >0.20 | | | | | |
| | | | 6Y-12Y | 0.00-0.20 x10E3/uL | >0.20 | | | | | |
| 12Y-18Y | 0.00-0.30 x10E3/uL | >0.30 | | | | | | | | |
| 18Y-150Y | 0.00-0.57 x10E3/uL | >0.57 | | | | | | | | |
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| Run: 11-Jun-13 11:58 PM | | Reference Range Report (Clinical) Reported in: Conventional Units Group: HEPATOLOGY&DIFFERENTIAL PANEL | | | | Page: 7 Project: B00225 | | | | |
|----------------------------|--------|--|----------|------------------|-------------|----------------------------|------|------|----------------|-------------|
| Test | Ethnic | Sex | Age | Range | Alert Flags | | | | Effective Date | |
| Platelets (HIT13) | | Female | 00-10 | 200-400 x10E3/uL | LP | LT | L | H | HT | 26-Apr-1995 |
| | | | 10-80 | 200-400 x10E3/uL | <100 | <110 | <200 | >400 | >600 | |
| | | | 80-150 | 200-400 x10E3/uL | <100 | <110 | <200 | >400 | >600 | |
| | | | 150-210 | 200-400 x10E3/uL | <100 | <110 | <200 | >400 | >600 | |
| | | | 31D-4M | 200-400 x10E3/uL | <100 | <110 | <200 | >400 | >600 | |
| | | | 4M-7M | 200-400 x10E3/uL | <100 | <110 | <200 | >400 | >600 | |
| | | | 7M-2Y | 200-400 x10E3/uL | <100 | <110 | <200 | >400 | >600 | |
| | | | 2Y-3Y | 252-582 x10E3/uL | <100 | <110 | <252 | >582 | >600 | |
| | | | 3Y-6Y | 240-570 x10E3/uL | <100 | <110 | <240 | >570 | >600 | |
| | | | 6Y-12Y | 130-394 x10E3/uL | <100 | <110 | <130 | >394 | >600 | |
| | | | 12Y-60Y | 140-400 x10E3/uL | <100 | <110 | <140 | >400 | >600 | |
| | | | 60Y-150Y | 130-394 x10E3/uL | <100 | <110 | <130 | >394 | >600 | |
| | | Male | 00-10 | 200-400 x10E3/uL | <100 | <110 | <200 | >400 | >600 | |
| | | | 10-80 | 200-400 x10E3/uL | <100 | <110 | <200 | >400 | >600 | |
| | | | 80-150 | 200-400 x10E3/uL | <100 | <110 | <200 | >400 | >600 | |
| | | | 150-210 | 200-400 x10E3/uL | <100 | <110 | <200 | >400 | >600 | |
| | | | 31D-4M | 200-400 x10E3/uL | <100 | <110 | <200 | >400 | >600 | |
| | | | 4M-7M | 200-400 x10E3/uL | <100 | <110 | <200 | >400 | >600 | |
| | | | 7M-2Y | 200-400 x10E3/uL | <100 | <110 | <200 | >400 | >600 | |
| | | | 2Y-3Y | 252-582 x10E3/uL | <100 | <110 | <252 | >582 | >600 | |
| | | | 3Y-6Y | 240-570 x10E3/uL | <100 | <110 | <240 | >570 | >600 | |
| | | | 6Y-12Y | 130-394 x10E3/uL | <100 | <110 | <130 | >394 | >600 | |
| | | | 12Y-60Y | 140-400 x10E3/uL | <100 | <110 | <140 | >400 | >600 | |
| | | | 60Y-150Y | 130-394 x10E3/uL | <100 | <110 | <130 | >394 | >600 | |

Key:
Alert flags: H High
HP High Panic
HT High - Telephone
L Low
LP Low Panic
LT Low - Telephone

(b) (4)

| Run: 11-Jun-13 11:58 PM | | Reference Range Report (Clinical) Reported in: Conventional Units Group: CBC MORPHOLOGY | | | | Page: 1 Project: B00225 | | | | |
|--|--------|---|---------|--------------------|-------------|----------------------------|--|--|----------------|--|
| Test | Ethnic | Sex | Age | Range | Alert Flags | | | | Effective Date | |
| Bands (HIT20) | | Both | 0Y-150Y | 0.00-0.27 x10E3/uL | H | | | | 29-Sep-1993 | |
| | | | | | >0.27 | | | | | |
| Neutrophils (HIT93) | | Both | 0Y-150Y | 0 x10E3/uL | H | | | | 19-Jul-1994 | |
| | | | | | >0 | | | | | |
| Myelocytes (HIT92) | | Both | 0Y-150Y | 0 x10E3/uL | H | | | | 19-Jul-1994 | |
| | | | | | >0 | | | | | |
| Procytology (HIT91) | | Both | 0Y-150Y | 0 x10E3/uL | H | | | | 19-Jul-1994 | |
| | | | | | >0 | | | | | |
| Myeloblast (HIT90) | | Both | 0Y-150Y | 0 x10E3/uL | HT | | | | 19-Jul-1994 | |
| | | | | | >0.00 | | | | | |
| Key: Alert flags: H High HT High - Telephone | | | | | | | | | | |
| (b) (4) | | | | | | | | | | |

5_TMEA_Printed: 20140922

Page: 121



| Run: 11-Jun-13 11:58 PM | | Reference Range Report (Clinical) Reported in: Conventional Units Group: SICM-1 | | | | Page: 1 Project: 800225 | | | |
|----------------------------|--------|---|--------------------|--------------------------------------|-------------|----------------------------|----------------|--|--|
| Test | Ethnic | Sex | Age | Range | Alert Flags | | Effective Date | | |
| sICM-1 (IMT1789) | | Both | 0Y-10Y 10Y-150Y | ng/mL No Ref Prg 66.8-320.0 ng/mL | L | H | 04-May-2013 | | |
| | | | | | <66.8 | >320.0 | | | |
| Key: | | | | | | | | | |
| Alert flags: H High | | | | | | | | | |
| L Low | | | | | | | | | |
| (b) (4) | | | | | | | | | |

| Run: 11-Jun-13 11:58 PM | | Reference Range Report (Clinical) Reported in: Conventional Units Group: TRIGLYCERIDES | | | | Page: 1 Project: 800225 | | | |
|----------------------------|--------|--|--|--|-------------|----------------------------|----------------|--|--|
| Test | Ethnic | Sex | Age | Range | Alert Flags | | Effective Date | | |
| Triglyceride (RET19) | | Female | 0Y-10Y 10Y-15Y 15Y-20Y 20Y-30Y 30Y-40Y 40Y-50Y 50Y-60Y 60Y-150Y | 26-110 mg/dL 27-131 mg/dL 28-124 mg/dL 26-144 mg/dL 26-176 mg/dL 45-214 mg/dL 52-262 mg/dL 56-240 mg/dL | L | H | 06-May-1997 | | |
| | | | | | <26 | >110 | | | |
| | | | | | <27 | >131 | | | |
| | | | | | <28 | >124 | | | |
| | | | | | <26 | >144 | | | |
| | | | | | <26 | >176 | | | |
| | | | | | <45 | >214 | | | |
| | | | | | <52 | >262 | | | |
| | | | | | <56 | >240 | | | |
| | | Male | 0Y-10Y 10Y-15Y 15Y-20Y 20Y-30Y 30Y-40Y 40Y-50Y 50Y-60Y 60Y-150Y | 30-100 mg/dL 22-125 mg/dL 27-148 mg/dL 44-249 mg/dL 50-321 mg/dL 55-327 mg/dL 58-320 mg/dL 59-260 mg/dL | L | H | | | |
| | | | | | <30 | >100 | | | |
| | | | | | <22 | >125 | | | |
| | | | | | <27 | >148 | | | |
| | | | | | <44 | >249 | | | |
| | | | | | <50 | >321 | | | |
| | | | | | <55 | >327 | | | |
| | | | | | <58 | >320 | | | |
| | | | | | <59 | >260 | | | |
| Key: | | | | | | | | | |
| Alert flags: H High | | | | | | | | | |
| L Low | | | | | | | | | |
| (b) (4) | | | | | | | | | |



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|--|--------|--|---------|--------------|-------------|----------------------------|----------|-----------|------------|----------------|-------------|
| Run: 11-Jun-13 11:58 PM | | Reference Range Report (Clinical) Reported in: Conventional Units Group: FASTING GLUCOSE | | | | Page: 1 Project: 800225 | | | | | |
| Test | Ethnic | Sex | Age | Range | Alert Flags | | | | | Effective Date | |
| Fast. Glu. (RCT142) | | Both | 0Y-150Y | 70-100 mg/dL | LP <40 | LT <45 | L <70 | H >100 | HT >300 | HP >400 | 10-Aug-2009 |
| Key: Alert flags: H High HP High Panic HT High - Telephone L Low LP Low Panic LT Low - Telephone | | | | | | | | | | | |
| (b) (4) | | | | | | | | | | | |

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|--------------------------------------|--------|--|----------|---------------|-------------|----------------------------|--|--|--|----------------|-------------|
| Run: 11-Jun-13 11:58 PM | | Reference Range Report (Clinical) Reported in: Conventional Units Group: TOTAL CHOLESTEROL | | | | Page: 1 Project: 800225 | | | | | |
| Test | Ethnic | Sex | Age | Range | Alert Flags | | | | | Effective Date | |
| Cholest (RCT20) | | Female | 0Y-1Y | 80-260 mg/dL | L <80 | H >260 | | | | | 06-May-1997 |
| | | | 1Y-6Y | 87-213 mg/dL | <87 | >213 | | | | | |
| | | | 6Y-10Y | 122-208 mg/dL | <122 | >209 | | | | | |
| | | | 10Y-15Y | 124-217 mg/dL | <124 | >217 | | | | | |
| | | | 15Y-20Y | 125-212 mg/dL | <125 | >212 | | | | | |
| | | | 20Y-30Y | 128-218 mg/dL | <128 | >218 | | | | | |
| | | | 30Y-40Y | 141-240 mg/dL | <141 | >240 | | | | | |
| | | | 40Y-50Y | 155-295 mg/dL | <155 | >295 | | | | | |
| | | | 50Y-60Y | 171-291 mg/dL | <171 | >291 | | | | | |
| | | | 60Y-70Y | 188-320 mg/dL | <188 | >320 | | | | | |
| | | | 70Y-150Y | 207-355 mg/dL | <207 | >355 | | | | | |
| | | Male | 0Y-1Y | 80-260 mg/dL | L <80 | H >260 | | | | | |
| | | | 1Y-6Y | 87-213 mg/dL | <87 | >213 | | | | | |
| | | | 6Y-10Y | 120-191 mg/dL | <120 | >191 | | | | | |
| | | | 10Y-15Y | 130-204 mg/dL | <130 | >204 | | | | | |
| | | | 15Y-20Y | 114-198 mg/dL | <114 | >198 | | | | | |
| | | | 20Y-30Y | 128-238 mg/dL | <128 | >238 | | | | | |
| | | | 30Y-40Y | 150-264 mg/dL | <150 | >264 | | | | | |
| | | | 40Y-50Y | 162-288 mg/dL | <162 | >288 | | | | | |
| | | | 50Y-60Y | 170-291 mg/dL | <170 | >291 | | | | | |
| | | | 60Y-70Y | 175-298 mg/dL | <175 | >298 | | | | | |
| | | | 70Y-150Y | 177-300 mg/dL | <177 | >300 | | | | | |
| Key: Alert flags: H High L Low | | | | | | | | | | | |
| (b) (4) | | | | | | | | | | | |



| Run: 11-Jun-13 11:58 PM | | Reference Range Report (Clinical) Reported in: Conventional Units Group: HDL | | | | Page: 1 Project: R00225 | | | |
|--------------------------------------|--------|--|----------|------------------|-------------|----------------------------|----------------|--|--|
| Test | Ethnic | Sex | Age | Range | Alert Flags | | Effective Date | | |
| HDL-C (RCT1684) | | | | | | | | | |
| | | Female | 0Y-5Y | mg/dL No Ref Rng | L | H | | | |
| | | | 5Y-10Y | 36-73 mg/dL | <36 | >73 | | | |
| | | | 10Y-15Y | 37-70 mg/dL | <37 | >70 | | | |
| | | | 15Y-20Y | 35-74 mg/dL | <35 | >74 | | | |
| | | | 20Y-25Y | 33-79 mg/dL | <33 | >79 | | | |
| | | | 25Y-30Y | 37-83 mg/dL | <37 | >83 | | | |
| | | | 30Y-35Y | 36-77 mg/dL | <36 | >77 | | | |
| | | | 35Y-40Y | 34-82 mg/dL | <34 | >82 | | | |
| | | | 40Y-45Y | 34-88 mg/dL | <34 | >88 | | | |
| | | | 45Y-50Y | 34-87 mg/dL | <34 | >87 | | | |
| | | | 50Y-55Y | 37-82 mg/dL | <37 | >82 | | | |
| | | | 55Y-60Y | 37-81 mg/dL | <37 | >81 | | | |
| | | | 60Y-65Y | 36-82 mg/dL | <36 | >82 | | | |
| | | | 65Y-70Y | 35-86 mg/dL | <35 | >86 | | | |
| | | | 70Y-150Y | 33-82 mg/dL | <33 | >82 | | | |
| | | Male | 0Y-5Y | mg/dL No Ref Rng | L | H | | | |
| | | | 5Y-10Y | 36-75 mg/dL | <36 | >75 | | | |
| | | | 10Y-15Y | 37-74 mg/dL | <37 | >74 | | | |
| | | | 15Y-20Y | 30-83 mg/dL | <30 | >83 | | | |
| | | | 20Y-25Y | 30-83 mg/dL | <30 | >83 | | | |
| | | | 25Y-30Y | 31-83 mg/dL | <31 | >83 | | | |
| | | | 30Y-35Y | 28-83 mg/dL | <28 | >83 | | | |
| | | | 35Y-40Y | 29-82 mg/dL | <29 | >82 | | | |
| | | | 40Y-45Y | 27-87 mg/dL | <27 | >87 | | | |
| | | | 45Y-50Y | 30-84 mg/dL | <30 | >84 | | | |
| | | | 50Y-55Y | 28-83 mg/dL | <28 | >83 | | | |
| | | | 55Y-60Y | 28-71 mg/dL | <28 | >71 | | | |
| | | | 60Y-65Y | 20-74 mg/dL | <20 | >74 | | | |
| | | | 65Y-70Y | 20-75 mg/dL | <20 | >75 | | | |
| | | | 70Y-150Y | 21-75 mg/dL | <21 | >75 | | | |
| Key: Alert flags: H High L Low | | | | | | | | | |
| (b) (4) | | | | | | | | | |

| Run: 11-Jun-13 11:58 PM | | Reference Range Report (Clinical) Reported in: Conventional Units Group: CHEMISTRY PANEL | | | | Page: 1 Project: R00225 | | | |
|----------------------------|--------|--|----------|----------------|-------------|----------------------------|----------------|-------|------|
| Test | Ethnic | Sex | Age | Range | Alert Flags | | Effective Date | | |
| Albumin (RCT13) | | | | | | | | | |
| | | Both | 0Y-2M | 2.4-4.8 g/dL | L | H | | | |
| | | | 2Y-4Y | 2.8-4.8 g/dL | <2.8 | >4.8 | | | |
| | | | 4Y-18Y | 2.9-4.7 g/dL | <2.9 | >4.7 | | | |
| | | | 18Y-18Y | 3.3-4.7 g/dL | <3.3 | >4.7 | | | |
| | | | 18Y-65Y | 3.3-4.9 g/dL | <3.3 | >4.9 | | | |
| | | | 65Y-80Y | 3.3-4.6 g/dL | <3.3 | >4.6 | | | |
| | | | 80Y-150Y | 3.0-4.6 g/dL | <3.0 | >4.6 | | | |
| Total Prot (RCT12) | | | | | | | | | |
| | | Both | 0Y-3M | 5.4-7.4 g/dL | LP | LT | L | H | HP |
| | | | 3Y-4Y | 5.5-7.1 g/dL | <1.5 | <2.0 | <5.4 | >7.4 | |
| | | | 4Y-18Y | 6.1-8.4 g/dL | <1.5 | <2.0 | <5.5 | >7.1 | |
| | | | 18Y-65Y | 6.1-8.4 g/dL | <2.0 | | <6.1 | >8.4 | >8.0 |
| | | | 65Y-150Y | 6.0-8.8 g/dL | <2.0 | | <6.0 | >8.8 | >8.0 |
| Total Bil (RCT1) | | | | | | | | | |
| | | Both | 0Y-2M | 0.2-11.7 mg/dL | L | H | HT | HP | |
| | | | 2Y-18Y | 0.2-1.2 mg/dL | <0.2 | >11.7 | >1.2 | >20.0 | |
| | | | 18Y-150Y | 0.2-1.2 mg/dL | <0.2 | >1.2 | >2.0 | >3.0 | |
| Dir Bil (RCT28) | | | | | | | | | |
| | | Both | 0Y-2M | 0.0-1.2 mg/dL | H | | | | |
| | | | 2Y-18Y | 0.0-0.4 mg/dL | >1.2 | | | | |
| | | | 18Y-150Y | 0.0-0.4 mg/dL | >0.4 | | | | |
| Alk Phos (RCT1407) | | | | | | | | | |
| | | Female | 0Y-1M | 48-406 U/L | L | H | HT | HP | |
| | | | 1Y-1Y | 124-341 U/L | <48 | >406 | >500 | >750 | |
| | | | 1Y-4Y | 108-317 U/L | <124 | >341 | >600 | >750 | |
| | | | 4Y-7Y | 96-297 U/L | <108 | >317 | >500 | >750 | |
| | | | 7Y-10Y | 89-325 U/L | <96 | >297 | >500 | >750 | |
| | | | 10Y-15Y | 51-300 U/L | <89 | >325 | >500 | >750 | |
| | | | 15Y-18Y | 31-110 U/L | <51 | >300 | >400 | >750 | |
| | | | 18Y-50Y | 31-106 U/L | <31 | >110 | >200 | >500 | |
| | | | 50Y-60Y | 35-123 U/L | <31 | >106 | >200 | >500 | |
| | | | 60Y-70Y | 25-123 U/L | <35 | >123 | >300 | >500 | |
| | | | 70Y-80Y | 35-123 U/L | <35 | >123 | >300 | >500 | |
| | | | 80Y-90Y | 35-136 U/L | <35 | >123 | >300 | >500 | |
| | | | 90Y-150Y | 35-140 U/L | <35 | >140 | >300 | >500 | |
| | | Male | 0Y-1M | 75-316 U/L | <75 | >316 | >500 | >750 | |
| | | | 1Y-1Y | 82-383 U/L | <82 | >383 | >500 | >750 | |
| | | | 1Y-4Y | 104-346 U/L | <104 | >346 | >500 | >750 | |
| (b) (4) | | | | | | | | | |



| Run: 11-Jun-13 11:58 PM | | Reference Range Report (Clinical) Reported in: Conventional Units Group: CHEMISTRY PANEL | | | | Page: 2 Project: B00225 | | | |
|---------------------------------|-----------|--|-------------------|------------|-------------|----------------------------|----------|------|----------------|
| Test | Ethnic | Sex | Age | Range | Alert Flags | | | | Effective Date |
| Continued Alk Phos (RCT1407) | Male | | 4Y-7Y | 93-309 U/L | L | H | HT | HP | 11-Jul-2007 |
| | | | 7Y-10Y | 86-315 U/L | <93 | >309 | >500 | >750 | |
| | | | 10Y-15Y | 95-385 U/L | <86 | >315 | >500 | >750 | |
| | | | 15Y-18Y | 50-250 U/L | <95 | >385 | >500 | >750 | |
| | | | 18Y-50Y | 31-129 U/L | <50 | >250 | >300 | >750 | |
| | | | 50Y-60Y | 26-121 U/L | <31 | >129 | >250 | >500 | |
| | | | 60Y-70Y | 26-125 U/L | <35 | >131 | >300 | >500 | |
| | | | 70Y-80Y | 35-130 U/L | <35 | >125 | >300 | >500 | |
| | | | 80Y-90Y | 35-125 U/L | <35 | >130 | >300 | >500 | |
| | | | 90Y-150Y | 25-125 U/L | <35 | >125 | >300 | >500 | |
| | | | ALT (SGPT) (RCT4) | Female | | 0Y-1Y | <=54 U/L | L | |
| 1Y-4Y | 6-34 U/L | <6 | | | | >54 | >100 | >200 | |
| 4Y-7Y | 6-34 U/L | <6 | | | | >34 | >100 | >200 | |
| 7Y-10Y | 6-34 U/L | <6 | | | | >34 | >100 | >200 | |
| 10Y-18Y | 6-34 U/L | <6 | | | | >34 | >200 | >300 | |
| 18Y-50Y | 6-34 U/L | <6 | | | | >34 | >200 | >300 | |
| 50Y-150Y | 6-32 U/L | <6 | | | | >32 | >200 | >300 | |
| 0Y-1Y | <=54 U/L | <6 | | | | >54 | >100 | >200 | |
| 1Y-4Y | 6-34 U/L | <6 | | | | >34 | >100 | >200 | |
| 4Y-7Y | 6-34 U/L | <6 | | | | >34 | >100 | >200 | |
| 7Y-10Y | 6-34 U/L | <6 | | | | >34 | >100 | >200 | |
| 10Y-18Y | 6-43 U/L | <6 | >43 | >200 | >300 | | | | |
| 18Y-50Y | 6-43 U/L | <6 | >43 | >200 | >300 | | | | |
| 50Y-150Y | 6-35 U/L | <6 | >35 | >200 | >300 | | | | |
| AST (SGOT) (RCT5) | Female | | 0Y-1Y | 10-80 U/L | L | H | HT | HP | 27-Dec-2000 |
| | | | 1Y-4Y | 10-58 U/L | <10 | >80 | >200 | >300 | |
| | | | 4Y-7Y | 10-48 U/L | <10 | >50 | >100 | >200 | |
| | | | 7Y-10Y | 10-48 U/L | <10 | >48 | >100 | >200 | |
| | | | 10Y-18Y | 10-48 U/L | <10 | >40 | >100 | >200 | |
| | | | 18Y-50Y | 6-34 U/L | <6 | >34 | >200 | >300 | |
| | | | 50Y-150Y | 6-34 U/L | <6 | >34 | >200 | >300 | |
| | | | 0Y-1Y | 10-80 U/L | <10 | >60 | >200 | >300 | |
| | | | 1Y-4Y | 10-58 U/L | <10 | >55 | >100 | >200 | |
| | | | 4Y-7Y | 10-58 U/L | <10 | >55 | >100 | >200 | |
| | | | 7Y-10Y | 10-48 U/L | <10 | >40 | >100 | >200 | |
| 10Y-18Y | 10-48 U/L | <10 | >40 | >100 | >200 | | | | |
| 18Y-50Y | 11-36 U/L | <11 | >36 | >200 | >300 | | | | |
| 50Y-150Y | 11-36 U/L | <11 | >36 | >200 | >300 | | | | |
| (b) (4) | | | | | | | | | |

| Run: 11-Jun-13 11:58 PM | | Reference Range Report (Clinical) Reported in: Conventional Units Group: CHEMISTRY PANEL | | | | Page: 3 Project: B00225 | | | |
|----------------------------|---------------|--|----------|---------------|-------------|----------------------------|------|------|----------------|
| Test | Ethnic | Sex | Age | Range | Alert Flags | | | | Effective Date |
| GGT (RCT3) | Female | | 0Y-6M | 15-132 U/L | L | H | HT | HP | 30-Mar-2000 |
| | | | 6Y-1Y | 1-38 U/L | <15 | >132 | >200 | >300 | |
| | | | 1Y-10Y | 0-24 U/L | <1 | >38 | >50 | >100 | |
| | | | 10Y-18Y | 0-33 U/L | <1 | >24 | >50 | >100 | |
| | | | 18Y-50Y | 4-48 U/L | <4 | >33 | >150 | >300 | |
| | | | 50Y-150Y | 4-48 U/L | <4 | >48 | >150 | >300 | |
| | | | 0Y-6M | 12-122 U/L | <4 | >50 | >200 | >300 | |
| | | | 6Y-1Y | 1-38 U/L | <4 | >38 | >50 | >100 | |
| | | | 1Y-10Y | 0-24 U/L | <1 | >24 | >50 | >100 | |
| | | | 10Y-18Y | 0-51 U/L | <1 | >122 | >200 | >300 | |
| | | | 18Y-50Y | 10-61 U/L | <10 | >51 | >250 | >300 | |
| 50Y-150Y | 10-50 U/L | <10 | >50 | >200 | >300 | | | | |
| Urea Nitr (RCT6) | Both | | 0Y-18Y | 4-24 mg/dL | L | H | HT | HP | 25-Jun-2005 |
| | | | 18Y-70Y | 4-24 mg/dL | <4 | >24 | >35 | >50 | |
| | | | 70Y-80Y | 4-28 mg/dL | <4 | >28 | >40 | >50 | |
| | | | 80Y-150Y | 4-34 mg/dL | <4 | >34 | >40 | >50 | |
| | | | 0Y-1Y | 0.2-0.6 mg/dL | L | H | HT | HP | |
| | | | 1Y-4Y | 0.1-0.3 mg/dL | <0.2 | >0.6 | >1.0 | >1.5 | |
| | | | 4Y-7Y | 0.1-0.4 mg/dL | <0.1 | >0.3 | >1.0 | >1.5 | |
| | | | 7Y-10Y | 0.2-0.5 mg/dL | <0.2 | >0.5 | >1.0 | >1.5 | |
| | | | 10Y-13Y | 0.2-0.6 mg/dL | <0.2 | >0.6 | >1.0 | >1.5 | |
| | | | 13Y-18Y | 0.3-0.7 mg/dL | <0.3 | >0.7 | >1.2 | >1.7 | |
| | | | 18Y-18Y | 0.4-0.8 mg/dL | <0.4 | >0.8 | >1.5 | >2.0 | |
| 18Y-18Y | 0.5-0.9 mg/dL | <0.5 | >0.9 | >2.0 | >3.0 | | | | |
| 18Y-50Y | 0.4-1.1 mg/dL | <0.4 | >1.1 | >2.0 | >3.0 | | | | |
| 50Y-70Y | 0.4-1.2 mg/dL | <0.4 | >1.2 | >2.0 | >3.0 | | | | |
| 70Y-80Y | 0.4-1.2 mg/dL | <0.4 | >1.2 | >2.0 | >3.0 | | | | |
| 80Y-150Y | 0.4-1.4 mg/dL | <0.4 | >1.4 | >2.0 | >3.0 | | | | |
| Creatinine (RCT382) | Female | | 0Y-1Y | 0.2-0.6 mg/dL | L | H | HT | HP | 24-Aug-2000 |
| | | | 1Y-1Y | 0.1-0.3 mg/dL | <0.2 | >0.6 | >1.0 | >1.5 | |
| | | | 1Y-4Y | 0.1-0.4 mg/dL | <0.1 | >0.3 | >1.0 | >1.5 | |
| | | | 4Y-7Y | 0.2-0.5 mg/dL | <0.2 | >0.5 | >1.0 | >1.5 | |
| | | | 7Y-10Y | 0.2-0.6 mg/dL | <0.2 | >0.6 | >1.0 | >1.5 | |
| | | | 10Y-13Y | 0.3-0.7 mg/dL | <0.3 | >0.7 | >1.2 | >1.7 | |
| | | | 13Y-18Y | 0.4-0.8 mg/dL | <0.4 | >0.8 | >1.5 | >2.0 | |
| | | | 18Y-18Y | 0.5-0.9 mg/dL | <0.5 | >0.9 | >2.0 | >3.0 | |
| | | | 18Y-50Y | 0.4-1.1 mg/dL | <0.4 | >1.1 | >2.0 | >3.0 | |
| | | | 50Y-70Y | 0.4-1.2 mg/dL | <0.4 | >1.2 | >2.0 | >3.0 | |
| | | | 70Y-80Y | 0.4-1.2 mg/dL | <0.4 | >1.2 | >2.0 | >3.0 | |
| 80Y-150Y | 0.4-1.4 mg/dL | <0.4 | >1.4 | >2.0 | >3.0 | | | | |
| | Male | | 0Y-1Y | 0.2-0.6 mg/dL | L | H | HT | HP | |
| | | | 1Y-1Y | 0.1-0.4 mg/dL | <0.2 | >0.6 | >1.0 | >1.5 | |
| | | | 1Y-4Y | 0.1-0.4 mg/dL | <0.1 | >0.4 | >1.0 | >1.5 | |
| | | | 4Y-7Y | 0.2-0.5 mg/dL | <0.2 | >0.5 | >1.0 | >1.5 | |
| | | | 7Y-10Y | 0.3-0.6 mg/dL | <0.3 | >0.6 | >1.0 | >1.5 | |
| | | | 10Y-13Y | 0.3-0.7 mg/dL | <0.3 | >0.7 | >1.2 | >1.7 | |
| | | | 13Y-18Y | 0.3-0.8 mg/dL | <0.3 | >0.8 | >1.5 | >2.0 | |
| | | | 18Y-18Y | 0.5-1.1 mg/dL | <0.5 | >1.1 | >2.0 | >3.0 | |
| | | | 18Y-50Y | 0.5-1.2 mg/dL | <0.5 | >1.2 | >2.0 | >3.0 | |
| | | | 50Y-70Y | 0.5-1.3 mg/dL | <0.5 | >1.3 | >2.0 | >3.0 | |
| | | | 70Y-80Y | 0.5-1.5 mg/dL | <0.5 | >1.5 | >2.0 | >3.0 | |
| 80Y-150Y | 0.5-1.6 mg/dL | <0.5 | >1.6 | >2.0 | >3.0 | | | | |
| (b) (4) | | | | | | | | | |



| Run: 11-Jun-13 11:56 PM | | | Reference Range Report (Clinical) Reported In: Conventional Units Group: CHEMISTRY PANEL | | | | Page: 4 Project: B00225 | | |
|--|--------|-----|--|---------------|-----------|-----------|----------------------------|-------------|-------------|
| Test | Ethnic | Sex | Age | Range | A l e r t | F l a g s | Effective Date | | |
| LDH (RCT1408) | Female | | 01-1M | 145-765 U/L | L | H | HP | 24-Jan-2000 | |
| | | | 11-1Y | 190-420 U/L | <145 | >765 | >1000 | | |
| | | | 1Y-2Y | 165-395 U/L | <180 | >420 | >1000 | | |
| | | | 3Y-6Y | 135-345 U/L | <165 | >395 | >500 | | |
| | | | 6Y-9Y | 140-280 U/L | <135 | >345 | >500 | | |
| | | | 9Y-12Y | 120-260 U/L | <140 | >280 | >500 | | |
| | | | 12Y-15Y | 100-275 U/L | <120 | >260 | >600 | | |
| | | | 15Y-18Y | 105-230 U/L | <180 | >275 | >500 | | |
| | | | 18Y-150Y | 53-234 U/L | <105 | >230 | >500 | | |
| | | | 18Y-150Y | 53-234 U/L | <53 | >234 | >350 | | |
| | Male | | 01-1M | 125-735 U/L | L | H | HP | 24-Jan-2000 | |
| | | | 11-1Y | 170-450 U/L | <125 | >735 | >1000 | | |
| | | | 1Y-2Y | 155-345 U/L | <170 | >450 | >1000 | | |
| | | | 3Y-6Y | 155-345 U/L | <155 | >345 | >500 | | |
| | | | 6Y-9Y | 145-300 U/L | <155 | >345 | >500 | | |
| | | | 9Y-12Y | 120-325 U/L | <145 | >300 | >600 | | |
| | | | 12Y-15Y | 120-280 U/L | <120 | >325 | >500 | | |
| | | | 15Y-18Y | 105-235 U/L | <120 | >280 | >500 | | |
| | | | 18Y-150Y | 53-234 U/L | <105 | >235 | >500 | | |
| | | | 18Y-150Y | 53-234 U/L | <53 | >234 | >350 | | |
| Sodium (RCT15) | Both | | 0Y-10Y | 132-147 mEq/L | LP | LT | L | HP | 20-Apr-1997 |
| | | | 18Y-58Y | 132-147 mEq/L | <115 | <125 | <132 | >147 | |
| | | | 58Y-150Y | 135-145 mEq/L | <115 | <125 | <132 | >147 | |
| | | | 58Y-150Y | 135-145 mEq/L | <115 | <125 | <135 | >145 | |
| Potassium (RCT16) | Both | | 0Y-1Y | 3.7-5.6 mEq/L | LP | LT | L | HT | 20-Apr-1997 |
| | | | 1Y-18Y | 3.4-5.4 mEq/L | <2.6 | <3.0 | <3.7 | >5.6 | |
| | | | 18Y-58Y | 3.4-5.4 mEq/L | <2.6 | <3.0 | <3.4 | >5.4 | |
| | | | 58Y-150Y | 3.4-5.4 mEq/L | <2.6 | <3.0 | <3.4 | >5.4 | |
| Key: Alert flags: H High HP High Panic HT High - Telephone L Low LP Low Panic LT Low - Telephone | | | | | | | | | |

(b) (4)

| Run: 11-Jun-13 11:56 PM | | | Reference Range Report (Clinical) Reported In: Conventional Units Group: LDL | | | | Page: 1 Project: B00225 | | |
|--------------------------------------|--------|-----|--|---------------------|-----------|-----------|----------------------------|--|--|
| Test | Ethnic | Sex | Age | Range | A l e r t | F l a g s | Effective Date | | |
| LDL (RCT2394) | Female | | 0Y-6Y | ng/dL, No Ref. Rang | L | H | 14-Mar-2011 | | |
| | | | 6Y-10Y | 66-124 ng/dL | <66 | >124 | | | |
| | | | 8Y-10Y | 67-142 ng/dL | <67 | >142 | | | |
| | | | 10Y-12Y | 70-140 ng/dL | <70 | >140 | | | |
| | | | 12Y-14Y | 68-133 ng/dL | <68 | >133 | | | |
| | | | 14Y-16Y | 60-129 ng/dL | <60 | >129 | | | |
| | | | 16Y-18Y | 57-138 ng/dL | <57 | >138 | | | |
| | | | 18Y-20Y | 59-143 ng/dL | <58 | >143 | | | |
| | | | 20Y-25Y | 60-148 ng/dL | <60 | >148 | | | |
| | | | 25Y-30Y | 70-151 ng/dL | <70 | >151 | | | |
| | | | 30Y-35Y | 67-150 ng/dL | <67 | >150 | | | |
| | | | 35Y-40Y | 76-172 ng/dL | <76 | >172 | | | |
| | | | 40Y-45Y | 77-174 ng/dL | <77 | >174 | | | |
| | | | 45Y-50Y | 80-187 ng/dL | <80 | >187 | | | |
| | | | 50Y-55Y | 80-215 ng/dL | <80 | >215 | | | |
| | | | 55Y-60Y | 95-213 ng/dL | <95 | >213 | | | |
| | | | 60Y-65Y | 100-234 ng/dL | <100 | >234 | | | |
| | | | 65Y-70Y | 97-223 ng/dL | <97 | >223 | | | |
| | | | 70Y-150Y | 86-207 ng/dL | <86 | >207 | | | |
| | Male | | 0Y-6Y | ng/dL, No Ref. Rang | | | | | |
| | | | 6Y-10Y | 69-129 ng/dL | <69 | >129 | | | |
| | | | 8Y-10Y | 65-123 ng/dL | <65 | >123 | | | |
| | | | 10Y-12Y | 64-131 ng/dL | <64 | >131 | | | |
| | | | 12Y-14Y | 64-129 ng/dL | <64 | >129 | | | |
| | | | 14Y-16Y | 57-130 ng/dL | <57 | >130 | | | |
| | | | 16Y-18Y | 64-129 ng/dL | <64 | >129 | | | |
| | | | 18Y-20Y | 62-142 ng/dL | <62 | >142 | | | |
| | | | 20Y-25Y | 66-147 ng/dL | <66 | >147 | | | |
| | | | 25Y-30Y | 70-165 ng/dL | <70 | >165 | | | |
| | | | 30Y-35Y | 78-185 ng/dL | <78 | >185 | | | |
| | | | 35Y-40Y | 81-189 ng/dL | <81 | >189 | | | |
| | | | 40Y-45Y | 98-202 ng/dL | <98 | >202 | | | |
| | | | 45Y-50Y | 88-203 ng/dL | <88 | >203 | | | |
| | | | 50Y-55Y | 89-197 ng/dL | <89 | >197 | | | |
| | | | 55Y-60Y | 88-203 ng/dL | <88 | >203 | | | |
| | | | 60Y-65Y | 83-210 ng/dL | <83 | >210 | | | |
| | | | 65Y-70Y | 86-210 ng/dL | <86 | >210 | | | |
| | | | 70Y-150Y | 86-186 ng/dL | <86 | >186 | | | |
| Key: Alert flags: H High L Low | | | | | | | | | |

(b) (4)

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| Run: 11-Jun-13 11:58 PM | | Reference Range Report (Clinical) Reported in: Conventional Units Group: CRP | | | | Page: 1 Project: 800225 | |
|-----------------------------|--------|--|--------------------|--------------------------------|-----------------------|----------------------------|----------------|
| Test | Ethnic | Sex | Age | Range | Alert Flags | | Effective Date |
| CRP-RS (SCT1528) | | Both | 0Y-18Y 18Y-150Y | <=0.287 mg/dL <=0.287 mg/dL | H >0.287 >0.287 | | 02-Apr-2012 |
| Key: Alert flags: H High | | | | | | | |
| (b) (4) | | | | | | | |

| Run: 11-Jun-13 11:58 PM | | Reference Range Report (Clinical) Reported in: Conventional Units Group: URINE MACRO PANEL | | | | Page: 1 Project: 800225 | |
|----------------------------|--------|--|--|--|---|----------------------------|----------------|
| Test | Ethnic | Sex | Age | Range | Alert Flags | | Effective Date |
| Spec Grav (UAT2) | | Both | 0Y-59Y 59Y-150Y | 1.002-1.035 1.006-1.030 | L <1.002 <1.006 | H >1.035 >1.030 | 12-May-2008 |
| pH (UAT3) | | Both | 0Y-18Y 18Y-150Y | 5.0-8.0 5.0-8.0 | L <5.0 <5.0 | H >8.0 >8.0 | 12-May-2008 |
| Protein (UAT4B) | | Both | 0Y-18Y 18Y-150Y | Ref Rng:Negative H: Ref Rng:Negative H: | H Trace, +1, +2, +3, +4 Trace, +1, +2, +3, +4 | | 16-Oct-2008 |
| Glucose (UAT5) | | Both | 0Y-18Y 18Y-150Y | Ref Rng:Negative H: Ref Rng:Negative H: | H Trace, +1, +2, +3, +4 Trace, +1, +2, +3, +4 | | 16-Oct-2008 |
| Bilirubin (UAT7) | | Both | 0Y-18Y 18Y-150Y | Ref Rng:Negative H: Ref Rng:Negative H: | H +1, +2, +3, +4 +1, +2, +3, +4 | | 03-Jul-2008 |
| Blood (UAT43) | | Female Male | 0Y-18Y 18Y-150Y 0Y-18Y 18Y-150Y | Ref Rng: Negative-Trace H: Ref Rng: Negative-Trace H: Ref Rng:Negative H: Ref Rng:Negative H: | H +1, +2, +3 +1, +2, +3 Trace, +1, +2, +3 Trace, +1, +2, +3 | | 16-Oct-2008 |
| Nitrite (UAT10) | | Both | 0Y-18Y 18Y-150Y | Ref Rng:Negative H: Ref Rng:Negative | H +1, +2 | | 03-Jul-2008 |
| (b) (4) | | | | | | | |



| | | | | | | |
|-----------------------------|--------|--|-----|-------|----------------------------|----------------|
| Run: 11-Jun-13 11:58 PM | | Reference Range Report (Clinical) Reported in: Conventional Units | | | Page: 2 Project: 800225 | |
| Group: URINE MACRO PANEL | | | | | | |
| Test | Ethnic | Sex | Age | Range | A l e r t F l a g s | Effective Date |
| Continued ... Ur Nitrite | | Both | | | H , +2 | 03-Jul-2008 |
| Key: Alert flags: | H L | High Low | | | | |
| (b) (4) | | | | | | |





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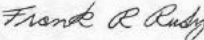
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Clinical Trial Laboratory CB Lab
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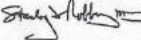
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Chair, Commission on Laboratory Accreditation



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16.1.9.3 Bioanalytical Reports

Determination of Nicotine and Cotinine in Human Plasma (K₂EDTA) Samples by LC-MS/MS - Study AA99127-01

Determination of Nicotine and Cotinine in Human Plasma (K₂EDTA) Samples by LC-MS/MS - Study AA99127-02

Determination of 3-HPMA (3-hydroxypropyl mercapturic ty l mercapturic acid), HBMA (Hydroxybutyl mercapturic acid or HMPMA), and CEMA (Cyanoethyl mercapturic acid) in Human Urine Samples by LC-MS/MS - Study AA99127-03

Determination of Total NNAL (4-(methylnitrosamino)-1-(3-pyridyl)-1-butanol) and NNN (N'-Nitrosoanonicotine) in Human Urine Samples by LC-MS/MS - Study AA99127-04

Determination of HEMA (Hydroxyethyl Mercapturic Acid) in Human Urine Samples by LC-MS/MS - Study AA99127-05

Determination of Nicotine, Cotinine, *trans*-3'-Hydroxycotinine, Nicotine-N-Glucuronide, Cotinine-N-Glucuronide, *trans*-3'-Hydroxycotinine-O-Glucuronide in Human Urine Samples by LC-MS/MS - Study AA99127-06

Determination of Total 3-Hydroxybenzo[a]pyrene in Human Urine Samples by LC-MS/MS - Study AA99127-07

Determination of Caffeine and Paraxanthine in Human Plasma (Lithium Heparin) Samples by LC-MS/MS - Study AA99127-08

Determination of Total 4-Aminobiphenyl, *o*-Toluidine, 2-Aminonaphthalene, and 1-Aminonaphthalene in Human Urine Samples by LC-MS/MS - Study AA99127-09

Determination of Cotinine and *trans*-3'-Hydroxycotinine in Human Plasma (K₂EDTA) Samples by LC-MS/MS - Study AA99127-10

Determination of 11-Dehydrothromboxane B₂ in Human Urine Samples by LC-MS/MS - Study AA99127-11

Determination of 8-Iso-Prostaglandin-F_{2α} (Type III) in Human Urine Samples by LC-MS/MS - Study AA99127-12

Determination if Nicotine, Cotinine, *trans*-3'-Hydroxycotinine, Nicotine-N-Glucuronide, Cotinine-N-Glucuronide, *trans*-3'-Hydroxycotinine-O-Glucuronide in Human Urine Samples by LC-MS/MS - Study AA99127-13



Determination of Creatinine in Human Urine by Spectrophotometry – Study AA99127-14

Determination of S-Benzyl Mercapturic Acid (SBMA) and S-Phenyl Mercapturic Acid (SPMA) in Human Urine Samples by LC-MS/MS – Amendment 1 to Bioanalytical Report No. AAA99599-01

Determination of S-Benzyl Mercapturic Acid (SBMA) and S-Phenyl Mercapturic Acid (SPMA) in Human Urine Samples by LC-MS/MS - Study AA99599-01

Determination of Monohydroxy-Butenyl-Mercapturic Acid (MHBMA) in Human Urine Samples by LC-MS/MS – Amendment 1 to Bioanalytical Report No. AAA99599-02

Determination of Monohydroxy-Butenyl-Mercapturic Acid (MHBMA) in Human Urine Samples by LC-MS/MS - Study AA99599-02

Determination of Total 1-Hydroxypyrene (1-OHP) in Human Urine Samples by LC-MS/MS - Amendment 1 to Bioanalytical Report No. AAA99599-03

Determination of Total 1-Hydroxypyrene (1-OHP) in Human Urine Samples by LC-MS/MS - Study AAA99599-03

Determination of Urine Mutagenicity - CN2-GLP Final Study Phase Report

Analytical Report - Quantitative Determination of Soluble Intercellular Adhesion Molecule-1 (sICAM-1) in Human Serum

Analytical Report - Quantitative Determination of Homocysteine (HCY) in EDTA Human Plasma

Analytical Report - Quantitative Determination of Low Density Lipoprotein Cholesterol (LDL-c) in Human Serum

Analytical Report - Quantitative Determination of Hemoglobin A1c (HbA1c) in Human EDTA Whole Blood

Analytical Report - Quantitative Determination of High Density Lipoprotein Cholesterol (HDL-c) in Human Serum

Analytical Report - Quantitative Determination of High Sensitivity C-Reactive Protein (hsCRP) in Human Serum

Bioanalysis of COHb in Human Whole Blood



Analytical Report - Quantitative Determination of Fibrinogen (FIB) in Human Sodium Citrate Plasma



16.1.9.4 Bioanalytical References

Please refer to Section 14 of the CSR for all publications referenced in the report. Copies of these publications are available upon request.