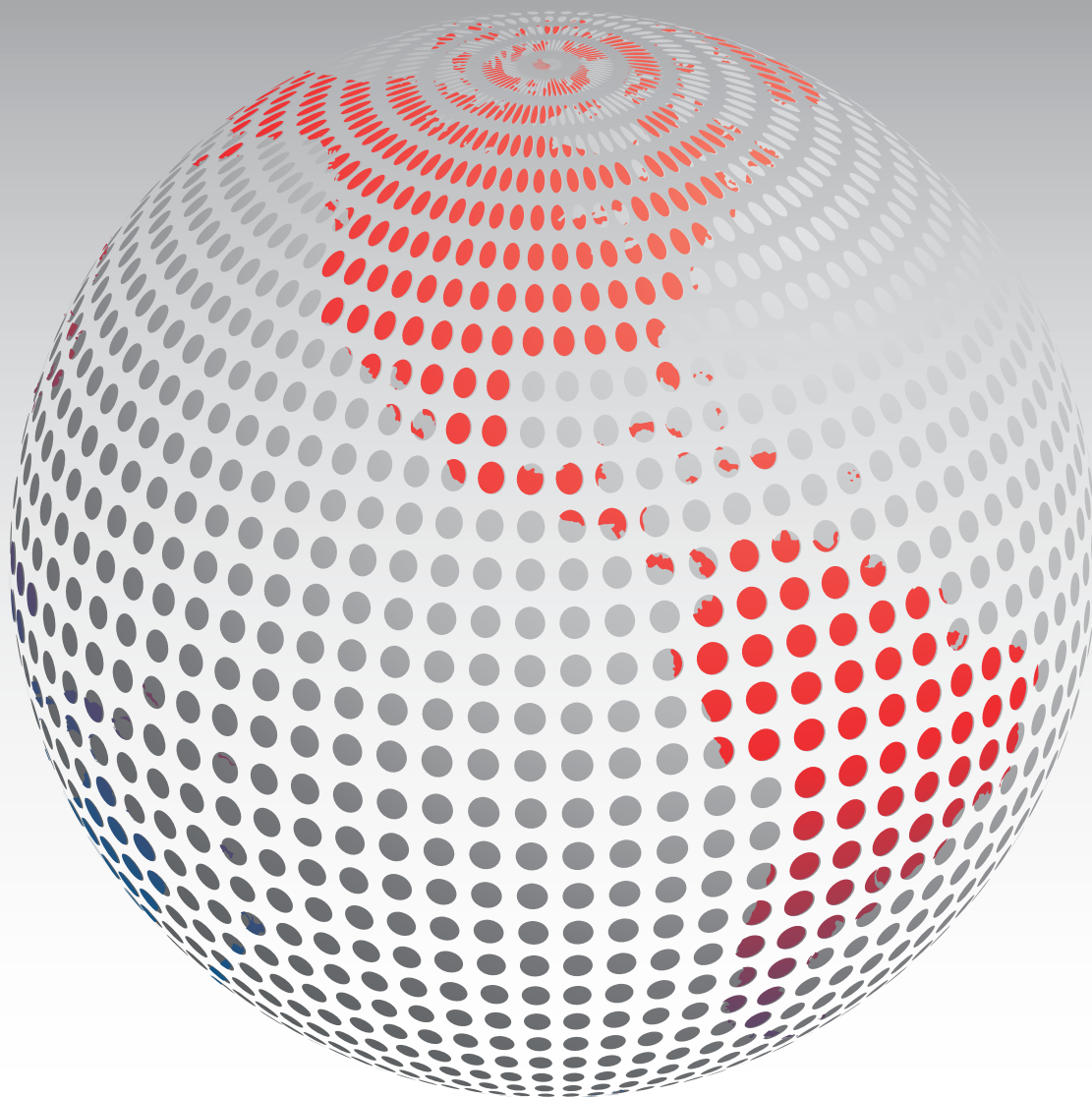


NEWBORN SCREENING

Annual Summary Report
volume 33b

2015

Quality Assurance Program



National Center for Environmental Health
Division of Laboratory Sciences



Centers for Disease Control and Prevention
National Center for Environmental Health
Division of Laboratory Sciences
Newborn Screening and Molecular Biology Branch
Atlanta, Georgia 30341-3724

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NEWBORN SCREENING

Quality Assurance Program Annual Report 2015

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2016 Shipping Schedule for Newborn Screening Quality Assurance Program Proficiency Testing (PT) and Quality Control (QC) Materials*

*Note that shipment dates are subject to change due to unexpected temporary CDC closures

| PT Panels | Enrollment Deadline | Shipping Date | Data Deadline | Report Available |
|--------------------|---------------------|---------------|---------------|------------------|
| Quarter 1 | November 1, 2015 | January 11 | February 8 | February 12 |
| Quarter 2 (UDOT**) | March 1 | April 4 | April 25 | May |
| Quarter 3 | May 1 | July 11 | August 8 | August 12 |
| Quarter 4 | August 1 | October 3 | October 31 | November 4 |

** Domestic Laboratories only

SECOND-TIER CONGENITAL ADRENAL HYPERPLASIA, CYSTIC FIBROSIS DNA MUTATION DETECTION, LYSOSOMAL STORAGE DISORDERS, ANTI-TOXOPLASMA ANTIBODIES, T-CELL RECEPTOR EXCISION CIRCLE, AND X-LINKED ADRENOLEUKODYSTROPHY PT PANELS ONLY

| CAH, CFDNA, LSD, Toxo, TREC, & XALD PT Panels | Enrollment Deadline | Shipping Date | Data Deadline | Report Available |
|---|---------------------|---------------|---------------|------------------|
| Quarter 1 | November 1, 2015 | January 11 | February 8 | March |
| Quarter 2 (No CAH or XALD) | March 1 | April 4 | May 2 | May |
| Quarter 3 | May 1 | July 11 | August 8 | August |
| Quarter 4 | August 1 | October 3 | October 31 | November |

ANTI-HIV-1 ANTIBODIES PT PANELS

| HIVPT & HIVQC | Enrollment Deadline | Shipping Date | Data Deadline | Report Available |
|--------------------------------|---------------------|------------------|---------------|------------------|
| Quarter 1 (HIVPT and HIVQC) | November 1, 2015 | January 12 | February 15 | March |
| Quarter 2 (HIV PT only) | March 1 | April 11 | May 9 | May |
| Quarter 3 (HIVPT and HIVQC) | May 1 | July 12 | August 8 | August |
| Quarter 4 (HIV PT only) | August 1 | Tues: October 11 | November 7 | November |

SICKLE CELL AND OTHER HEMOGLOBINOPATHIES PT PANELS

| Hemoglobinopathies PT Panels | Enrollment Deadline | Shipping Date | Data Deadline | Report Available |
|---------------------------------|---------------------|---------------|---------------|------------------|
| Panel 1 | Waiting List | January 11 | February 8 | February |
| Panel 2 | Waiting List | May 2 | May 30 | June |
| Panel 3 | Waiting List | October 3 | October 31 | November |

PRIMARY AND SECOND-TIER QUALITY CONTROL MATERIALS

| All Newborn Screening QC Materials | Enrollment Deadline | Shipping Date | Data Deadline | Report Available |
|--|---------------------|---------------|---------------|------------------|
| Set 1 | November 1, 2015 | January 11 | April 1 | July 2016 |
| Set 2 | May 1 | July 12 | October 1 | February 2017 |

Introduction

Newborn screening is one of the most successful preventative public health programs in the United States. State public health laboratories or their associated laboratories routinely screen dried blood spot (DBS) specimens collected from newborns shortly after birth for certain genetic, metabolic, or endocrine disorders. Effective screening, along with follow up, diagnosis, and intervention, helps prevent mental retardation and premature death caused by these inherited diseases. Healthcare professionals collect DBS specimens from more than 98% of all newborns in the United States. The Centers for Disease Control and Prevention's (CDC) Newborn Screening Quality Assurance Program (NSQAP) assists newborn screening laboratories with these testing processes.

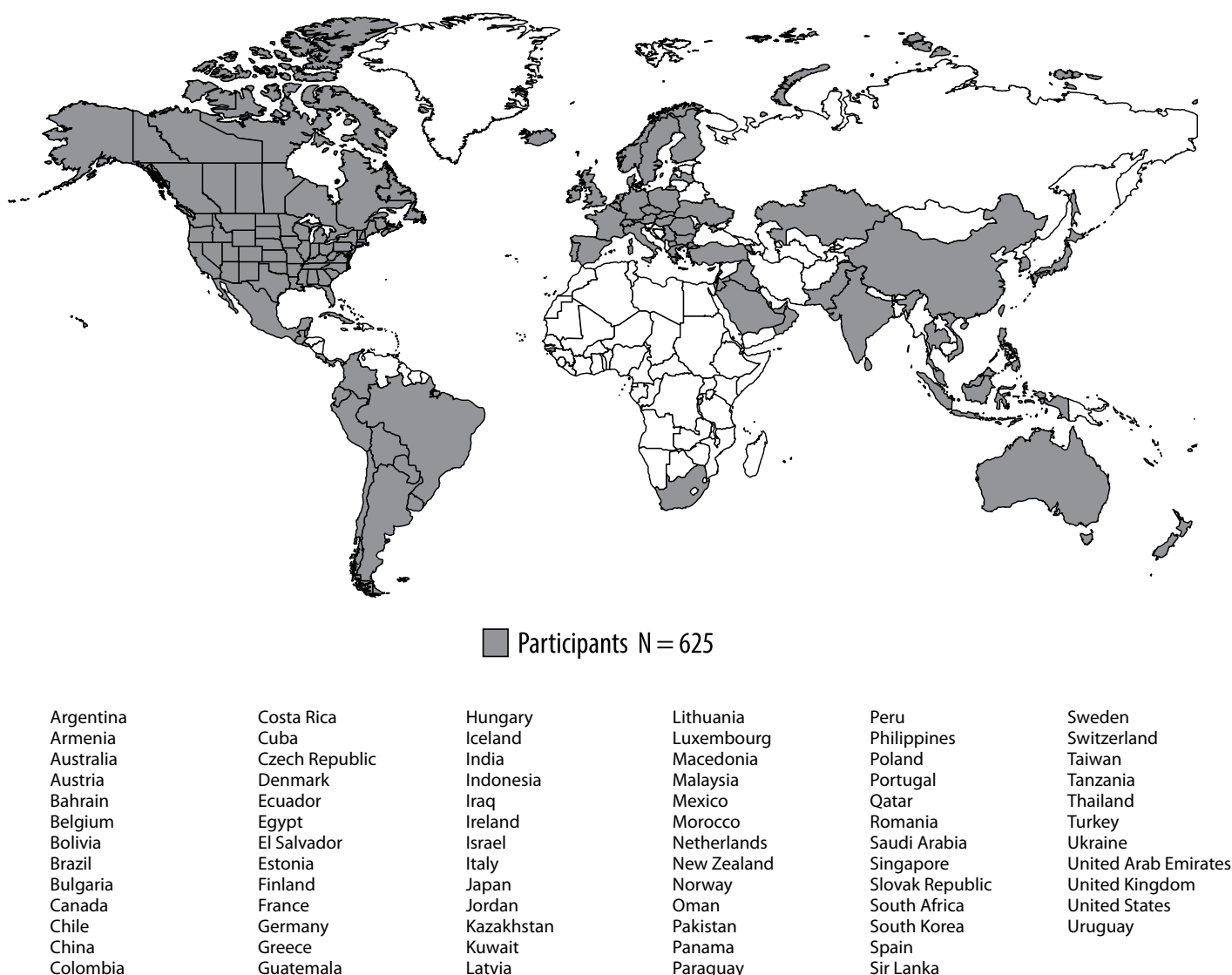
NSQAP produces certified DBS materials for proficiency testing (PT) and quality control (QC) analysis, works to improve the quality and scope of laboratory services, and provides consultative assistance to laboratories. Both state-operated and private newborn screening laboratories process large numbers of DBS specimens daily. NSQAP helps newborn screening laboratories ensure that testing accurately detects disorders, does not delay diagnosis, minimizes false positive reports, and sustains high-quality performance. Our job is to serve our participating newborn screening laboratories. We welcome comments and suggestions about how we can better serve participants' needs at NSQAPDMT@cdc.gov.

For more than 35 years, NSQAP, with its cosponsor the Association of Public Health Laboratories (APHL) has researched the development of DBS screening test materials and has assisted laboratories with DBS-related quality assurance (QA). NSQAP primarily supports U.S. newborn screening laboratories, but also allows private and international laboratories to enroll in the program. Participation is voluntary. NSQAP provides QA services for the core (primary) and secondary conditions listed in the U.S. Recommended Uniform Screening Panel (RUSP) [1]. These disorders include, but are not limited to, the following:

- congenital hypothyroidism
- congenital adrenal hyperplasia
- galactosemia
- phenylketonuria
- maple syrup urine disease
- homocystinuria
- tyrosinemia
- citrullinemia
- argininemia
- biotinidase deficiency
- cystic fibrosis
- hemoglobinopathies
- urea cycle disorders
- fatty acid oxidation disorders
- organic acid metabolic disorders
- X-linked adrenoleukodystrophy (XALD)
- severe combined immunodeficiency (SCID)

Over the years, NSQAP has grown substantially. In 2015, active program participants included 625 newborn screening laboratories in 77 countries (at least one laboratory per country) (Figure 1). Of these laboratories, 534 participated in PT (Figure 2) and 481 in QC (Figure 3). The program distributed DBS materials for 52 analytes to participating laboratories (Figures 2–3).

Figure 1. Seventy-seven Countries Participated in the Newborn Screening Quality Assurance Program in 2015



To offer more specialized services, NSQAP works with the Biochemical Mass Spectrometry Laboratory (BMSL), the Newborn Screening Translation Research Initiative (NSTRI), and the Molecular Quality Improvement Program (MQIP).

BMSL offers newborn screening tandem mass spectrometry (MS/MS) services, education, and research opportunities as well as overseeing amino acids, acylcarnitines, biotinidase, total galactose (TGal), galactose-1-phosphate uridylyltransferase (GALT), and the filter paper evaluation program. MQIP was created to enhance molecular testing assistance provided to newborn screening laboratories. MQIP also offers the Molecular

Assessment Program (MAP) which conducts onsite visits to U.S. newborn screening laboratories. These visits encompass all components of molecular testing procedures, including program-tailored guidance for laboratory-specific needs and assistance in evaluating ongoing and future molecular testing procedures. MQIP oversees the cystic fibrosis DNA mutation detection (CFDNA) PT program. NSTRI is an ongoing collaboration between the CDC Foundation and CDC's Newborn Screening Molecular Biology Branch (NSMBB) and it developed the PT program for T-cell receptor excision circle (TREC) and lysosomal storage disorders (LSD)[2].

This report summarizes all phases of NSQAP's PT activities and all QC data reported in 2015.

Figure 2. Number of Participants in Proficiency Testing Program, 2015 Total-534

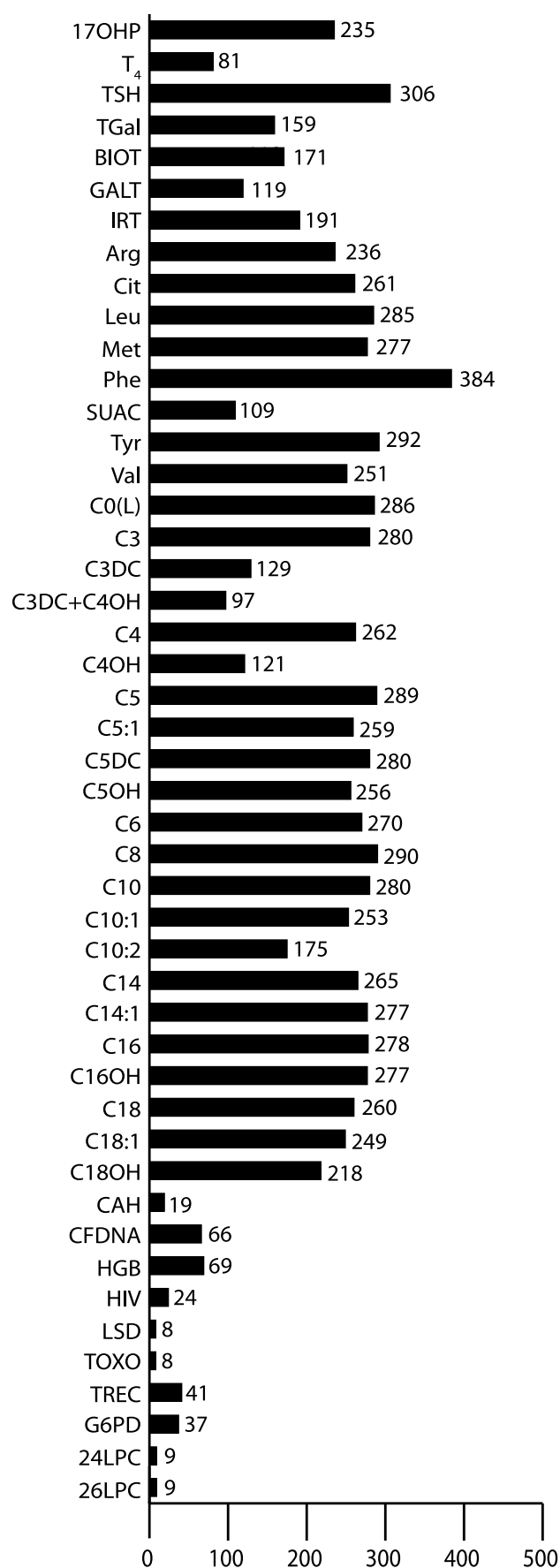
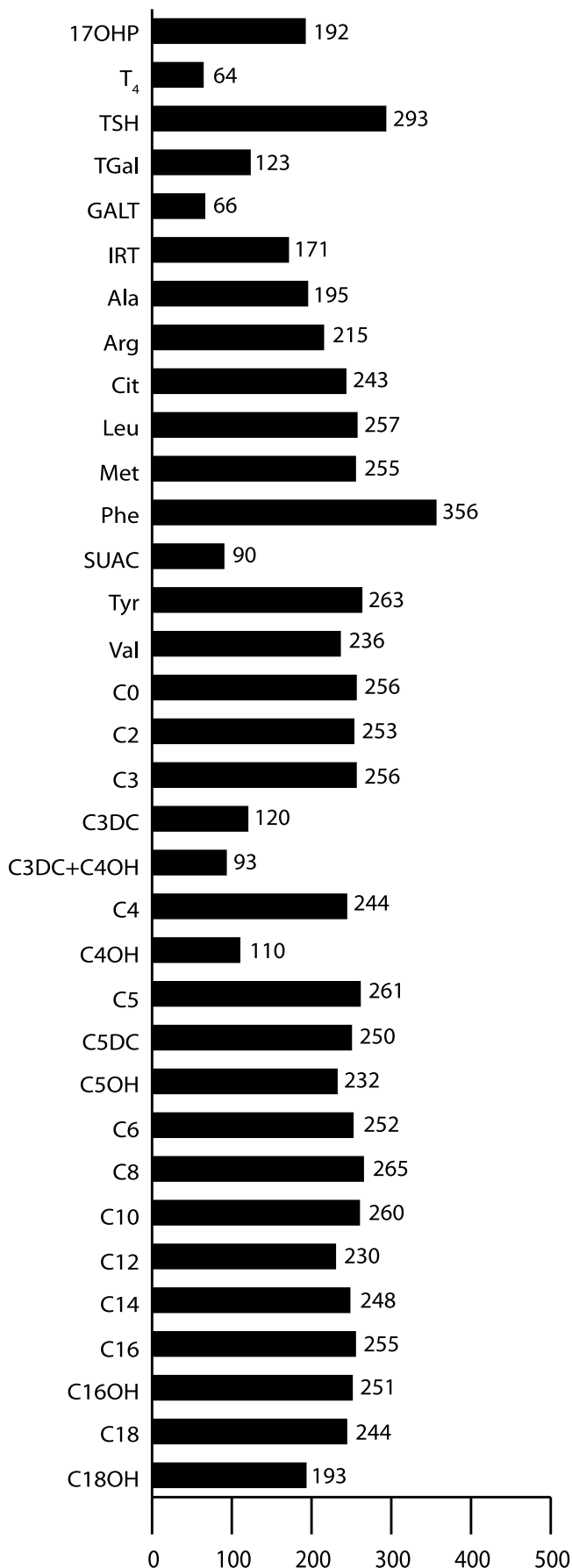


Figure 3. Number of Participants in Quality Control Program, 2015 Total- 481



2015 NEWBORN SCREENING PROGRAM HIGHLIGHTS

January

BMSL shipped the first X-linked adrenoleukodystrophy (XALD) QC materials containing 24:0- and 26:0-lysophosphatidylcholines. Summary data for these materials are included in the QC tables of this report.

February

BMSL and APHL convened a two-day workshop titled *National Conversation: Tandem Mass Spectrometry in Newborn Screening*. State newborn screening laboratorians, lab directors, and MS/MS directors attended the meeting.

March

In cooperation with APHL, MQIP hosted its annual *Newborn Screening Molecular Training Workshop*. This dynamic hands-on workshop included lectures and laboratory training activities directly related to the detection of newborn disorders using molecular methods.

April

BMSL shipped a nine-level set of QC materials to enrolled NSQAP participants. These materials are used to assess the linearity of newborn screening MS/MS assays and cover 34 amino acid and acylcarnitine analytes.

MQIP hosted the APHL Molecular Subcommittee face-to-face meeting on the CDC campus in Atlanta. Information from these meetings is used to improve molecular services to NSQAP participants.

BMSL hosted a five-day workshop: *Newborn Screening by Tandem Mass Spectrometry (MS/MS): A Hands-On Course in Understanding Laboratory Issues and Interpreting Test Results*. CDC co-sponsored the workshop at CDC's laboratories in Atlanta, GA.

NSTRI and APHL convened a two-day workshop: *Newborn Bloodspot Screening for Pompe Disease and Other Lysosomal Storage Disorders*. Attendees included physicians and scientists from newborn screening programs, medical centers, federal agencies, and APHL. You can view presentations from the workshop at <http://www.aphl.org/aphlprograms/newborn-screening-and-genetics/Pages/2015-LSDs-Workshop.aspx>

May

NSQAP and APHL hosted the QA/QC Subcommittee of the Newborn Screening and Genetics in Public Health Program in Atlanta. This subcommittee provides guidance to NSQAP on procedures, policies, and activities for quality assessment of laboratory testing. Input from this subcommittee enhances our continuing efforts to serve our participants.

June

Inter-laboratory Comparison of Assays to Measure SMN2 Copy Number in Dried Blood Spots from Patients with Spinal Muscular Atrophy, Carriers, and Controls was presented at the annual CDC Division of Laboratory Sciences Summer Symposium. The presentation focused on confirmatory testing and genetic characterization of Spinal Muscular Atrophy screen-positive results on dried blood spots.

July

NSTRI participated in the APHL NewSTEPS meeting on newborn screening for SCID. Dr. Francis Lee presented an overview of the technical and scientific support offered by the CDC including consultations, trainings, and access to reference materials. NSTRI guest researcher Dr. Lisa Kobrynski, Marcus Professor of Immunology and director of the Jeffrey Modell Foundation Center for Excellence at the Emory University School of Medicine, provided an overview of the definitions and clinical presentations associated with SCID.

September

MAP completed four site visits in 2015. These onsite visits assess a state newborn screening laboratory's molecular testing program. To request a MAP visit, go to the Newborn Screening Molecular Resources Web site at <http://www.aphl.org/aphlprograms/newborn-screening-and-genetics/Pages/Molecular-Assessment-Program.aspx>

October

PT programs for glucose-6-phosphate deficiency (G6PD) and XALD launched. Email NSQAPDMT@cdc.gov for more information or to register for these PT programs.

FILTER PAPER

NSQAP evaluates absorption characteristics of all filter paper lots that have Food and Drug Administration (FDA) approval as a newborn screening collection device [3]. The manufacturers must establish their own parallel evaluation. NSQAP's evaluations are an impartial and voluntary service offered as a function of our QA program; they do not constitute endorsement of any product.

The disk punched from DBS specimens is a volumetric measurement that requires a high degree of uniformity among and within production lots. NSQAP uses an isotopic method developed at CDC to evaluate and compare different lots of filter paper. Mean counts per minute of added radioisotope-labeled thyroxine (T_4) contained within a 3.2-mm disk are equated with the serum absorption volume of the disks made from washed intact red blood cells (RBCs). A description of the method is in the latest version of the Clinical and Laboratory Standards Institute (CLSI) Standard NBS01-A6, Blood Collection on Filter Paper for Newborn Screening Programs [3].

FDA-approved newborn screening filter paper manufacturers (GE Healthcare Biosciences Corporation and PerkinElmer Health Sciences) provide NSQAP with statistically valid sample sets of unprinted filter paper from each production lot. Tables 1 and 2 show serum absorption volumes from the last 10 lots of these two filter paper sources. The published and standardized acceptable serum absorption volume per 3.2-mm disk is (mean value and 95% confidence interval [CI]) $1.44 \pm 0.20 \mu\text{L}$ for washed intact RBCs [3]. The testing results provided in Tables 1 and 2 are for information purposes only. Each mean value was within the acceptable range for the matrix used. All lots were homogeneous (i.e., the measured within-spot, within-sheet, and among-sheets variances were within acceptable limits).

Filter paper lots used in the CDC production of QC and PT specimens distributed in 2015 were W112, W113, and W141 of Whatman 903.

Table 1. PerkinElmer 226 Specimen Collection Paper Filter Paper Absorption Characteristics by Lot Number - Intact Red Cells

| Filter Paper Lot | Date of Evaluation (month/year) | Serum Absorption Volume (μL) per 3.2mm (1/8") punch | | Absorption Time (sec) | | Spot Diameter (mm) | |
|------------------|------------------------------------|--|-------|-----------------------|-------|--------------------|-------|
| | | Avg | StDev | Avg | StDev | Avg | StDev |
| 105178 | Aug-15 | 1.46 | 0.09 | 7.8 | 1.1 | 15.9 | 0.6 |
| 104568 | Mar-15 | 1.56 | 0.10 | 10.1 | 2.1 | 15.9 | 0.7 |
| 103649 | Mar-14 | 1.53 | 0.10 | 9.7 | 3.1 | 15.7 | 0.7 |
| 102928 | Aug-13 | 1.38 | 0.09 | 8.5 | 0.9 | 16.1 | 0.5 |
| 102277 | Dec-12 | 1.47 | 0.11 | 13.0 | 4.9 | 15.8 | 0.6 |
| 101535 | Apr-12 | 1.49 | 0.08 | 14.7 | 3.1 | 15.7 | 0.5 |
| 100535 | May-11 | 1.45 | 0.08 | 8.9 | 2.2 | 15.7 | 0.5 |
| 0120201 | Apr-10 | 1.47 | 0.11 | 14.0 | 3.7 | 16.0 | 0.6 |
| 9461001 | Feb-10 | 1.53 | 0.09 | 8.8 | 1.8 | 15.4 | 0.6 |
| 8040201 | Feb-08 | 1.60 | 0.10 | 7.2 | 1.8 | 15.6 | 0.6 |

Table 2. Whatman 903 Specimen Collection Paper Filter Paper Absorption Characteristics by Lot Number - Intact Red Cells

| Filter Paper Lot | Date of Evaluation | Serum Absorption Volume (μL) per 3.2mm (1/8") punch | | Absorption Time (sec) | | Spot Diameter (mm) | |
|------------------|--------------------|---|-------|-----------------------|-------|--------------------|-------|
| | | Avg | StDev | Avg | StDev | Avg | StDev |
| W152 | Aug-15 | 1.37 | 0.09 | 15.8 | 2.4 | 16.2 | 0.6 |
| W151 | Aug-15 | 1.39 | 0.08 | 15.2 | 2.6 | 16.2 | 0.8 |
| W142 | Apr-15 | 1.46 | 0.08 | 11.0 | 2.2 | 16.0 | 0.7 |
| W141 | Mar-14 | 1.53 | 0.10 | 13.8 | 3.6 | 15.9 | 0.6 |
| W131 | Aug-13 | 1.40 | 0.07 | 10.4 | 1.4 | 16.1 | 0.5 |
| W122 | May-13 | 1.41 | 0.11 | 14.8 | 2.9 | 16.3 | 0.5 |
| W121 | Jan-13 | 1.49 | 0.09 | 13.7 | 3.8 | 16.0 | 0.6 |
| W113 | Mar-12 | 1.44 | 0.08 | 9.9 | 2.0 | 15.8 | 0.6 |
| W112 | Oct-11 | 1.38 | 0.13 | 12.9 | 2.1 | 16.0 | 0.5 |
| W111 | Feb-11 | 1.42 | 0.08 | 10.2 | 1.5 | 16.1 | 0.5 |

PROFICIENCY TESTING

NSQAP distributes PT materials three times a year. All PT panels consist of five blind-coded, 75-μL DBS specimens. Specimen sets are packaged in a zip-closed, metallized bag with desiccant, along with instructions for analysis and reporting data. These specimens provide an independent, external assessment of each laboratory's performance.

PT MATERIALS AND METHODS

NSQAP certifies PT specimens for homogeneity, accuracy, stability, and suitability for newborn screening assays. The PT analytes include: 17α-hydroxyprogesterone (17OHP), T_4 , thyroid-stimulating hormone (TSH), biotinidase (Bio), TGal, GALT, G6PD, immunoreactive trypsinogen (IRT), arginine (Arg), citrulline (Cit), leucine (Leu), methionine (Met), phenylalanine (Phe), succinylacetone (SUAC), tyrosine (Tyr), and valine (Val), low free carnitine (C0(L)), C3, C3DC, C4, C4OH, C5, C5:1, C5OH, C5DC, C6, C8, C10, C10:1, C10:2, C14, C14:1, C16, C16OH, C18, C18:1, and C18OH, X-linked adrenoleukodystrophy (XALD).

- All PT specimens are prepared from whole blood of 50% hematocrit. PT materials are produced from single donors.
- Purified analytes or unaltered donor blood are used for PT enrichments. Enrichments made with purchased or custom-synthesized acylcarnitines

are based on weighed quantities. Small variances in enrichments and recoveries might result from impurities in the purchased (synthesized) materials and endogenous analyte concentrations.

- Congenital hypothyroidism PT specimens are enriched with calculated amounts of T_4 after T_4 depletion of the base serum.
- TGal materials are enriched with galactose and galactose-1-phosphate, allowing measurement of both free galactose (galactose alone) and total galactose (free galactose plus galactose present as TGal).
- Biotinidase PT pools are made using heat-treated serum combined with compatible donor RBCs.
- Deficient GALT PT specimens are made using a 50/50 saline/serum solution combined with compatible washed RBCs and then heat-treating the pool.
- Low free carnitine (C0(L)) materials are produced by washing fresh RBCs at least six times and then combining with charcoal-stripped serum.
- CFDNA PT materials are made with blood from individual donors who express CF mutations.
- Hemoglobin specimens are made from individual umbilical cord blood units.

PT DATA HANDLING

Participants submit PT data and clinical assessments through the NSQAP data reporting website or by email. Laboratories that submit results before the data-reporting deadline will receive an individual laboratory evaluation and their data will be included in the data summary reports.

tories because each laboratory establishes its own cutoff level. For PT evaluations, the participating laboratory's reported cutoff value is applied to our grading algorithm. If no cutoff value is reported for a particular analytical result, the grading algorithm will default to the NSQAP-assigned working cutoff values, which are based on the domestic mean cutoff value. (Figure 4)

PT CUTOFFS

Participants report the decision level for sorting test results as presumptive positive (outside normal limits) from results reported as negative (within normal limits) based on their laboratory's established cutoff value. Cutoff values vary among participating labora-

Tables 3–5 summarize the reported cutoff values for domestic and foreign laboratories; the values for mean, median, and mode are shown for each analyte. Tables 6–9 summarize the mean, median, mode, and min/max range for reported domestic cutoffs by method.

Table 3. 2015 Summary of Non-MSMS Cutoff Values for Domestic and Foreign Laboratories

Domestic

| Analyte | N | Mean | Median | Mode | Min | Max |
|------------------------------|----|-------|--------|------|-------|-------|
| 17OHP (ng/mL serum) | 43 | 33.7 | 33.0 | 30.0 | 7.0 | 65.0 |
| GALT (U/g Hb) | 19 | 3.2 | 3.1 | 3.0 | 2.0 | 5.5 |
| IRT (ng/mL blood) | 43 | 66.3 | 65.0 | 60.0 | 35.2 | 114.9 |
| T ₄ (µg/dL serum) | 24 | 6.1 | 6.0 | 5.0 | 4.0 | 8.5 |
| TGal (mg/dL blood) | 24 | 10.7 | 10.0 | 10.0 | 6.0 | 20.0 |
| TSH (µIU/mL serum) | 43 | 30.8 | 25.0 | 20.0 | 19.0 | 58.0 |
| Phe (µmol/L blood) | 6 | 169.3 | 166.7 | N/A* | 133.0 | 224.2 |

Foreign

| Analyte | N | Mean | Median | Mode | Min | Max |
|------------------------------|-----|-------|--------|-------|-------|-------|
| 17OHP (ng/mL serum) | 167 | 25.7 | 20.0 | 19.8 | 2.6 | 110.0 |
| GALT (U/g Hb) | 43 | 3.0 | 3.1 | 3.5 | 1.5 | 5.3 |
| IRT (ng/mL blood) | 137 | 65.7 | 65.0 | 60.0 | 40.0 | 99.6 |
| T ₄ (µg/dL serum) | 42 | 6.3 | 6.0 | 6.0 | 1.8 | 22.0 |
| TGal (mg/dL blood) | 116 | 12.0 | 10.0 | 10.0 | 4.1 | 30.0 |
| TSH (µIU/mL serum) | 231 | 22.4 | 20.0 | 20.0 | 5.0 | 45.0 |
| Phe (µmol/L blood) | 65 | 183.4 | 169.9 | 121.2 | 120.0 | 820.8 |

*Not Applicable

Table 4. 2015 Summary of MS/MS Cutoff Values of Domestic Laboratories (μmol/L blood)

| Analyte | N | Mean | Median | Mode | Min | Max |
|-----------|----|-------|--------|-------|-------|-------|
| Arg | 38 | 70.2 | 60.0 | 50.0 | 20.0 | 125.0 |
| Cit | 45 | 55.5 | 55.0 | 60.0 | 18.0 | 100.0 |
| Leu | 46 | 285.1 | 281.0 | 250.0 | 175.0 | 400.0 |
| Met | 46 | 74.5 | 72.5 | 100.0 | 35.0 | 100.0 |
| Phe | 51 | 141.4 | 140.0 | 130.0 | 75.0 | 182.0 |
| SUAC | 30 | 2.7 | 2.3 | 4.5 | 0.5 | 5.4 |
| Tyr | 52 | 386.7 | 338.0 | 400.0 | 88.0 | 850.0 |
| Val | 32 | 293.9 | 277.0 | 250.0 | 200.0 | 530.0 |
| C0(L) | 49 | 8.81 | 8.00 | 8.00 | 4.00 | 33.00 |
| C3 | 50 | 5.68 | 6.00 | 6.30 | 2.82 | 8.00 |
| C3DC | 22 | 0.22 | 0.20 | 0.20 | 0.10 | 0.45 |
| C3DC+C4OH | 20 | 0.57 | 0.41 | 0.38 | 0.25 | 3.03 |
| C4 | 46 | 1.27 | 1.30 | 1.40 | 0.49 | 1.90 |
| C4OH | 20 | 0.65 | 0.70 | 0.70 | 0.35 | 1.00 |
| C5 | 50 | 0.69 | 0.66 | 1.00 | 0.38 | 1.20 |
| C5:1 | 49 | 0.22 | 0.16 | 0.50 | 0.05 | 0.60 |
| C5DC | 49 | 0.35 | 0.32 | 0.50 | 0.05 | 0.80 |
| C5OH | 49 | 0.79 | 0.80 | 0.80 | 0.25 | 1.18 |
| C6 | 47 | 0.39 | 0.29 | 0.24 | 0.16 | 0.95 |
| C8 | 50 | 0.45 | 0.40 | 0.35 | 0.25 | 0.79 |
| C10 | 46 | 0.44 | 0.41 | 0.40 | 0.22 | 0.80 |
| C10:1 | 43 | 0.29 | 0.30 | 0.30 | 0.14 | 0.45 |
| C10:2 | 30 | 0.16 | 0.12 | 0.10 | 0.06 | 0.50 |
| C14 | 45 | 0.75 | 0.70 | 0.70 | 0.26 | 1.20 |
| C14:1 | 50 | 0.61 | 0.65 | 0.60 | 0.17 | 0.80 |
| C16 | 47 | 7.64 | 7.70 | 7.00 | 2.14 | 10.00 |
| C16OH | 50 | 0.13 | 0.12 | 0.10 | 0.07 | 0.25 |
| C18 | 42 | 2.35 | 2.28 | 2.50 | 0.70 | 4.00 |
| C18:1 | 44 | 3.48 | 3.00 | 3.00 | 2.00 | 7.00 |
| C18OH | 39 | 0.11 | 0.10 | 0.10 | 0.04 | 0.26 |

Table 5. 2015 Summary of MS/MS Cutoff Values of Foreign Laboratories (μmol/L blood)

| Analyte | N | Mean | Median | Mode | Min | Max |
|-----------|-----|-------|--------|-------|-------|-------|
| Arg | 177 | 56.9 | 51.0 | 70.0 | 10.0 | 150.0 |
| Cit | 194 | 53.6 | 50.0 | 55.0 | 19.5 | 200.0 |
| Leu | 215 | 308.7 | 300.0 | 300.0 | 147.0 | 600.0 |
| Met | 210 | 57.6 | 55.2 | 75.0 | 19.0 | 121.0 |
| Phe | 232 | 135.8 | 129.0 | 120.0 | 48.0 | 242.4 |
| SUAC | 69 | 2.4 | 1.6 | 1.5 | 0.1 | 10.0 |
| Tyr | 214 | 297.1 | 275.0 | 400.0 | 35.0 | 600.0 |
| Val | 199 | 268.2 | 260.0 | 250.0 | 139.3 | 470.0 |
| C0(L) | 221 | 11.71 | 8.80 | 10.00 | 3.50 | 80.00 |
| C3 | 214 | 5.30 | 5.25 | 6.00 | 1.80 | 11.00 |
| C3DC | 101 | 0.31 | 0.28 | 0.30 | 0.04 | 3.70 |
| C3DC+C4OH | 66 | 0.58 | 0.50 | 0.50 | 0.19 | 2.20 |
| C4 | 200 | 1.01 | 0.98 | 1.30 | 0.31 | 4.00 |
| C4OH | 91 | 0.60 | 0.61 | 0.65 | 0.05 | 1.40 |
| C5 | 223 | 0.69 | 0.64 | 1.00 | 0.20 | 2.00 |
| C5:1 | 192 | 0.17 | 0.15 | 0.25 | 0.01 | 0.50 |
| C5DC | 216 | 0.33 | 0.30 | 0.35 | 0.07 | 1.00 |
| C5OH | 191 | 0.78 | 0.80 | 1.00 | 0.16 | 2.20 |
| C6 | 203 | 0.32 | 0.25 | 0.45 | 0.05 | 1.50 |
| C8 | 228 | 0.36 | 0.32 | 0.30 | 0.07 | 1.42 |
| C10 | 215 | 0.39 | 0.40 | 0.40 | 0.09 | 1.46 |
| C10:1 | 188 | 0.30 | 0.28 | 0.30 | 0.06 | 2.03 |
| C10:2 | 125 | 0.16 | 0.12 | 0.10 | 0.00 | 0.56 |
| C14 | 200 | 0.63 | 0.60 | 0.80 | 0.14 | 1.50 |
| C14:1 | 210 | 0.46 | 0.42 | 0.60 | 0.08 | 1.30 |
| C16 | 213 | 6.62 | 6.90 | 7.50 | 0.51 | 14.00 |
| C16OH | 211 | 0.13 | 0.10 | 0.05 | 0.02 | 0.48 |
| C18 | 199 | 2.18 | 2.03 | 2.50 | 0.71 | 5.00 |
| C18:1 | 189 | 2.96 | 3.00 | 3.50 | 0.20 | 5.80 |
| C18OH | 163 | 0.11 | 0.10 | 0.10 | 0.01 | 2.00 |

Table 6. 2015 Domestic Cutoff Summary by Analyte and Method - Hormones and Galactose

| Analyte | Method | CUTOFF VALUE | | | | | |
|-------------------------------------|---|--------------|-------------|-------------|-------------|-------------|-------------|
| | | N | Mean | Median | Mode | Min | Max |
| 17OHP ng/mL serum | ALL METHODS | 43 | 33.7 | 33.0 | 30.0 | 7.0 | 65.0 |
| | AutoDelfia | 7 | 46.6 | 46.2 | N/A* | 30.0 | 65.0 |
| | AutoDelfia Neonatal 17-OHP (B024) | 17 | 31.4 | 33.0 | 33.0 | 19.0 | 40.0 |
| | PerkinElmer GSP Neonatal | 18 | 32.4 | 30.0 | 25.0 | 25.0 | 60.0 |
| TSH μU/mL serum | ALL METHODS | 43 | 30.8 | 25.0 | 20.0 | 19.0 | 58.0 |
| | AutoDelfia | 24 | 35.1 | 30.0 | 20.0 | 20.0 | 58.0 |
| | PerkinElmer GSP Neonatal | 18 | 25.7 | 25.0 | 25.0 | 19.0 | 35.0 |
| T₄ μg/dL serum | ALL METHODS | 24 | 6.1 | 6.0 | 5.0 | 4.0 | 8.5 |
| | AutoDelfia | 8 | 6.2 | 6.3 | 6.5 | 4.0 | 8.0 |
| | PerkinElmer GSP Neonatal | 15 | 6.1 | 5.5 | 5.0 | 4.0 | 8.5 |
| TGal mg/dL blood | ALL METHODS | 24 | 10.7 | 10.0 | 10.0 | 6.0 | 20.0 |
| | Astoria-Pacific 50 Hour Reagent Kit | 6 | 10.4 | 10.0 | 10.0 | 6.5 | 15.0 |
| | Fluorometric manual (e.g. Hill or Misuma) | 5 | 12.8 | 10.0 | 10.0 | 10.0 | 20.0 |
| | PerkinElmer GSP Neonatal | 3 | 11.4 | 13.0 | N/A* | 7.3 | 14.0 |
| | PerkinElmer Neonatal Kit | 5 | 8.0 | 8.0 | 9.5 | 6.0 | 9.5 |

Table 7. 2015 Domestic Cutoff Summary by Analyte and Method - GALT and IRT

| Analyte | Method | CUTOFF VALUE | | | | | |
|---------------------------|---|--------------|-------------|-------------|-------------|-------------|--------------|
| | | N | Mean | Median | Mode | Min | Max |
| GALT U/g Hb | ALL METHODS | 19 | 3.2 | 3.1 | 3.0 | 2.0 | 5.5 |
| | Astoria-Pacific Neonatal Microplate Reagent Kit | 5 | 2.7 | 2.9 | 3.1 | 2.0 | 3.1 |
| | PerkinElmer Neonatal Kit | 13 | 3.2 | 3.2 | 3.0 | 2.4 | 4.0 |
| IRT ng/mL blood | ALL METHODS | 43 | 66.3 | 65.0 | 60.0 | 35.2 | 114.9 |
| | Auto Delfia | 25 | 69.3 | 66.0 | 67.0 | 37.7 | 114.9 |
| | PerkinElmer GSP Neonatal | 18 | 62.1 | 57.0 | 55.0 | 35.2 | 100.0 |

*N/A - Not Applicable

Table 8. 2015 Domestic Cutoff Summary by Analyte and Method - Amino Acids

| Analyte μmol/ L blood | Method | CUTOFF VALUE | | | | | |
|-----------------------------|---|--------------|--------------|--------------|--------------|--------------|--------------|
| | | N | Mean | Median | Mode | Min | Max |
| Arg | ALL MS/MS Methods | 38 | 70.2 | 60.0 | 50.0 | 20.0 | 125.0 |
| | Derivatized - MS/MS PerkinElmer NeoGram Kit | 6 | 77.5 | 75.0 | 100.0 | 55.0 | 100.0 |
| | Derivatized - MS/MS non-kit | 13 | 48.3 | 35.0 | 30.0 | 20.0 | 125.0 |
| | Non-derivatized - MS/MS PerkinElmer NeoBase Kit | 19 | 83.0 | 100.0 | 50.0 | 50.0 | 125.0 |
| Cit | ALL MS/MS Methods | 45 | 55.5 | 55.0 | 60.0 | 18.0 | 100.0 |
| | Derivatized - MS/MS PerkinElmer NeoGram Kit | 8 | 61.6 | 54.0 | N/A* | 40.0 | 100.0 |
| | Derivatized - MS/MS non-kit | 14 | 45.0 | 40.0 | 40.0 | 18.0 | 75.0 |
| | Non-derivatized - MS/MS PerkinElmer NeoBase Kit | 22 | 59.9 | 60.0 | 60.0 | 50.0 | 85.0 |
| Leu | ALL MS/MS Methods | 46 | 285.1 | 281.0 | 250.0 | 175.0 | 400.0 |
| | Derivatized - MS/MS PerkinElmer NeoGram Kit | 8 | 285.0 | 281.0 | 275.0 | 250.0 | 325.0 |
| | Derivatized - MS/MS non-kit | 15 | 265.3 | 256.0 | 300.0 | 200.0 | 333.0 |
| | Non-derivatized - MS/MS PerkinElmer NeoBase Kit | 22 | 297.7 | 281.5 | 250.0 | 175.0 | 400.0 |
| Met | ALL MS/MS Methods | 46 | 74.5 | 72.5 | 100.0 | 35.0 | 100.0 |
| | Derivatized - MS/MS PerkinElmer NeoGram Kit | 8 | 76.0 | 72.5 | N/A | 60.0 | 100.0 |
| | Derivatized - MS/MS non-kit | 15 | 62.5 | 60.0 | 60.0 | 35.0 | 100.0 |
| | Non-derivatized - MS/MS PerkinElmer NeoBase Kit | 22 | 82.2 | 82.5 | 100.0 | 54.5 | 100.0 |
| Phe | ALL MS/MS Methods | 57 | 144.3 | 150.0 | 130.0 | 75.0 | 224.2 |
| | Derivatized - MS/MS PerkinElmer NeoGram Kit | 8 | 137.6 | 130.0 | 130.0 | 120.0 | 178.0 |
| | Derivatized - MS/MS non-kit | 18 | 136.5 | 137.0 | 150.0 | 99.0 | 182.0 |
| | Non-derivatized - MS/MS PerkinElmer NeoBase Kit | 22 | 150.2 | 157.5 | 165.0 | 120.0 | 180.0 |
| | Non-derivatized - MS/MS non-kit | 3 | 115.3 | 121.0 | N/A* | 75.0 | 150.0 |
| SUAC | ALL MS/MS Methods | 30 | 2.7 | 2.3 | 4.5 | 0.5 | 5.4 |
| | Derivatized - MS/MS non-kit | 10 | 2.5 | 2.8 | 3.3 | 0.5 | 5.0 |
| | Non-derivatized - MS/MS PerkinElmer NeoBase Kit | 19 | 2.6 | 2.0 | 4.5 | 1.0 | 4.5 |
| Tyr | ALL MS/MS Methods | 52 | 386.7 | 358.0 | 400.0 | 88.0 | 850.0 |
| | Derivatized - MS/MS PerkinElmer NeoGram Kit | 8 | 307.3 | 288.0 | 300.0 | 200.0 | 552.0 |
| | Derivatized - MS/MS non-kit | 17 | 311.2 | 300.0 | 400.0 | 88.0 | 442.0 |
| | Non-derivatized - MS/MS PerkinElmer NeoBase Kit | 22 | 518.4 | 445.0 | 850.0 | 300.0 | 850.0 |
| | Non-derivatized - MS/MS non-kit | 3 | 218.3 | 204.0 | N/A* | 91.0 | 360.0 |
| Val | ALL MS/MS Methods | 32 | 293.9 | 277.0 | 250.0 | 200.0 | 530.0 |
| | Derivatized - MS/MS PerkinElmer NeoGram Kit | 6 | 291.3 | 274.0 | 250.0 | 250.0 | 400.0 |
| | Derivatized - MS/MS non-kit | 11 | 269.7 | 250.0 | 200.0 | 200.0 | 420.0 |
| | Non-derivatized - MS/MS PerkinElmer NeoBase Kit | 14 | 317.2 | 312.5 | 250.0 | 250.0 | 530.0 |

Table 9. 2015 Domestic Cutoff Summary by Analyte and Method - Acylcarnitines

| Analyte μmol/ L blood | Method | CUTOFF VALUE | | | | | |
|-----------------------------|---|--------------|-------------|-------------|-------------|-------------|--------------|
| | | N | Mean | Median | Mode | Min | Max |
| C0(L) | ALL MS/MS Methods | 49 | 8.81 | 8.00 | 8.00 | 4.00 | 33.00 |
| | Derivatized - MS/MS PerkinElmer NeoGram Kit | 8 | 11.12 | 10.00 | 12.00 | 10.00 | 13.00 |
| | Derivatized - MS/MS non-kit | 18 | 10.40 | 5.00 | 8.00 | 5.00 | 33.00 |
| | Non-derivatized - MS/MS PerkinElmer NeoBase Kit | 22 | 6.70 | 6.50 | 6.00 | 4.00 | 10.00 |
| C3 | ALL MS/MS Methods | 50 | 5.68 | 6.00 | 6.30 | 2.82 | 8.00 |
| | Derivatized - MS/MS PerkinElmer NeoGram Kit | 8 | 5.52 | 5.38 | 5.00 | 5.00 | 6.23 |
| | Derivatized - MS/MS non-kit | 19 | 5.01 | 5.00 | 5.25 | 2.82 | 7.30 |
| | Non-derivatized - MS/MS PerkinElmer NeoBase Kit | 22 | 6.26 | 6.30 | 6.30 | 4.00 | 8.00 |
| C3DC | ALL MS/MS Methods | 22 | 0.22 | 0.20 | 0.20 | 0.10 | 0.45 |
| | Derivatized - MS/MS PerkinElmer NeoGram Kit | 6 | 0.27 | 0.26 | 0.35 | 0.19 | 0.35 |
| | Derivatized - MS/MS non-kit | 16 | 0.20 | 0.17 | 0.20 | 0.10 | 0.45 |
| C3DC+C4OH | ALL MS/MS Methods | 20 | 0.57 | 0.41 | 0.38 | 0.25 | 3.03 |
| | Non-derivatized - MS/MS PerkinElmer NeoBase Kit | 19 | 0.44 | 0.40 | 0.38 | 0.25 | 0.70 |
| C4 | ALL MS/MS Methods | 46 | 1.27 | 1.30 | 1.30 | 0.49 | 1.90 |
| | Derivatized - MS/MS PerkinElmer NeoGram Kit | 6 | 1.08 | 1.04 | N/A* | 0.81 | 1.40 |
| | Derivatized - MS/MS non-kit | 17 | 1.16 | 1.20 | 1.40 | 0.49 | 1.90 |
| | Non-derivatized - MS/MS PerkinElmer NeoBase Kit | 22 | 1.41 | 1.32 | 1.30 | 1.10 | 1.70 |
| C4OH | ALL MS/MS Methods | 20 | 0.65 | 0.70 | 0.70 | 0.35 | 1.00 |
| | Derivatized - MS/MS PerkinElmer NeoGram Kit | 6 | 0.73 | 0.70 | N/A* | 0.52 | 1.00 |
| | Derivatized - MS/MS non-kit | 14 | 0.68 | 0.70 | 0.70 | 0.35 | 1.00 |
| C5 | ALL MS/MS Methods | 50 | 0.69 | 0.66 | 1.00 | 0.38 | 1.20 |
| | Derivatized - MS/MS PerkinElmer NeoGram Kit | 8 | 0.63 | 0.70 | 0.70 | 0.45 | 0.71 |
| | Derivatized - MS/MS non-kit | 19 | 0.65 | 0.60 | 0.50 | 0.38 | 1.20 |
| | Non-derivatized - MS/MS PerkinElmer NeoBase Kit | 22 | 0.76 | 0.70 | 1.00 | 0.50 | 1.00 |
| C5:1 | ALL MS/MS Methods | 49 | 0.22 | 0.16 | 0.50 | 0.05 | 0.60 |
| | Derivatized - MS/MS PerkinElmer NeoGram Kit | 8 | 0.20 | 0.18 | 0.25 | 0.15 | 0.25 |
| | Derivatized - MS/MS non-kit | 19 | 0.21 | 0.14 | 0.08 | 0.05 | 0.60 |
| | Non-derivatized - MS/MS PerkinElmer NeoBase Kit | 21 | 0.25 | 0.19 | 0.50 | 0.06 | 0.50 |
| C5DC | ALL MS/MS Methods | 49 | 0.35 | 0.32 | 0.50 | 0.05 | 0.80 |
| | Derivatized - MS/MS PerkinElmer NeoGram Kit | 8 | 0.30 | 0.30 | 0.30 | 0.24 | 0.33 |
| | Derivatized - MS/MS non-kit | 19 | 0.18 | 0.18 | 0.21 | 0.05 | 0.32 |
| | Non-derivatized - MS/MS PerkinElmer NeoBase Kit | 21 | 0.52 | 0.50 | 0.50 | 0.35 | 0.80 |
| C5OH | ALL MS/MS Methods | 49 | 0.79 | 0.80 | 0.80 | 0.25 | 1.18 |
| | Derivatized - MS/MS PerkinElmer NeoGram Kit | 8 | 0.74 | 0.70 | 0.65 | 0.60 | 1.00 |
| | Derivatized - MS/MS non-kit | 19 | 0.75 | 0.76 | 1.00 | 0.25 | 1.18 |
| | Non-derivatized - MS/MS PerkinElmer NeoBase Kit | 21 | 0.84 | 0.85 | 0.85 | 0.60 | 1.05 |
| C6 | ALL MS/MS Methods | 47 | 0.39 | 0.29 | 0.24 | 0.16 | 0.95 |
| | Derivatized - MS/MS PerkinElmer NeoGram Kit | 7 | 0.26 | 0.25 | 0.24 | 0.20 | 0.31 |
| | Derivatized - MS/MS non-kit | 18 | 0.34 | 0.30 | 0.22 | 0.16 | 0.86 |
| | Non-derivatized - MS/MS PerkinElmer NeoBase Kit | 21 | 0.47 | 0.29 | 0.95 | 0.20 | 0.95 |

Table 9. (continued)

| Analyte μmol/ L blood | Method | CUTOFF VALUE | | | | | |
|-----------------------------|---|--------------|-------------|-------------|-------------|-------------|--------------|
| | | N | Mean | Median | Mode | Min | Max |
| C8 | ALL MS/MS Methods | 50 | 0.45 | 0.40 | 0.35 | 0.25 | 0.79 |
| | Derivatized - MS/MS PerkinElmer NeoGram Kit | 8 | 0.39 | 0.38 | 0.38 | 0.32 | 0.55 |
| | Derivatized - MS/MS non-kit | 19 | 0.39 | 0.35 | 0.50 | 0.25 | 0.72 |
| | Non-derivatized - MS/MS PerkinElmer NeoBase Kit | 22 | 0.52 | 0.51 | 0.60 | 0.35 | 0.79 |
| C10 | ALL MS/MS Methods | 46 | 0.44 | 0.41 | 0.40 | 0.22 | 0.80 |
| | Derivatized - MS/MS PerkinElmer NeoGram Kit | 7 | 0.38 | 0.40 | 0.42 | 0.27 | 0.50 |
| | Derivatized - MS/MS non-kit | 17 | 0.42 | 0.40 | 0.30 | 0.22 | 0.80 |
| | Non-derivatized - MS/MS PerkinElmer NeoBase Kit | 21 | 0.49 | 0.45 | 0.65 | 0.22 | 0.70 |
| C10:1 | ALL MS/MS Methods | 43 | 0.29 | 0.30 | 0.30 | 0.14 | 0.45 |
| | Derivatized - MS/MS PerkinElmer NeoGram Kit | 7 | 0.31 | 0.30 | 0.30 | 0.30 | 0.36 |
| | Derivatized - MS/MS non-kit | 15 | 0.25 | 0.23 | 0.18 | 0.17 | 0.40 |
| | Non-derivatized - MS/MS PerkinElmer NeoBase Kit | 20 | 0.31 | 0.28 | 0.45 | 0.14 | 0.45 |
| C10:2 | ALL MS/MS Methods | 30 | 0.16 | 0.12 | 0.10 | 0.06 | 0.50 |
| | Derivatized - MS/MS PerkinElmer NeoGram Kit | 6 | 0.15 | 0.15 | 0.15 | 0.10 | 0.20 |
| | Derivatized - MS/MS non-kit | 14 | 0.18 | 0.13 | 0.10 | 0.06 | 0.39 |
| | Non-derivatized - MS/MS PerkinElmer NeoBase Kit | 9 | 0.16 | 0.10 | 0.10 | 0.07 | 0.50 |
| C14 | ALL MS/MS Methods | 45 | 0.75 | 0.70 | 0.70 | 0.26 | 1.20 |
| | Derivatized - MS/MS PerkinElmer NeoGram Kit | 7 | 0.69 | 0.70 | 0.70 | 0.52 | 0.78 |
| | Derivatized - MS/MS non-kit | 16 | 0.65 | 0.70 | 0.70 | 0.26 | 0.85 |
| | Non-derivatized - MS/MS PerkinElmer NeoBase Kit | 21 | 0.84 | 0.75 | 1.20 | 0.58 | 1.20 |
| C14:1 | ALL MS/MS Methods | 50 | 0.61 | 0.65 | 0.60 | 0.17 | 0.80 |
| | Derivatized - MS/MS PerkinElmer NeoGram Kit | 8 | 0.60 | 0.63 | N/A* | 0.40 | 0.77 |
| | Derivatized - MS/MS non-kit | 19 | 0.55 | 0.64 | 0.65 | 0.17 | 0.75 |
| | Non-derivatized - MS/MS PerkinElmer NeoBase Kit | 22 | 0.67 | 0.67 | 0.80 | 0.50 | 0.80 |
| C16 | ALL MS/MS Methods | 47 | 7.64 | 7.70 | 7.00 | 2.14 | 10.00 |
| | Derivatized - MS/MS PerkinElmer NeoGram Kit | 6 | 7.19 | 7.10 | 7.00 | 6.65 | 7.80 |
| | Derivatized - MS/MS non-kit | 18 | 6.67 | 6.88 | 8.00 | 2.14 | 9.00 |
| | Non-derivatized - MS/MS PerkinElmer NeoBase Kit | 22 | 8.52 | 8.50 | 10.00 | 7.00 | 10.00 |
| C16OH | ALL MS/MS Methods | 50 | 0.13 | 0.12 | 0.10 | 0.07 | 0.25 |
| | Derivatized - MS/MS PerkinElmer NeoGram Kit | 8 | 0.17 | 0.17 | 0.12 | 0.12 | 0.25 |
| | Derivatized - MS/MS non-kit | 19 | 0.13 | 0.13 | 0.10 | 0.08 | 0.25 |
| | Non-derivatized - MS/MS PerkinElmer NeoBase Kit | 22 | 0.11 | 0.10 | 0.10 | 0.07 | 0.20 |
| C18 | ALL MS/MS Methods | 42 | 2.35 | 2.28 | 2.50 | 0.70 | 4.00 |
| | Derivatized - MS/MS PerkinElmer NeoGram Kit | 6 | 2.31 | 2.25 | N/A* | 1.89 | 3.00 |
| | Derivatized - MS/MS non-kit | 14 | 1.85 | 1.83 | 1.80 | 0.70 | 2.50 |
| | Non-derivatized - MS/MS PerkinElmer NeoBase Kit | 21 | 2.70 | 2.50 | 3.50 | 1.55 | 4.00 |
| C18:1 | ALL MS/MS Methods | 44 | 3.48 | 3.00 | 3.00 | 2.00 | 7.00 |
| | Derivatized - MS/MS PerkinElmer NeoGram Kit | 6 | 2.91 | 2.80 | N/A* | 2.43 | 3.50 |
| | Derivatized - MS/MS non-kit | 16 | 2.71 | 2.68 | 3.00 | 2.00 | 3.50 |
| | Non-derivatized - MS/MS PerkinElmer NeoBase Kit | 21 | 4.22 | 3.29 | 7.00 | 2.27 | 7.00 |
| C18OH | ALL MS/MS Methods | 39 | 0.11 | 0.10 | 0.10 | 0.04 | 0.26 |
| | Derivatized - MS/MS PerkinElmer NeoGram Kit | 7 | 0.14 | 0.14 | 0.10 | 0.10 | 0.20 |
| | Derivatized - MS/MS non-kit | 13 | 0.09 | 0.10 | 0.10 | 0.04 | 0.18 |
| | Non-derivatized - MS/MS PerkinElmer NeoBase Kit | 18 | 0.09 | 0.10 | 0.10 | 0.04 | 0.16 |

PT ERRORS

Screening programs are designed to minimize false negative reports, but this precautionary approach could result in false positive misclassifications. Laboratories should monitor false positive misclassifications to keep them as low as possible.

Tables 10 and 11 show the PT errors reported in 2015 by domestic and foreign laboratories for qualitative assessments by disorder/analyte. Because of specific clinical assessment practices, presumptive clinical classifications (qualitative assessments) of some specimens might differ by participant. As stated previously, if participants provided their cutoff values, those cutoffs were applied

Table 10. 2015 Summary of Proficiency Testing Errors by Domestic Laboratories

| Disorder | Positive Specimens Assayed (N) | False Negative Errors (%) | Negative Specimens Assayed (N) | False Positive Errors (%) |
|--------------------------------|--------------------------------|---------------------------|--------------------------------|---------------------------|
| Congenital Adrenal Hyperplasia | 129 | 0.0 | 511 | 0.4 |
| Biotinidase Deficiency | 170 | 0.0 | 470 | 0.0 |
| GALT Deficiency | 214 | 0.5 | 426 | 0.0 |
| G6PD Deficiency | 2 | 0.0 | 6 | 0.0 |
| Immunoreactive Trypsinogen | 260 | 0.0 | 390 | 0.0 |
| Congenital Hypothyroidism | 264 | 0.0 | 731 | 0.0 |
| Galactosemia | 47 | 0.0 | 308 | 0.0 |
| Arginine Screen | 113 | 0.0 | 452 | 0.0 |
| Citrulline Screen | 138 | 0.0 | 552 | 0.0 |
| Leucine Screen | 140 | 0.0 | 560 | 0.5 |
| Methionine Screen | 138 | 0.0 | 552 | 0.0 |
| Phenylalanine Screen | 175 | 0.6 | 700 | 0.0 |
| Succinylacetone Screen | 91 | 0.0 | 364 | 0.0 |
| Tyrosine Screen | 162 | 1.2 | 648 | 0.0 |
| Valine Screen | 98 | 0.0 | 392 | 0.0 |
| C0(L) Screen | 146 | 1.4 | 584 | 0.0 |
| C3 Screen | 149 | 0.0 | 596 | 0.0 |
| C3DC Screen | 65 | 0.0 | 260 | 0.0 |
| C3DC+C4OH Screen | 120 | 1.7 | 180 | 0.0 |
| C4 Screen | 136 | 5.2 | 544 | 0.0 |
| C4OH Screen | 63 | 1.6 | 252 | 1.2 |
| C5 Screen | 149 | 0.7 | 596 | 0.2 |
| C5:1 Screen | 146 | 4.1 | 584 | 0.0 |
| C5OH Screen | 146 | 0.0 | 584 | 1.2 |
| C6 Screen | 140 | 3.6 | 560 | 0.0 |
| C8 Screen | 149 | 0.0 | 596 | 0.0 |
| C10 Screen | 137 | 0.0 | 548 | 0.0 |
| C10:1 Screen | 131 | 0.0 | 524 | 0.0 |
| C10:2 Screen | 87 | 1.2 | 348 | 0.0 |
| C14 Screen | 138 | 4.4 | 552 | 0.0 |
| C16 Screen | 140 | 1.4 | 560 | 0.2 |
| C18 Screen | 128 | 0.0 | 512 | 0.0 |
| C5DC Screen | 146 | 0.0 | 584 | 0.0 |
| C14:1 Screen | 149 | 1.3 | 596 | 0.2 |
| C16OH Screen | 198 | 0.0 | 547 | 0.0 |
| C18:1 Screen | 131 | 0.0 | 524 | 0.0 |
| C18OH Screen | 115 | 1.7 | 460 | 0.0 |
| XALD screen | 8 | 0.0 | 12 | 0.0 |

in the final evaluation of the error judgment. (Figure 4). The rates for false positive misclassifications are based on the number of negative specimens tested, and the rates for false negative misclassifications on the number of positive specimens tested.

A few of our PT specimens fall close to the decision level for clinical assessment, and thus, rigorously tested the ability of laboratories to make the expected cutoff decision. Most specimens near the mean cutoff value are classified as not-evaluated specimens. As such, they are not included in the error calculations.

Table 11. 2015 Summary of Proficiency Testing Errors by Foreign Laboratories

| Disorder | Positive Specimens Assayed (N) | False Negative Errors (%) | Negative Specimens Assayed (N) | False Positive Errors (%) |
|--------------------------------|--------------------------------|---------------------------|--------------------------------|---------------------------|
| Congenital Adrenal Hyperplasia | 517 | 1.0 | 2093 | 1.1 |
| Biotinidase Deficiency | 453 | 0.9 | 1257 | 0.6 |
| GALT Deficiency | 343 | 0.9 | 682 | 0.2 |
| G6PD Deficiency | 30 | 3.3 | 90 | 1.1 |
| Immunoreactive Trypsinogen | 818 | 1.7 | 1227 | 0.3 |
| Congenital Hypothyroidism | 1142 | 0.6 | 3133 | 0.8 |
| Galactosemia | 246 | 0.4 | 1574 | 0.4 |
| Arginine Screen | 555 | 2.0 | 2220 | 0.8 |
| Citrulline Screen | 606 | 0.8 | 2424 | 0.6 |
| Leucine Screen | 674 | 0.9 | 2696 | 0.3 |
| Methionine Screen | 656 | 1.8 | 2624 | 0.8 |
| Phenylalanine Screen | 916 | 0.7 | 3664 | 1.5 |
| Succinylacetone Screen | 221 | 1.8 | 884 | 0.9 |
| Tyrosine Screen | 670 | 1.2 | 2680 | 0.4 |
| Valine Screen | 619 | 1.0 | 2476 | 0.5 |
| C0(L) Screen | 675 | 4.9 | 2700 | 1.2 |
| C3 Screen | 654 | 1.7 | 2616 | 0.9 |
| C3DC Screen | 308 | 1.3 | 1232 | 1.8 |
| C3DC+C4OH Screen | 422 | 5.7 | 633 | 1.3 |
| C4 Screen | 612 | 2.6 | 2448 | 0.9 |
| C4OH Screen | 282 | 3.9 | 1128 | 2.0 |
| C5 Screen | 680 | 1.3 | 2720 | 0.7 |
| C5OH Screen | 594 | 0.5 | 2376 | 3.8 |
| C5:1 Screen | 596 | 2.5 | 2384 | 1.0 |
| C5DC Screen | 664 | 1.4 | 2656 | 0.9 |
| C6 Screen | 632 | 1.4 | 2528 | 1.0 |
| C8 Screen | 692 | 1.0 | 2768 | 0.8 |
| C10 Screen | 665 | 1.5 | 2660 | 0.5 |
| C10:1 Screen | 594 | 2.7 | 2376 | 2.0 |
| C10:2 Screen | 404 | 2.0 | 1616 | 0.6 |
| C14 Screen | 623 | 2.1 | 2492 | 1.2 |
| C14:1 Screen | 652 | 1.7 | 2608 | 0.9 |
| C16 Screen | 657 | 2.0 | 2628 | 0.4 |
| C16OH Screen | 868 | 3.9 | 2387 | 1.1 |
| C18 Screen | 616 | 0.7 | 2464 | 0.7 |
| C18:1 Screen | 587 | 3.9 | 2348 | 0.9 |
| C18OH Screen | 504 | 3.0 | 2016 | 1.3 |
| XALD Screen | 4 | 0.0 | 6 | 0.0 |

SICKLE CELL DISEASE AND OTHER HEMOGLOBINOPATHIES PT PROGRAM

Table 12 show the summary of PT errors for the 2015 Sickle Cell and Hemoglobinopathy program by domestic and foreign laboratories. Table 13 shows the challenges distributed in 2015 for the sickle cell disease and other hemoglobinopathies and Table 14 shows the methods

used by laboratories testing for them. Participants are evaluated on hemoglobin presumptive phenotypes and ability to provide correct presumptive clinical assessments.

Table 12: Summary of Proficiency Testing Errors for Hemoglobinopathies by Domestic and Foreign Laboratories in 2015

| Testing Errors | Domestic | Foreign |
|--|----------|---------|
| Specimens assayed | 725 | 350 |
| Presumptive phenotype errors | 2.6% | 3.4% |
| Presumptive clinical assessment errors | 0.7% | 1.2% |

Table 13. 2015 Hemoglobinopathies Accepted Presumptive Phenotype Distribution

| Panel | Specimen 1 | Specimen 2 | Specimen 3 | Specimen 4 | Specimen 5 |
|---------|------------|------------|---|------------|------------|
| Panel 1 | FA | FAS | FAE FAV FAC for IEF only labs FA + Other | FA | FA |
| Panel 2 | FAC | FAS | FA | FA | FAS |
| Panel 3 | FAE or FAV | FA | FAC | FA | FAS |

Table 14. Frequency of Reported Hemoglobinopathy Methods

| Method | Bio-Rad Screening HPLC | Isoelectric Focusing | Primus Ultra 2 HPLC | Extended Gradient HPLC | Electrophoresis – Cellulose Acetate | PCR Amplification of DNA | Electrophoresis – Citrate Agar |
|------------|------------------------|----------------------|---------------------|------------------------|-------------------------------------|--------------------------|--------------------------------|
| Primary | 38 | 27 | 5 | 0 | 0 | 0 | 0 |
| Secondary | 7 | 23 | 4 | 3 | 1 | 1 | 0 |
| Tertiary | 2 | 1 | 0 | 0 | 0 | 0 | 2 |
| Quaternary | 1 | 0 | 0 | 0 | 0 | 0 | 0 |

CYSTIC FIBROSIS DNA MUTATION PT PROGRAM

Table 15 shows the PT errors for the CFDNA program. This program provides evaluations based on the allele identification and clinical assessment. Allele detection

is dependent on the method used. Table 16 summarizes the CF mutation challenges distributed in 2015.

TABLE 15. Summary of Proficiency Testing Errors for Cystic Fibrosis DNA Mutation Detection Specimens Distributed in 2015

| Quarter, Year | Specimens Assayed (N) | Number of Incorrect Genotypes | Correct Clinical Assessments | Incorrect Clinical Assessments | No Clinical Assessment Reported* | No Data Submitted |
|---------------|-----------------------|-------------------------------|------------------------------|--------------------------------|----------------------------------|-------------------|
| Q1, 2015 | 310 | 8 | 98.7% | 1.3% | 2.9% | 3.1% |
| Q2, 2015 | 310 | 3 | 99.4% | 0.6% | 0.3% | 4.6% |
| Q3, 2015 | 310 | 6 | 99.0% | 1.0% | 0.0% | 7.5% |
| Q4, 2015 | 315 | 2 | 99.4% | 0.6% | 0.0% | 6.0% |
| Total | 1245 | 19 | 99.1% | 0.9% | 0.8% | 5.3% |

*This includes specimens where the PCR failed or participant failed to include a clinical assessment.

TABLE 16. Cystic Fibrosis DNA Mutation (CFTR gene) Challenges Distributed in 2015

| Mutation (Legacy Name) | Mutation (HGVS Nomenclature) | Mutations sent |
|------------------------|------------------------------|----------------|
| F508del | c.1521_1523delCTT | 13 |
| Wild type/no mutation | Wild type/no mutation | 12 |
| G542X | c.1624G>T | 2 |
| R1158X | c.3472C>T | 1 |
| 3849+10kbC>T | c.3717+12191C>T | 1 |
| S549N | c.1646G>A | 1 |
| 3272-26A>G | c.3140-26A>G | 1 |
| W1282X | c.3846G>A | 2 |
| 1898+1G>A | c.1766+1G>A | 1 |
| F508C | c.1523C>G | 1 |
| 3659delC | c.3528delC | 1 |
| G551D | c.1652G>A | 1 |
| R117H | c.350G>A | 1 |
| 621+1G>T | c.489+1G>T | 1 |
| S492F | c. 1475C>T | 1 |

Note: Five specimens are sent each of the four quarters and each sample has two mutations or wild type sequences.

PT BIAS PLOTS

Figures 5 – 40 are illustrated for PT analytes reported using the NSQAP data reporting website. A wide range of quantitatively measured PT challenges are selected for the bias plots. Comparisons of results by different methods are illustrated with the participants' reported PT data for one selected challenge for each analyte.

The expected value of each specimen equals the sum of the enriched value and the endogenous (non-enriched) value. GALT, G6PD, and C0(L) use CDC-assayed values due to production methods for deficient analytes. IRT standard cannot be fully recovered by any IRT analytical method; therefore, IRT PT uses CDC-assayed values.

A growing number of NSQAP participants use a non-derivatized MS/MS method for amino acids and acyl-carnitine analysis. However, non-derivatized MS/MS methods cannot distinguish between analytes C3DC and C4OH (i.e., they are isobaric). Laboratories using a non-derivatized MS/MS method report C3DC+C4OH, while derivatized MS/MS method users continue to report those analytes separately.

These bias plots show the difference of the reported value (positive or negative) by laboratory and method subtracted from the expected or assayed value. To illustrate method-related differences in analyte recoveries, the PT quantitative results are grouped by kit or method.

For each plot, note the scale-changes of the Y-axis. A reported value matching the expected value falls on the plot's "0" line. For each figure, a summary of the specimen data for the selected PT challenge is tabulated in the left margin. Ideally, a reasonable bias is less than 20% of the expected value (EV).

The bias plots (Figures 5-40) illustrate the 95% CI for the participant mean. A tight scatter within this interval indicates good performance for a method or a group of methods. In general, the quantitative comparisons for PT challenges are reasonable within a method but vary among methods. Because some of the pools in a routine PT survey represent a unique donor specimen, differences in endogenous concentration levels in the donor specimens might influence differences in methods.

Figure 4. EXPLANATION OF THE NEWBORN SCREENING QUALITY ASSURANCE PROGRAM'S GRADING ALGORITHM

Part 1

The **NSQAP Expected Clinical Assessment** for PT specimens is determined by comparing the NSQAP Expected Certified Value and the NSQAP Cutoff. The **NSQAP Certified Expected Value** is the sum of the endogenous value plus the enrichment value for an individual analyte. The enrichments for each PT specimen are calculated so that the 95% confidence interval falls above or below the NSQAP cutoff value. The **NSQAP Cutoff Value** is determined annually by using the mean of all domestic laboratories' reported cutoff values as a guideline.

Part 2

The participant reports the clinical assessment as "within normal limits" or "outside normal limits." This is the **Participant Reported Clinical Assessment**. The **Participant Expected Clinical Assessment** is the assessment that is expected when the NSQAP Certified Expected Value and the participant cutoff are compared. When the Participant Reported Clinical Assessment differs from the NSQAP Expected Clinical Assessment, the grading algorithm is used to evaluate test performance. The algorithm will determine if the Participant Reported Clinical Assessment is correct, false negative, false positive or cutoff difference.

- If the NSQAP *Expected* Clinical Assessment is the same as the Participant *Expected* Clinical Assessment but the Participant *Reported* Assessment differs, the grade will be either false negative or false positive.
- If the NSQAP *Expected* Clinical Assessment and the Participant *Expected* Clinical Assessment differ, the Participant *Reported* clinical assessment will not be graded as incorrect. (If a cutoff is not provided by the participant, the evaluation will be based on the NSQAP Cutoff Value)

Part 3

Determination of a final evaluation for a specimen is based on the Clinical Laboratory Improvement Amendments (CLIA) regulations whereby the PT provider "must compare the laboratory's response for each analyte with the response that reflects agreement of either 80% of ten or more referee laboratories or 80% or more of all participating laboratories." (CLIA Regulations, 2004). An NSQAP gradable specimen must have 80% or more agreement among **domestic** laboratories. A specimen with less than 80% agreement is not-gradable/not-evaluated.

Example of TSH false positive –

NSQAP Certified Expected Value = 13 μ U/mL

NSQAP Cutoff = 30 μ U/mL

Participant cutoff = 35 μ U/mL

Participant's Reported Clinical Assessment =
2- Outside Normal Limits for this sample.

1. Comparison of the NSQAP Certified Expected Value and NSQAP Cutoff:

NSQAP Certified Expected Value = 13 μ U/mL

NSQAP Cutoff = 30 μ U/mL

Therefore, the NSQAP Expected Clinical Assessment = *1- Within Normal Limits*

2. Comparison of the NSQAP Certified Expected Value and Participant Cutoff

NSQAP Certified Expected Value = 13 μ U/mL

Participant Cutoff = 35 μ U/mL

Therefore the Participant Expected Clinical Assessment = *1- Within Normal Limits*

3. Participant Reported Clinical Assessment = 2-Outside Normal Limits

In this example, the NSQAP Expected Clinical Assessment and the Participant Expected Clinical Assessment were both "1- Within Normal Limits" but the Participant Reported Clinical Assessment is "2- Outside Normal Limits" therefore:

Participant Evaluation Result = false positive

Sample Table: Participant Evaluation Determination

| Analyte | Expected Value (EV) | NSQAP Cutoff | Participant Cutoff | Assessment: Comparison of EV and NSQAP Cutoff | Assessment: Comparison of EV and Participant Cutoff | Assessment: Participant Reported Clinical Assessment | Participant Evaluation Result |
|---------|---------------------|--------------|--------------------|---|---|--|-------------------------------|
| TSH | 13 | 30 | 35 | wnl | wnl | onl | false positive |
| TSH | 13 | 30 | 10 | wnl | onl | onl | cutoff difference |
| TSH | 50 | 30 | 35 | onl | onl | wnl | false negative |
| TSH | 50 | 30 | 60 | onl | wnl | wnl | cutoff difference |

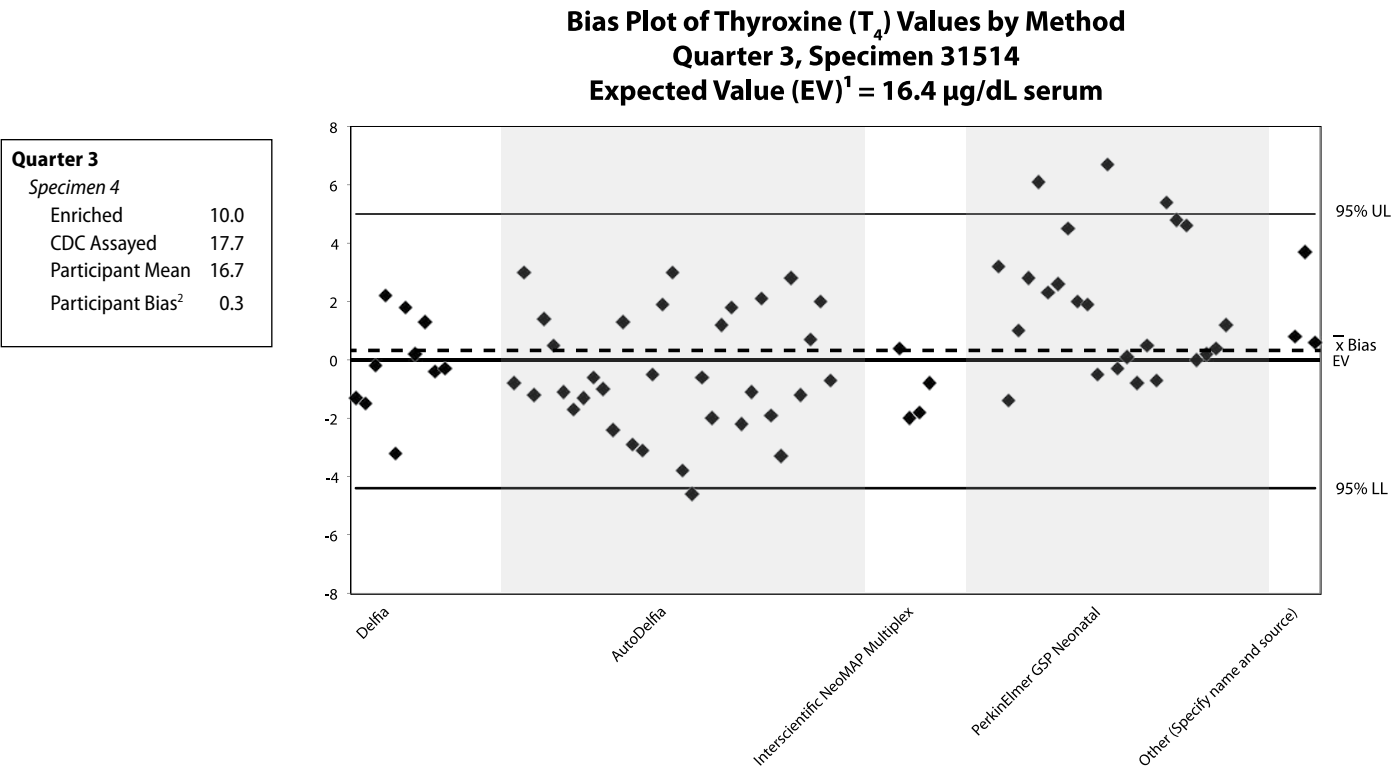
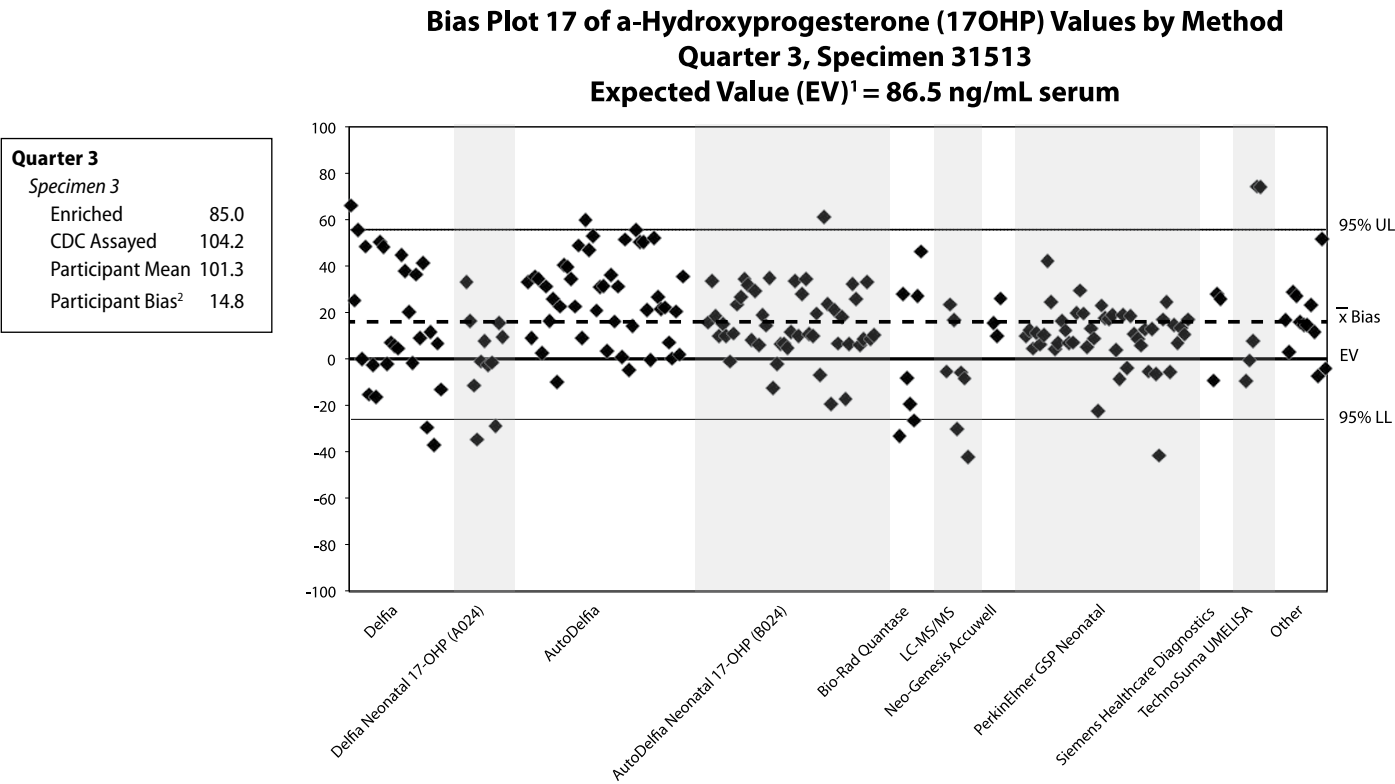
wnl- "1- Within Normal Limits"

onl -"2- Outside Normal limits"

Reference: CLIA Regulations Subpart I—Proficiency Testing Programs for Nonwaived Testing. [Updated 2004 July 7; accessed 2014 January 31]. Available from http://wwwn.cdc.gov/clia/regs/subpart_i.aspx#493.931

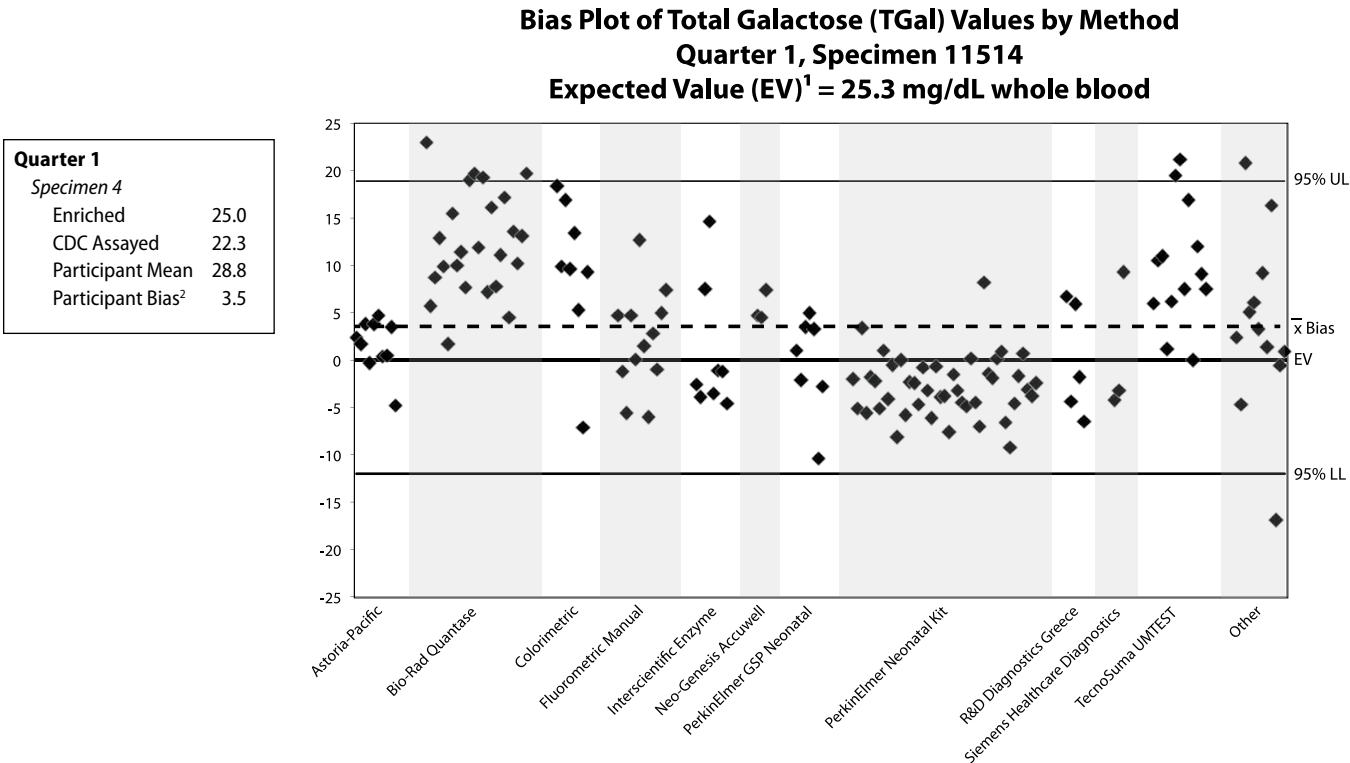
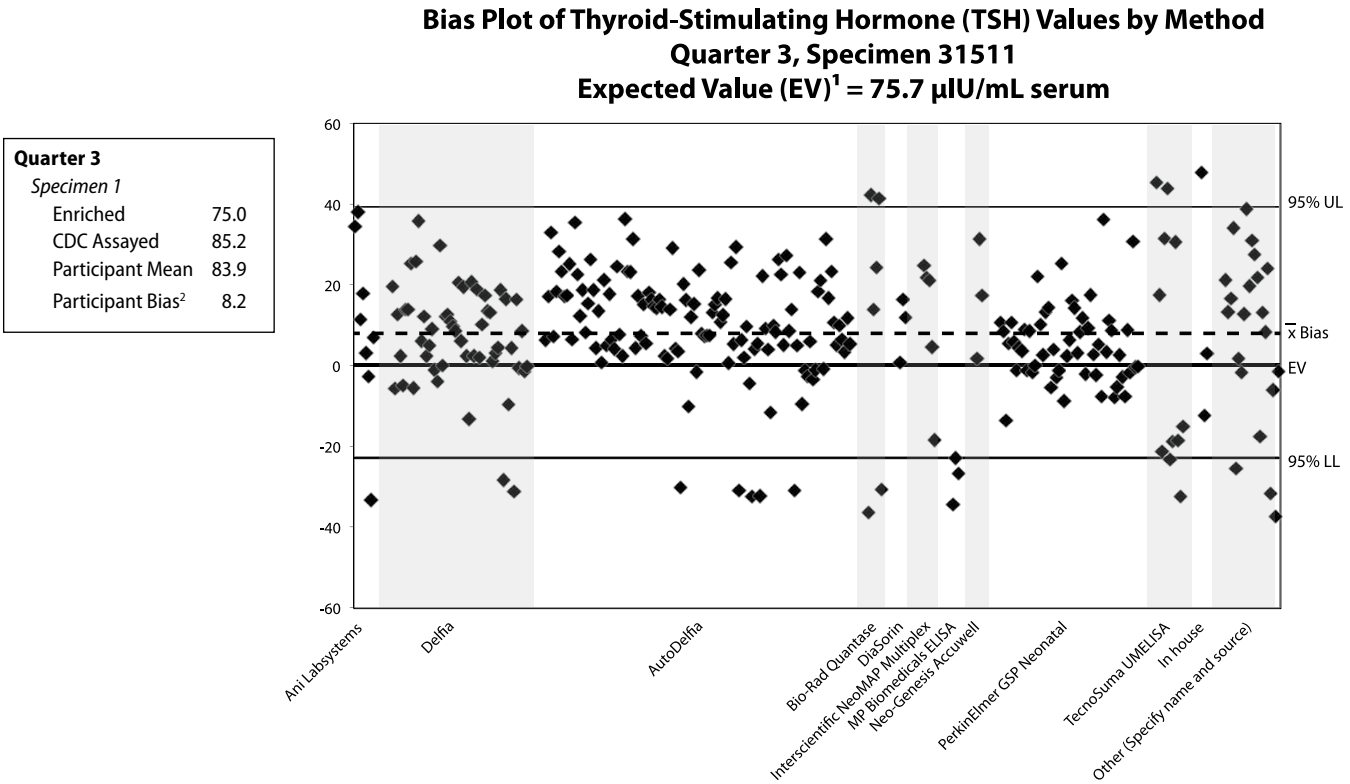
Grading is based on the participant reported clinical assessment, not on the reported value. Overall statistics, which are generated from all participant data, and mean reported concentrations by method are provided on the website for analytical reference only.

FIGURES 5-6. Reproducibility of Results by Method: 17 α -Hydroxyprogesterone (17OHP) and Thyroxine (T₄)



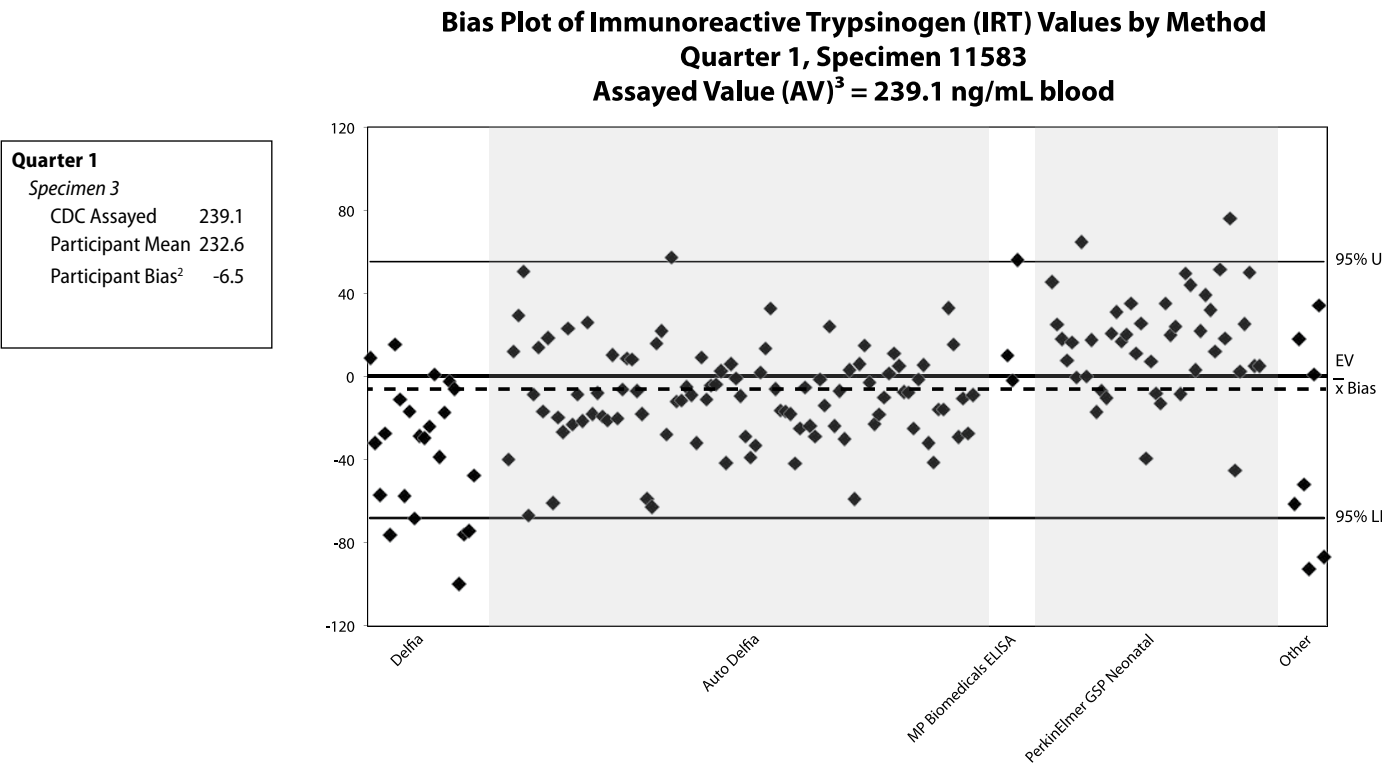
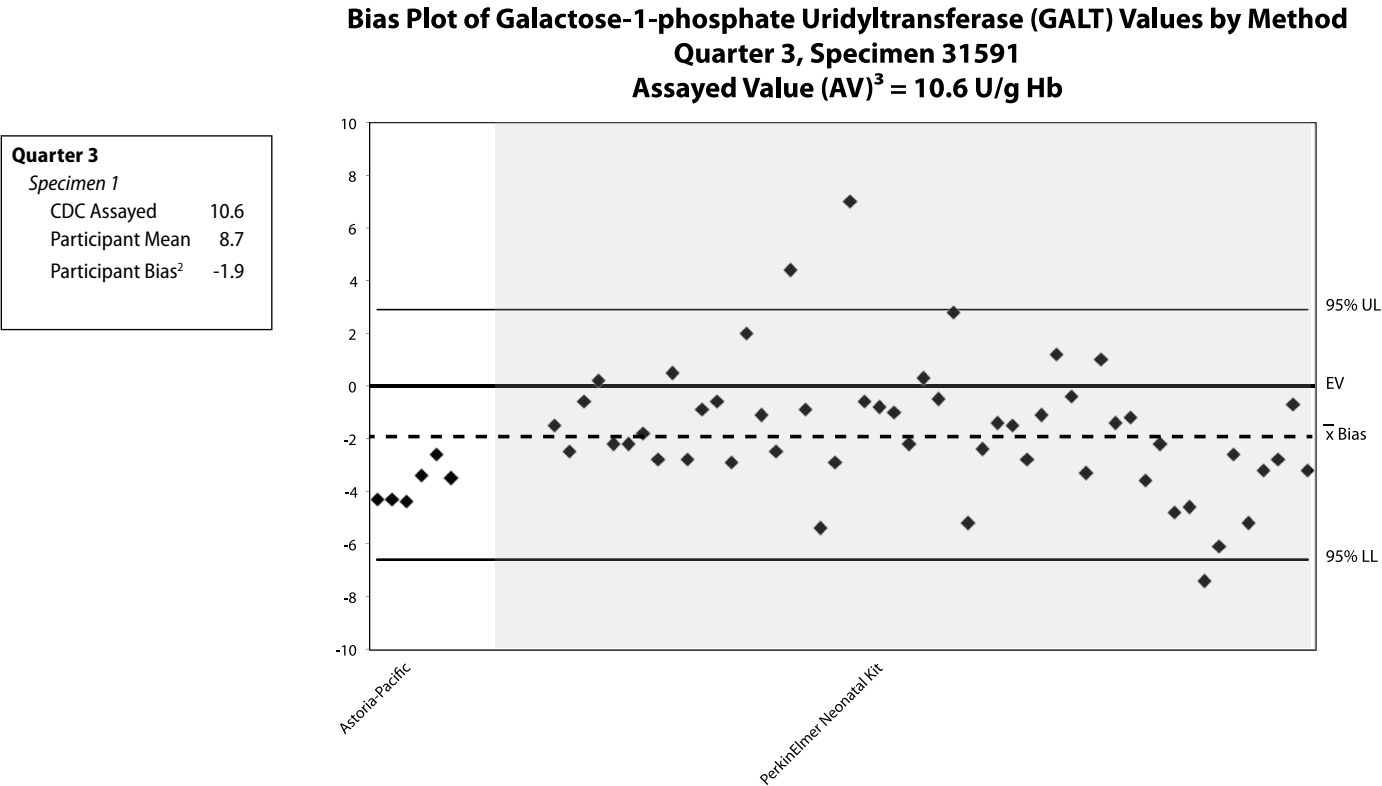
¹EV is the sum of the endogenous and enrichment values. The solid line represents perfect agreement with the EV or zero bias.
²Participant bias (X) is the mean value of all participants' assayed values minus EV; represented by the broken line. Participant bias (X) excludes outlier values.
The 95% confidence interval is shown.
³AV is the CDC assayed value. The solid line represents perfect agreement with the AV or zero bias.

FIGURES 7-8. Reproducibility of Results by Method: Thyroid-Stimulating Hormone (TSH) and Total Galactose (TGal)



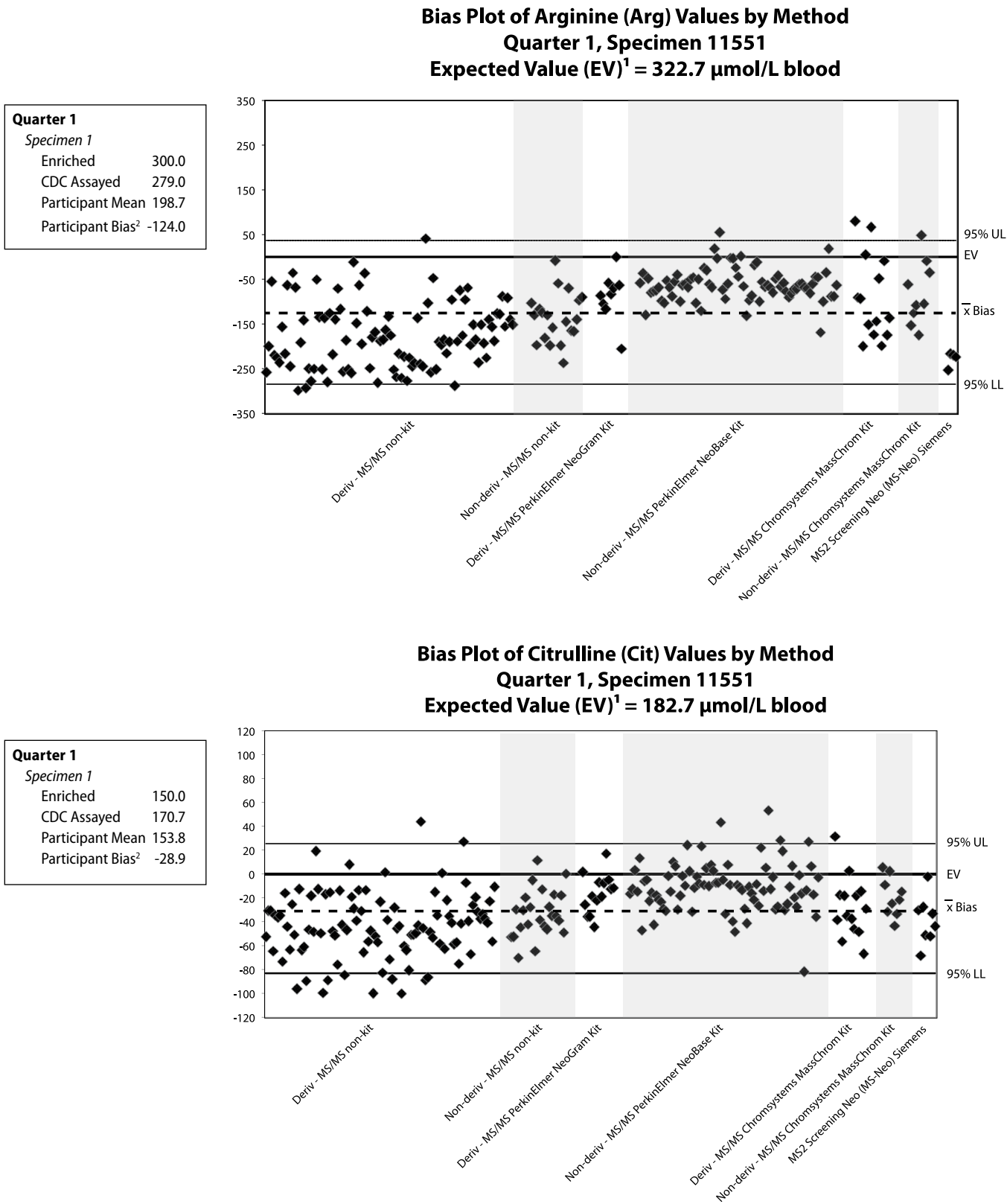
¹EV is the sum of the endogenous and enrichment values. The solid line represents perfect agreement with the EV or zero bias.
²Participant bias (X) is the mean value of all participants' assayed values minus EV; represented by the broken line. Participant bias (X) excludes outlier values.
The 95% confidence interval is shown.
³AV is the CDC assayed value. The solid line represents perfect agreement with the AV or zero bias.

FIGURES 9-10. Reproducibility of Results by Method: Galactose-1-phosphate Uridyltransferase (GALT) and Immunoreactive Trypsinogen (IRT)



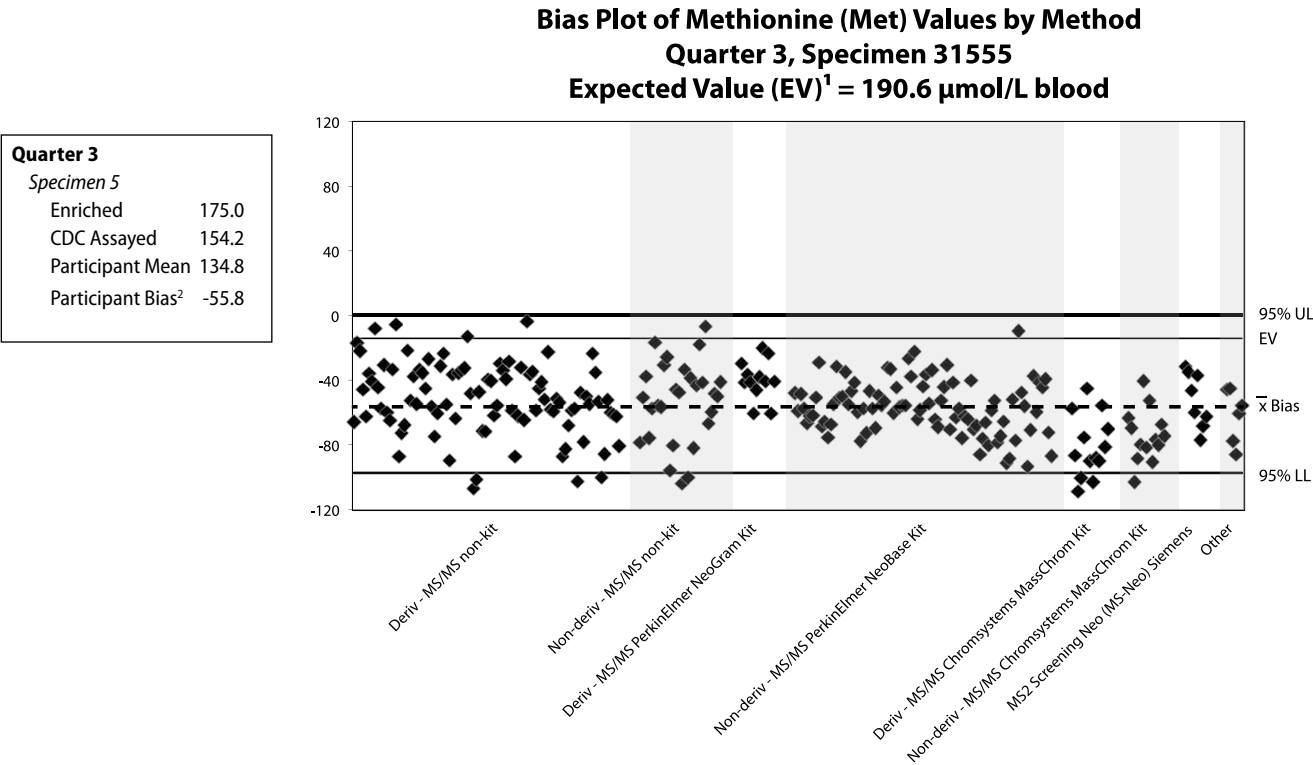
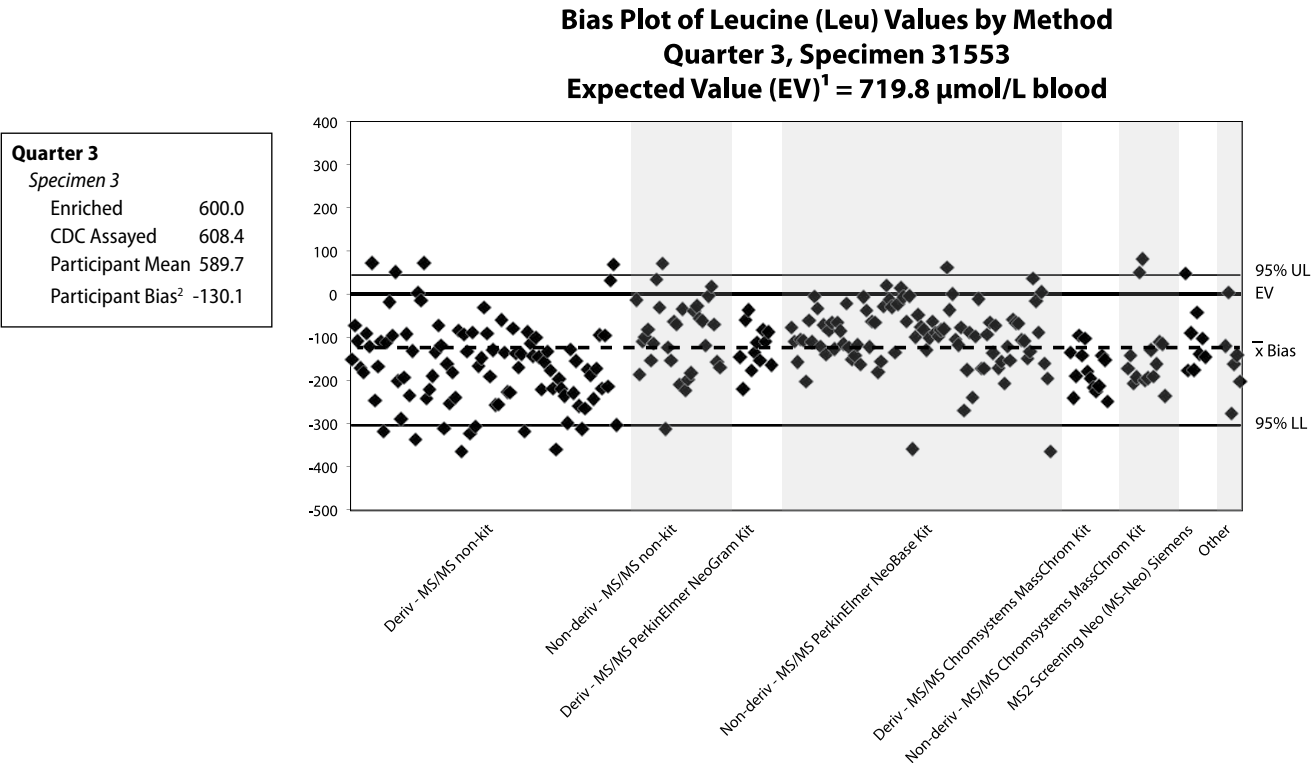
¹EV is the sum of the endogenous and enrichment values. The solid line represents perfect agreement with the EV or zero bias.
²Participant bias (X) is the mean value of all participants' assayed values minus EV; represented by the broken line. Participant bias (X) excludes outlier values.
The 95% confidence interval is shown.
³AV is the CDC assayed value. The solid line represents perfect agreement with the AV or zero bias.

FIGURES 11-12. Reproducibility of Results by Method: Arginine (Arg) and Citrulline (Cit)



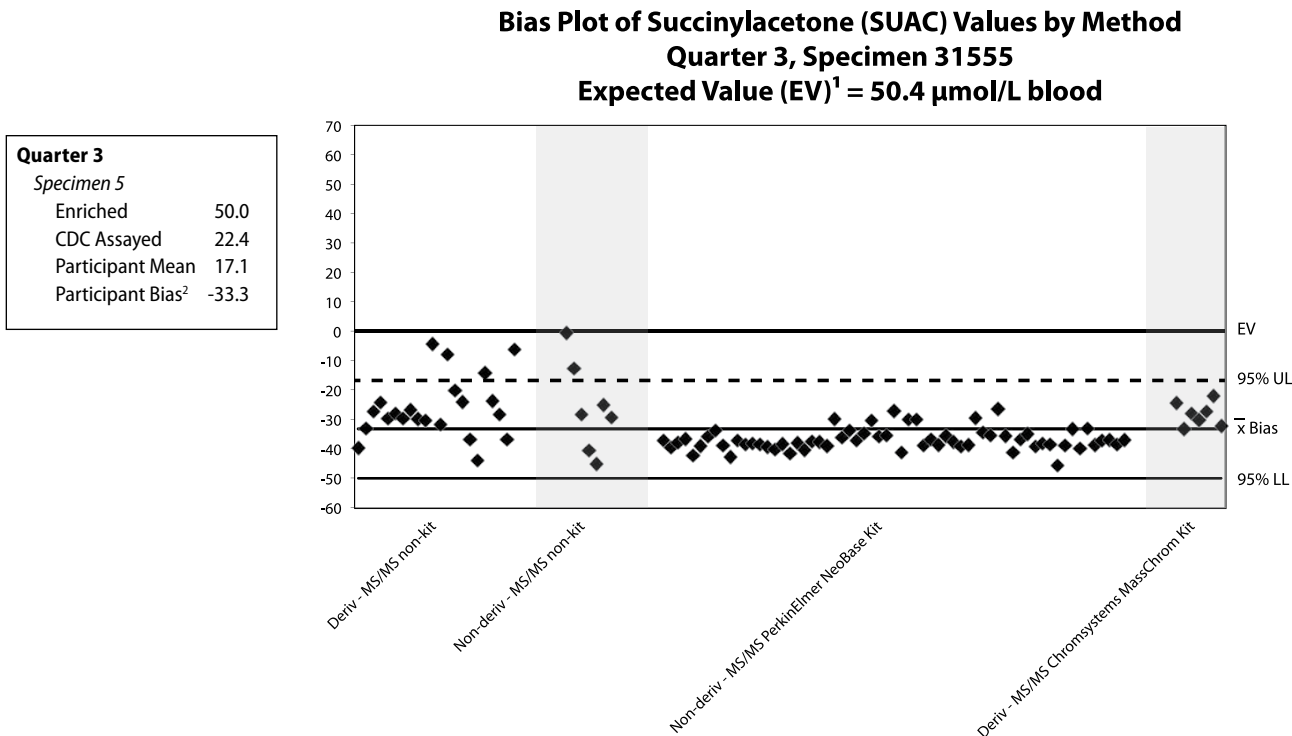
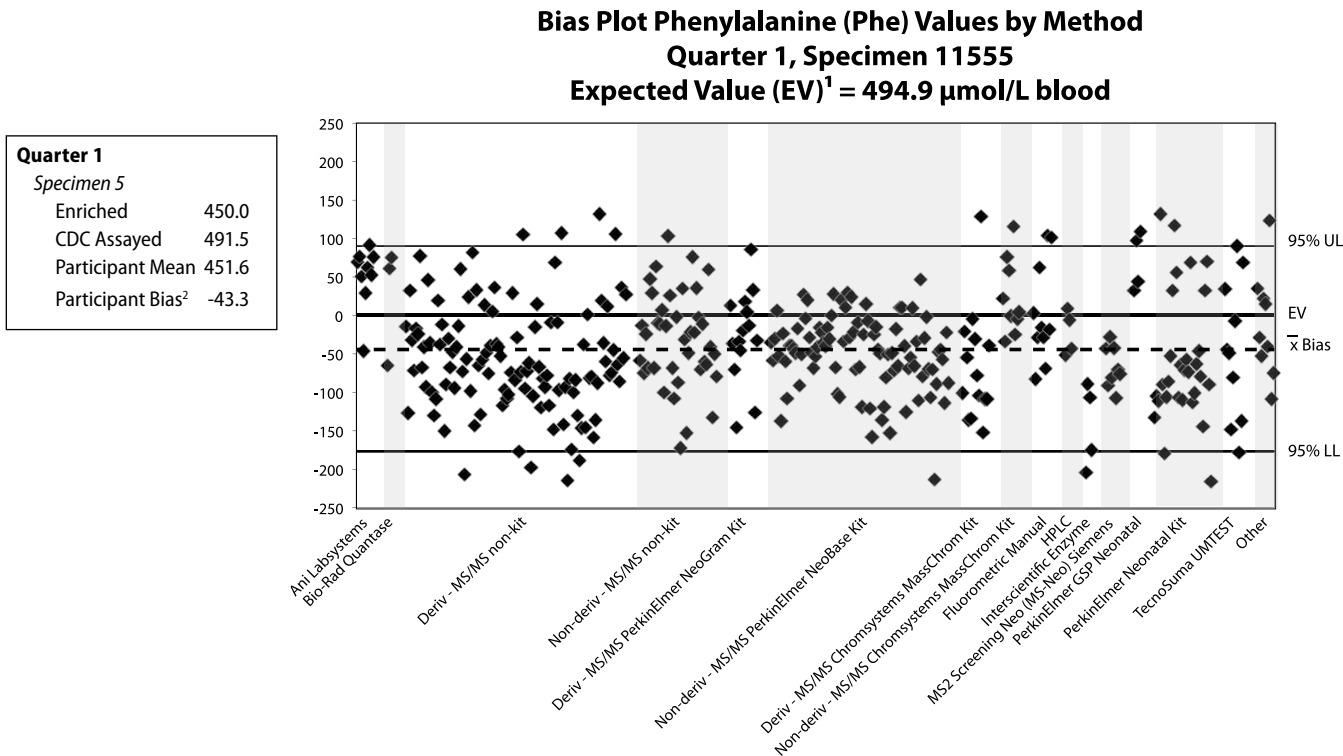
¹EV is the sum of the endogenous and enrichment values. The solid line represents perfect agreement with the EV or zero bias.
²Participant bias (X) is the mean value of all participants' assayed values minus EV; represented by the broken line. Participant bias (X) excludes outlier values.
The 95% confidence interval is shown.
³AV is the CDC assayed value. The solid line represents perfect agreement with the AV or zero bias.

FIGURES 13-14. Reproducibility of Results by Method: Leucine (Leu) and Methionine (Met)



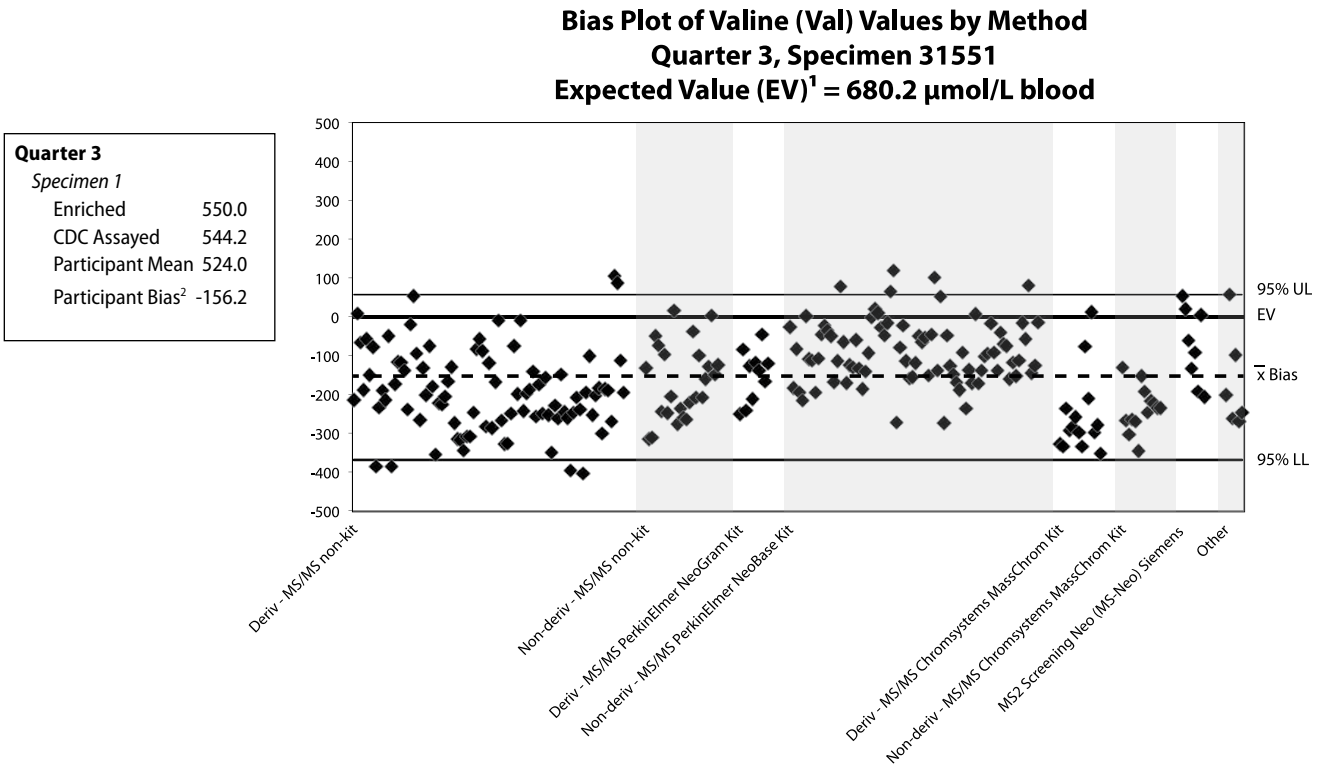
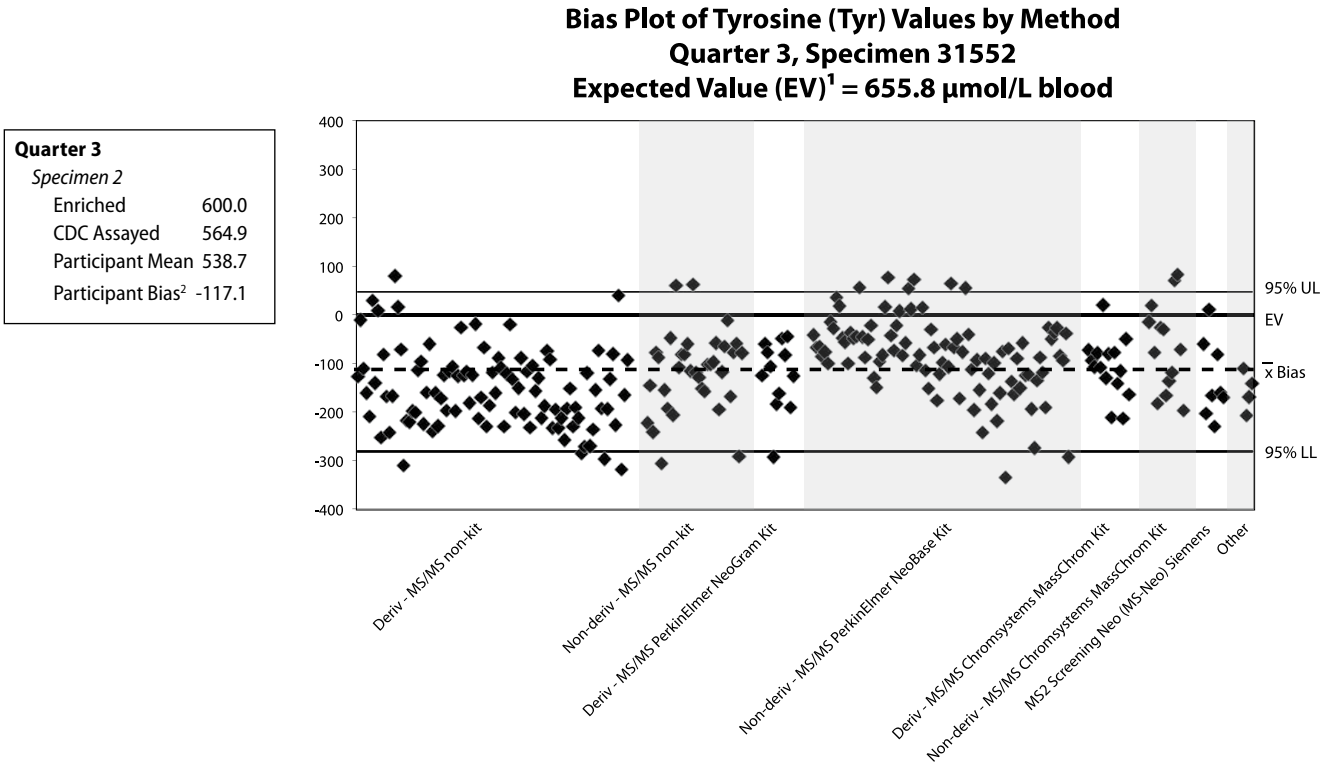
¹EV is the sum of the endogenous and enrichment values. The solid line represents perfect agreement with the EV or zero bias.
²Participant bias (X) is the mean value of all participants' assayed values minus EV; represented by the broken line. Participant bias (X) excludes outlier values.
The 95% confidence interval is shown.
³AV is the CDC assayed value. The solid line represents perfect agreement with the AV or zero bias.

FIGURES 15-16. Reproducibility of Results by Method: Phenylalanine (Phe) and Succinylacetone (SUAC)



¹EV is the sum of the endogenous and enrichment values. The solid line represents perfect agreement with the EV or zero bias.
²Participant bias (X) is the mean value of all participants' assayed values minus EV; represented by the broken line. Participant bias (X) excludes outlier values. The 95% confidence interval is shown.
³AV is the CDC assayed value. The solid line represents perfect agreement with the AV or zero bias.

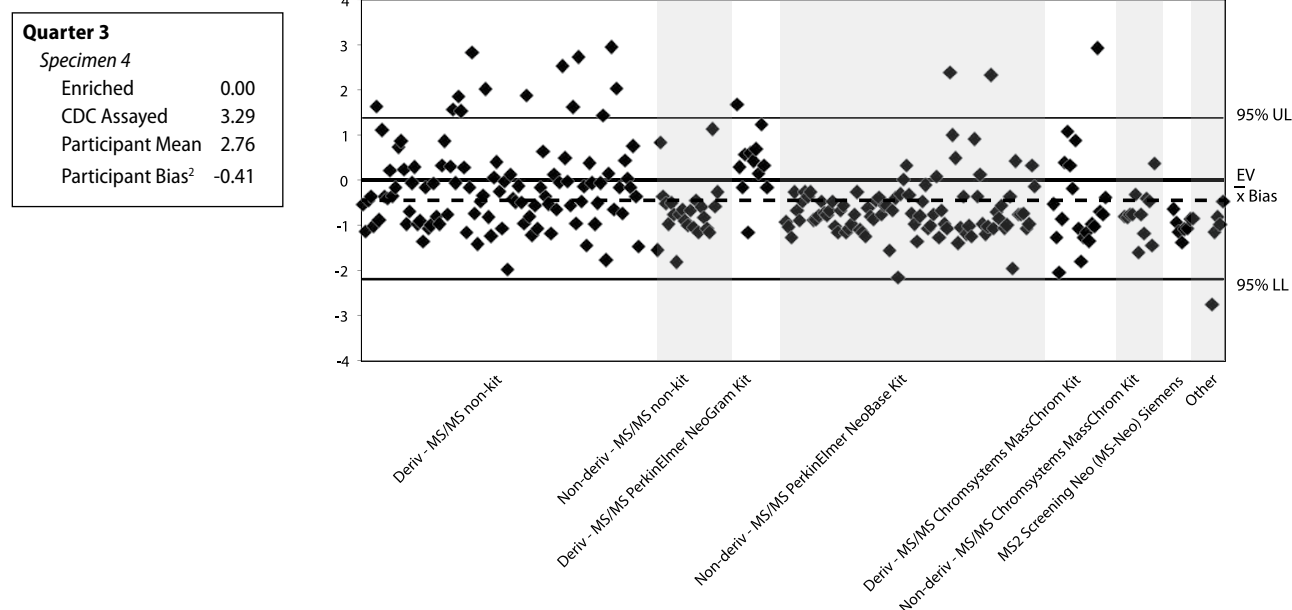
FIGURES 17-18. Reproducibility of Results by Method: Tyrosine (Tyr) and Valine (Val)



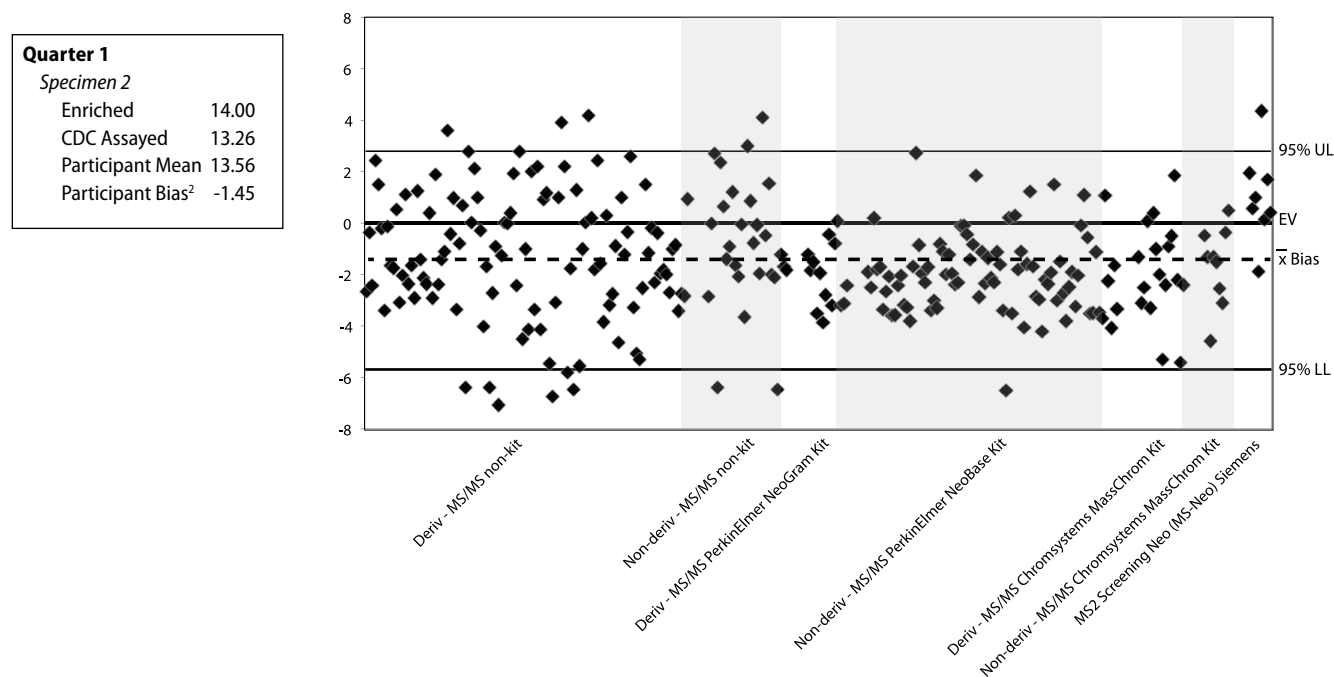
¹EV is the sum of the endogenous and enrichment values. The solid line represents perfect agreement with the EV or zero bias.
²Participant bias (X) is the mean value of all participants' assayed values minus EV; represented by the broken line. Participant bias (X) excludes outlier values.
The 95% confidence interval is shown.
³AV is the CDC assayed value. The solid line represents perfect agreement with the AV or zero bias.

FIGURES 19-20. Reproducibility of Results by Method: Low Free Carnitine (C0(L)) and Propionylcarnitine (C3)

Bias Plot of Low Free Carnitine (C0(L)) Values by Method
Quarter 3, Specimen 31564
Assayed Value (AV)³ = 3.17 μ mol/L blood



Bias Plot of Propionylcarnitine (C3) Values by Method
Quarter 1, Specimen 11562
Expected Value (EV)¹ = 15.01 μ mol/L blood

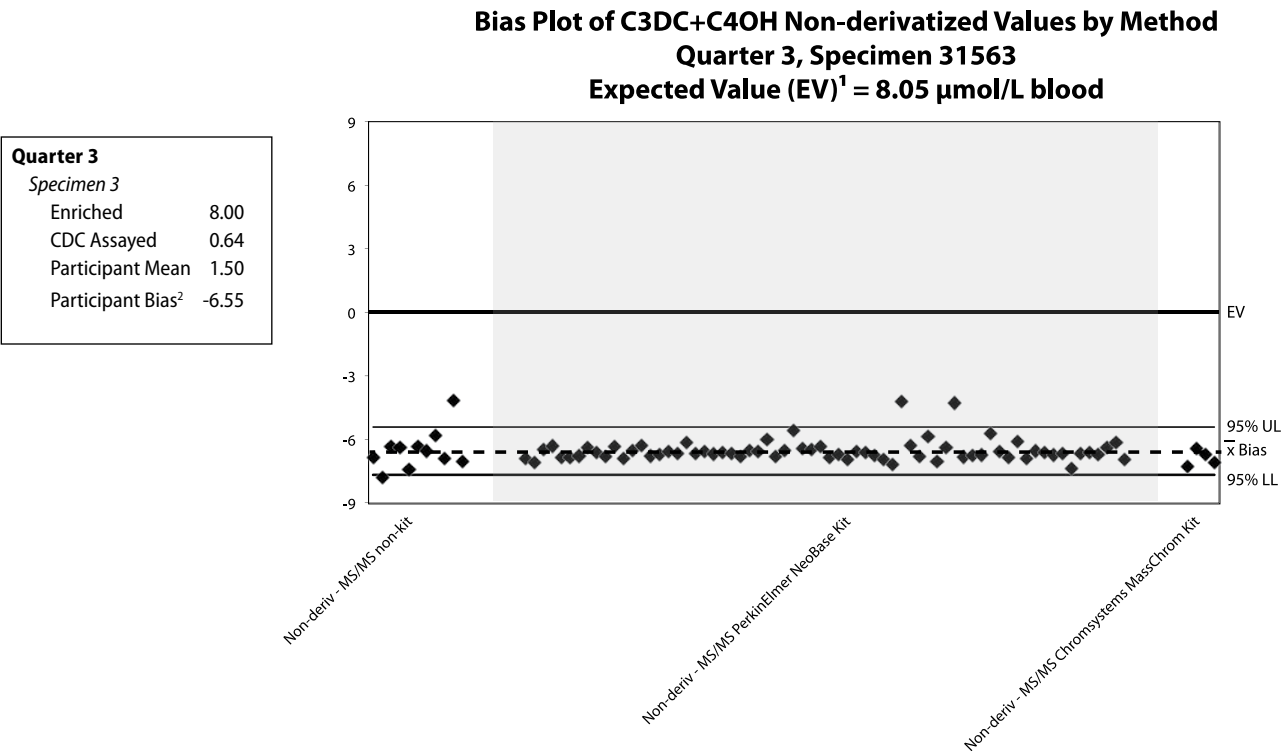
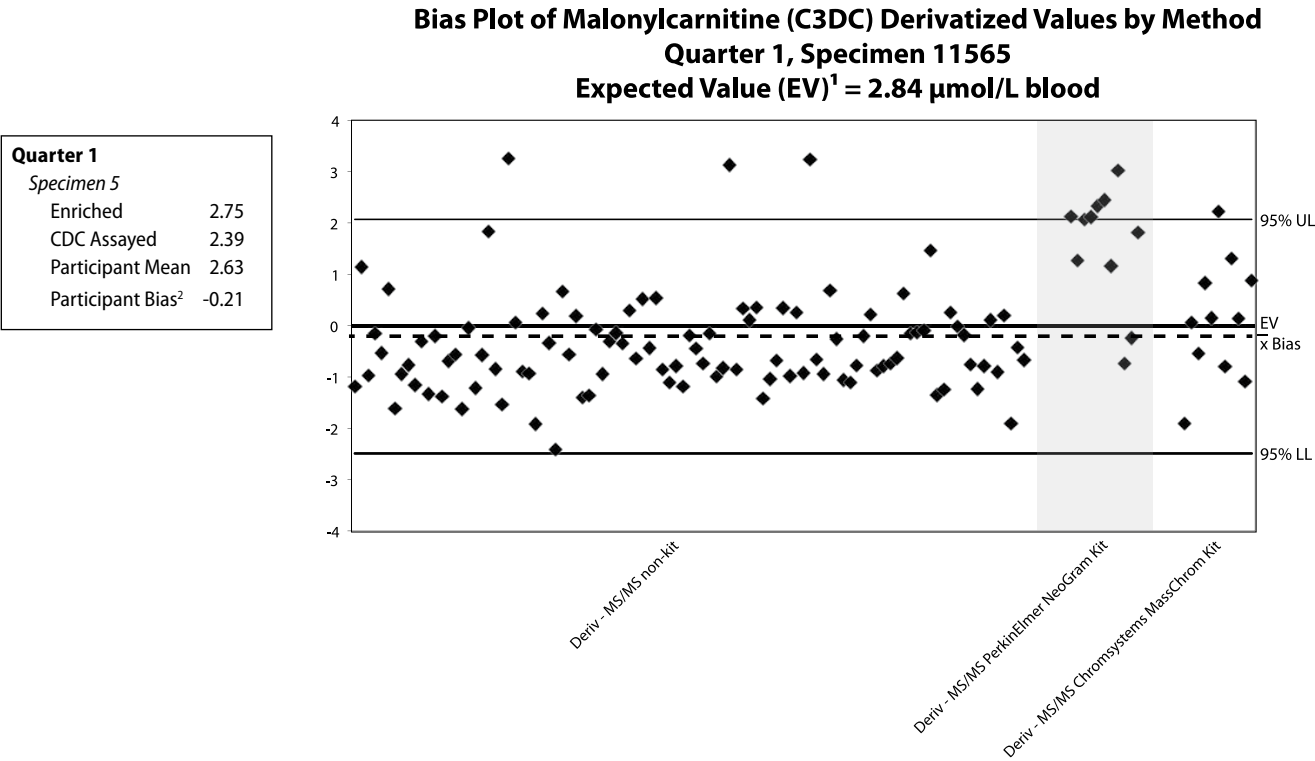


¹EV is the sum of the endogenous and enrichment values. The solid line represents perfect agreement with the EV or zero bias.

²Participant bias (X) is the mean value of all participants' assayed values minus EV; represented by the broken line. Participant bias (X) excludes outlier values. The 95% confidence interval is shown.

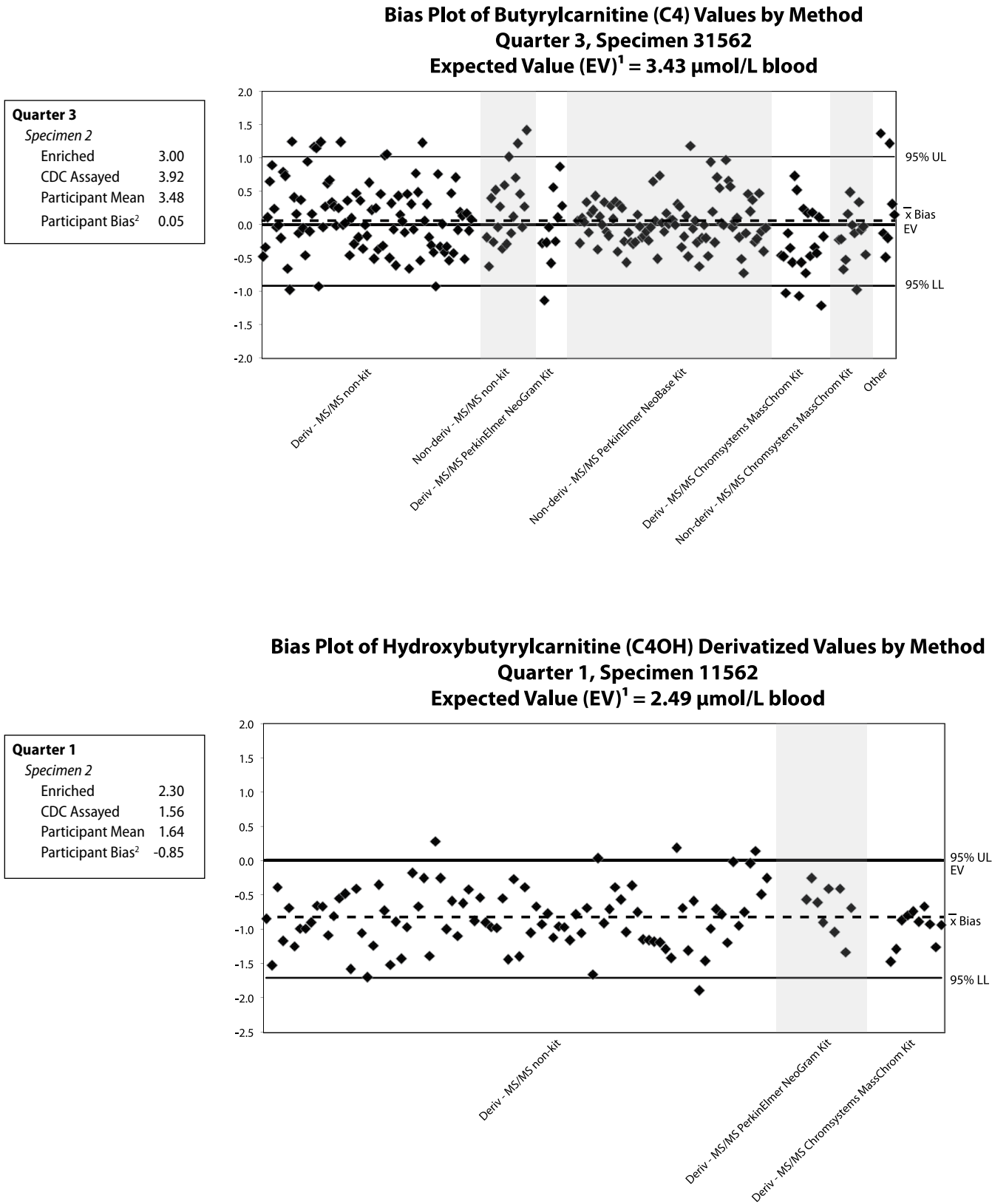
³AV is the CDC assayed value. The solid line represents perfect agreement with the AV or zero bias.

FIGURES 21-22. Reproducibility of Results by Method: Malonylcarnitine (C3DC) Derivatized and C3DC+C40H Non-derivatized



¹EV is the sum of the endogenous and enrichment values. The solid line represents perfect agreement with the EV or zero bias.
²Participant bias (X) is the mean value of all participants' assayed values minus EV; represented by the broken line. Participant bias (X) excludes outlier values.
The 95% confidence interval is shown.
³AV is the CDC assayed value. The solid line represents perfect agreement with the AV or zero bias.

FIGURES 23-24. Reproducibility of Results by Method: Butyrylcarnitine (C4) and Hydroxybutyrylcarnitine (C4OH) Derivatized

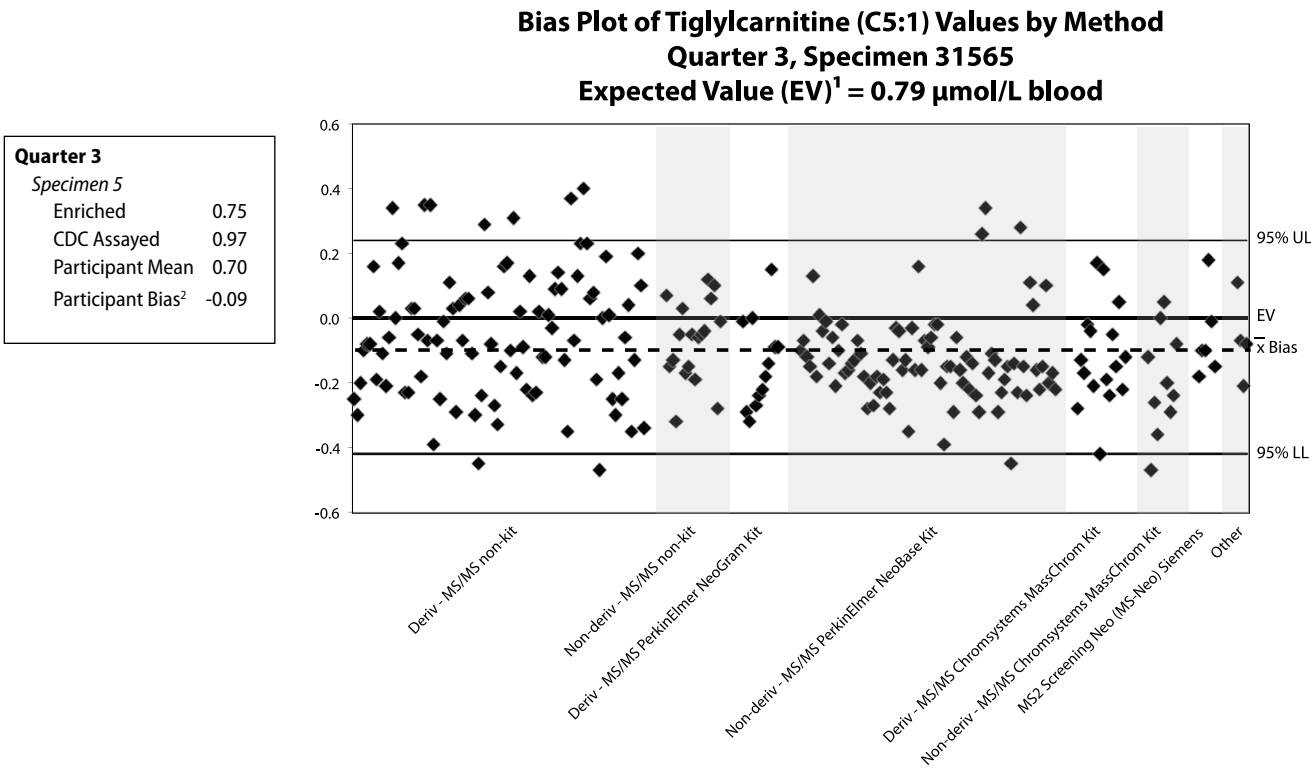
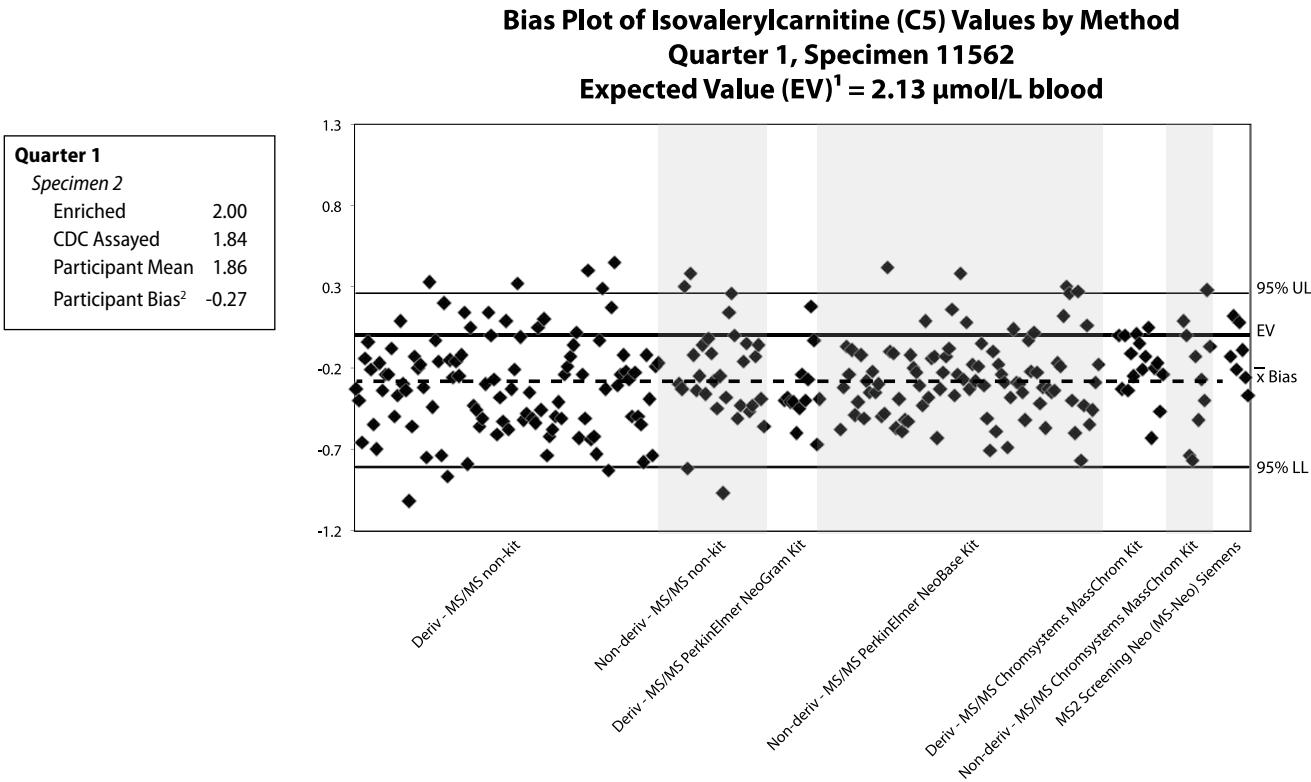


¹EV is the sum of the endogenous and enrichment values. The solid line represents perfect agreement with the EV or zero bias.

²Participant bias (X) is the mean value of all participants' assayed values minus EV; represented by the broken line. Participant bias (X) excludes outlier values. The 95% confidence interval is shown.

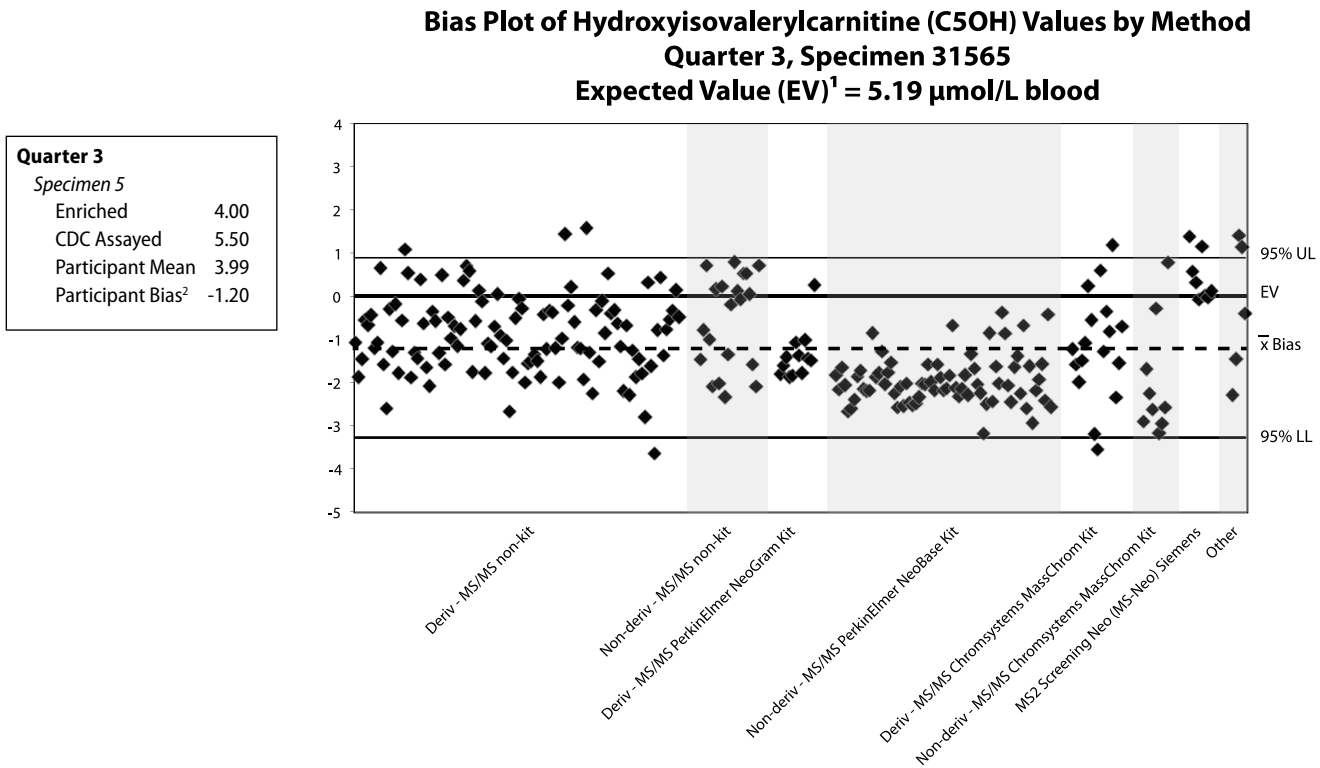
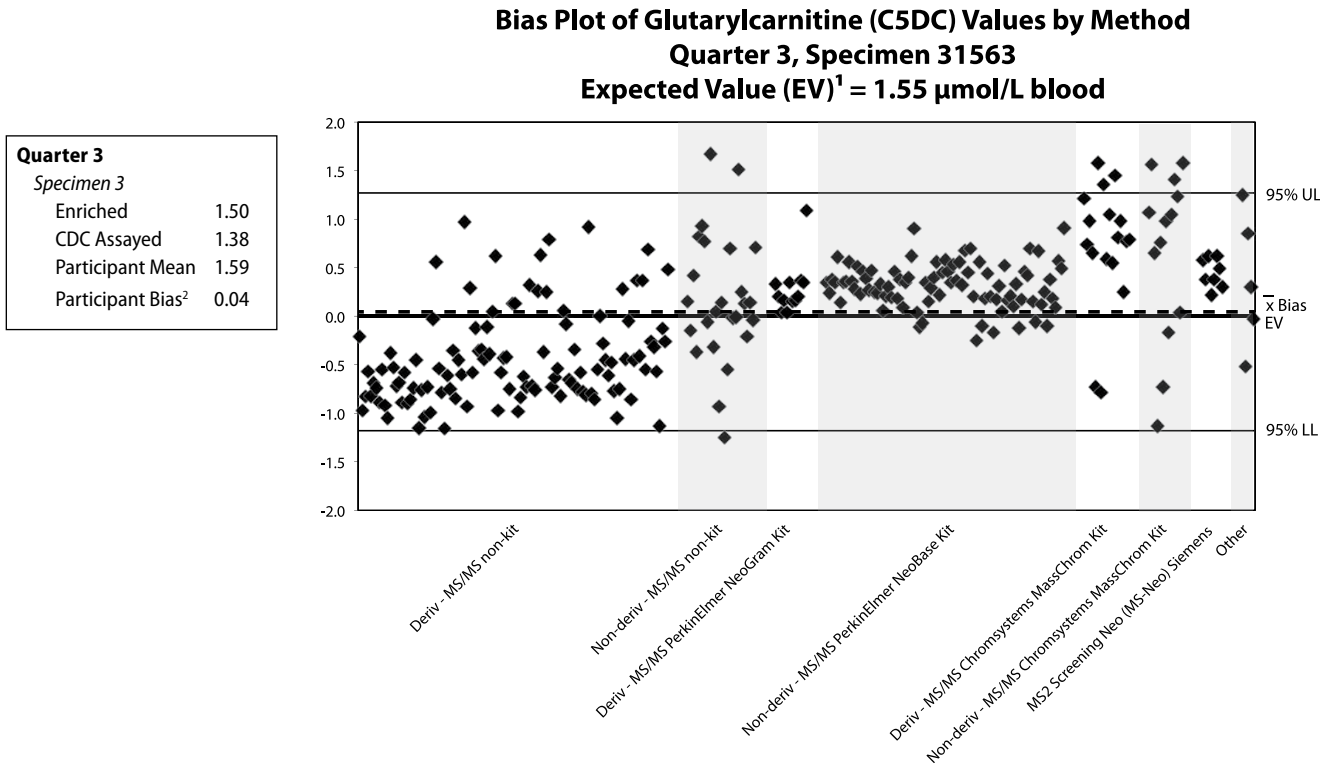
³AV is the CDC assayed value. The solid line represents perfect agreement with the AV or zero bias.

FIGURES 25-26. Reproducibility of Results by Method: Isovalerylcarnitine (C5) and Tiglylcarnitine (C5:1)



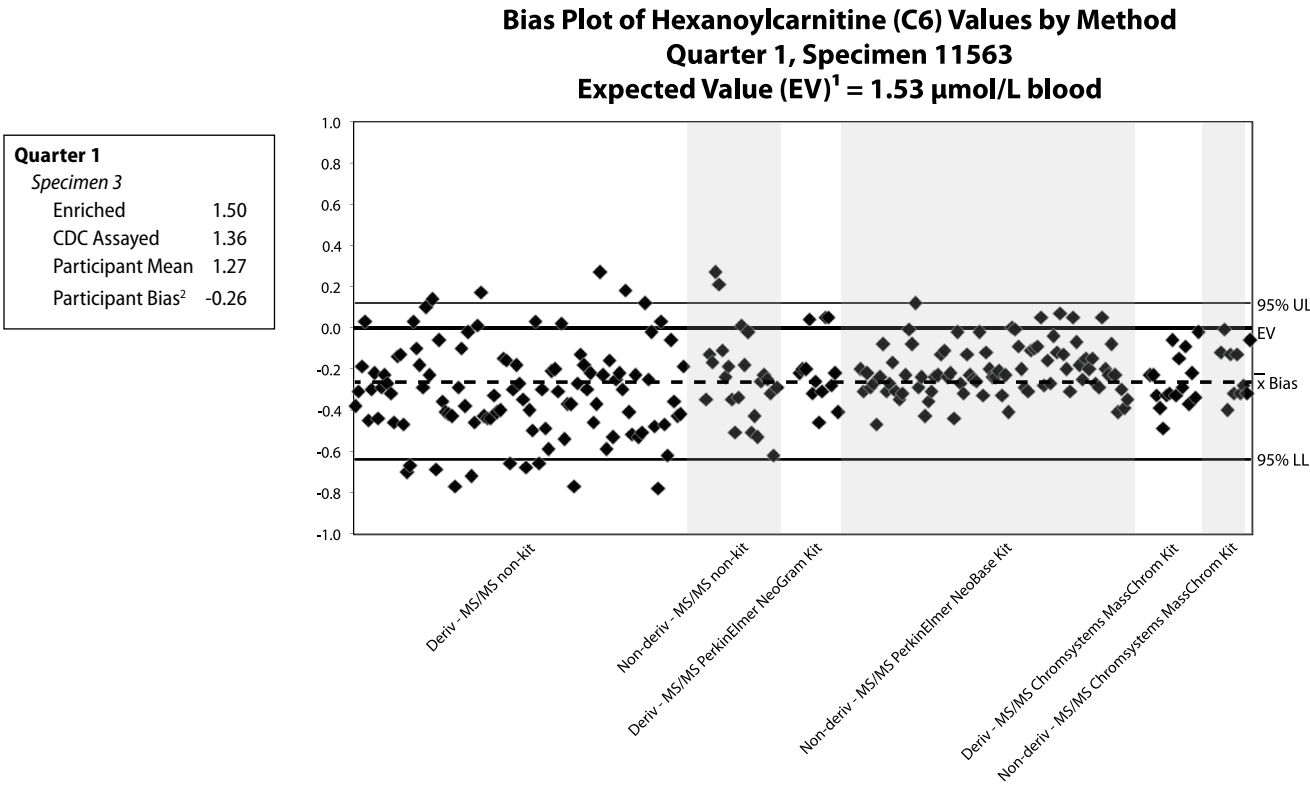
¹EV is the sum of the endogenous and enrichment values. The solid line represents perfect agreement with the EV or zero bias.
²Participant bias (X) is the mean value of all participants' assayed values minus EV; represented by the broken line. Participant bias (X) excludes outlier values.
The 95% confidence interval is shown.
³AV is the CDC assayed value. The solid line represents perfect agreement with the AV or zero bias.

FIGURES 27-28. Reproducibility of Results by Method: Glutarylcarnitine (C5DC) and Hydroxyisovalerylcarnitine (C5OH)

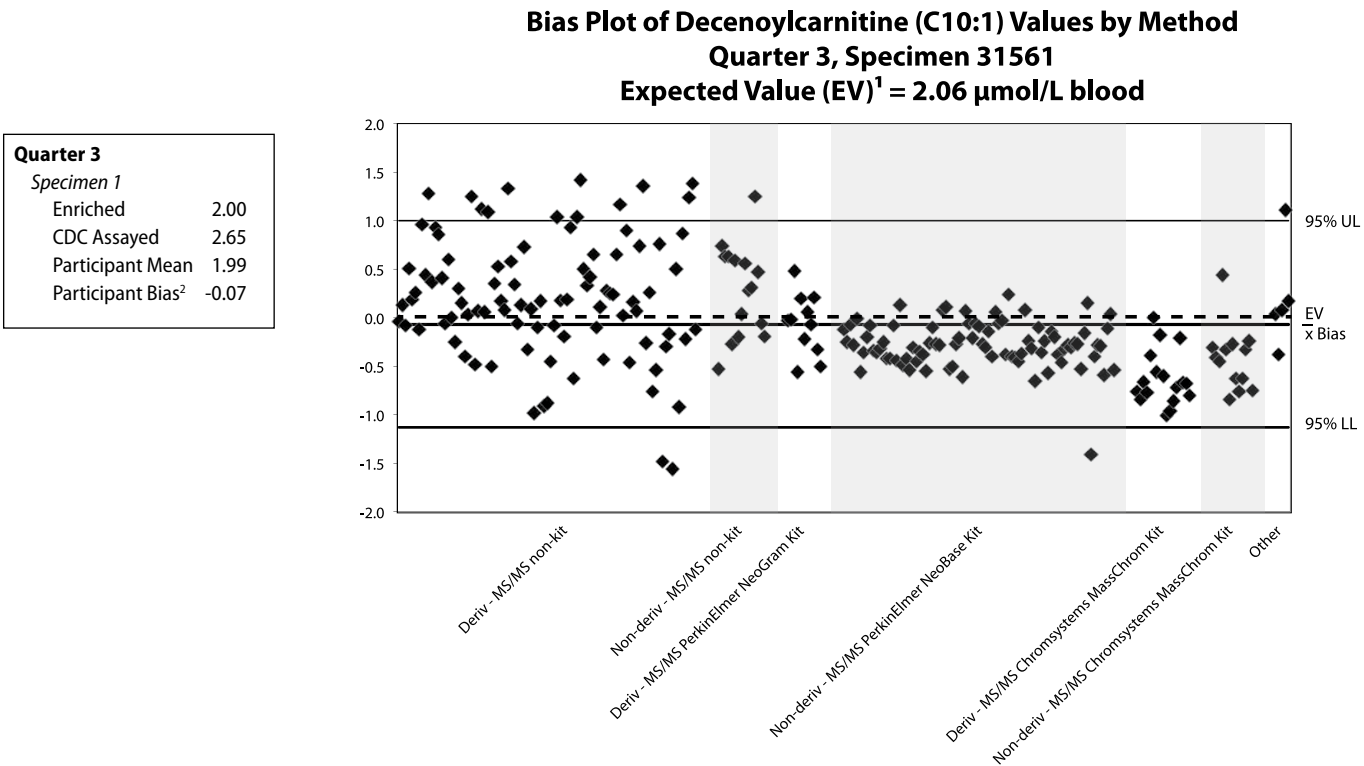
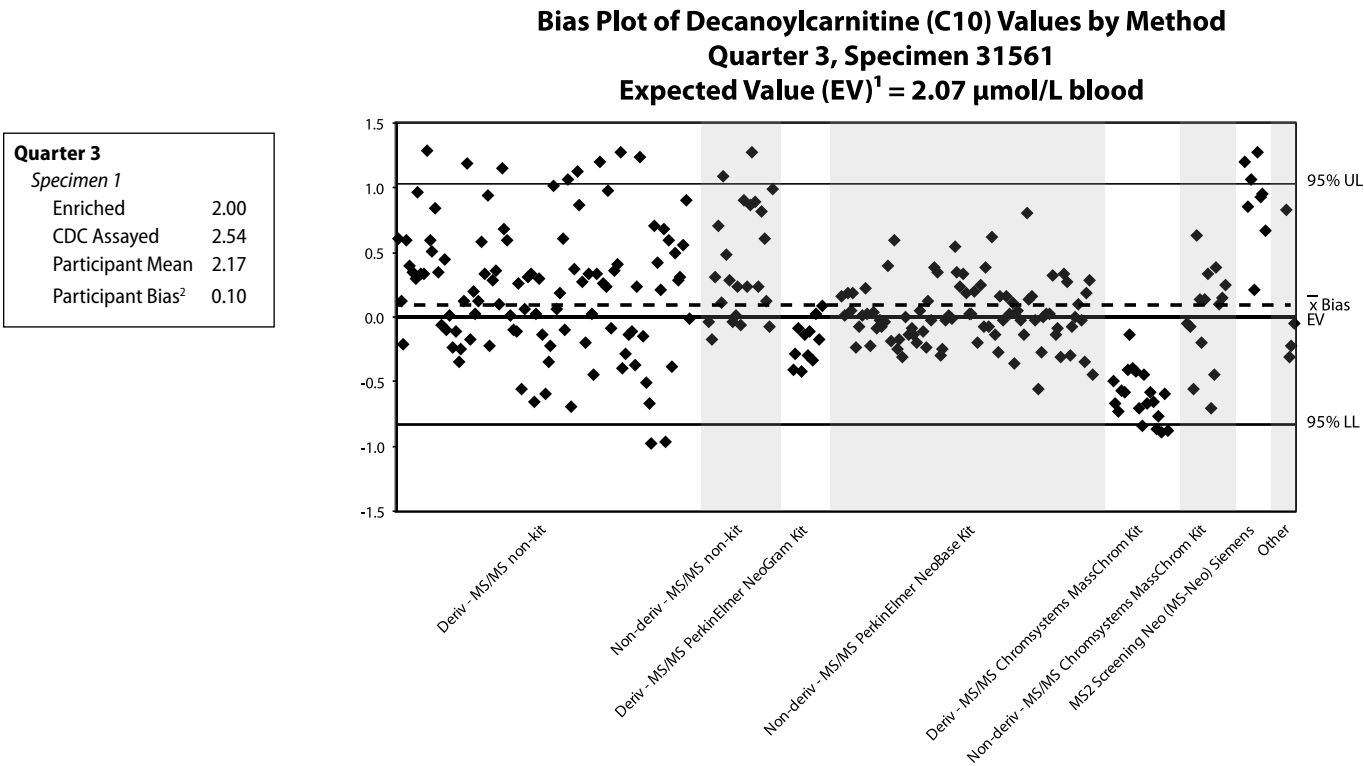


¹EV is the sum of the endogenous and enrichment values. The solid line represents perfect agreement with the EV or zero bias.
²Participant bias (X) is the mean value of all participants' assayed values minus EV; represented by the broken line. Participant bias (X) excludes outlier values.
The 95% confidence interval is shown.
³AV is the CDC assayed value. The solid line represents perfect agreement with the AV or zero bias.

FIGURES 29-30. Reproducibility of Results by Method: Hexanoylcarnitine (C6) and Octanoylcarnitine (C8)

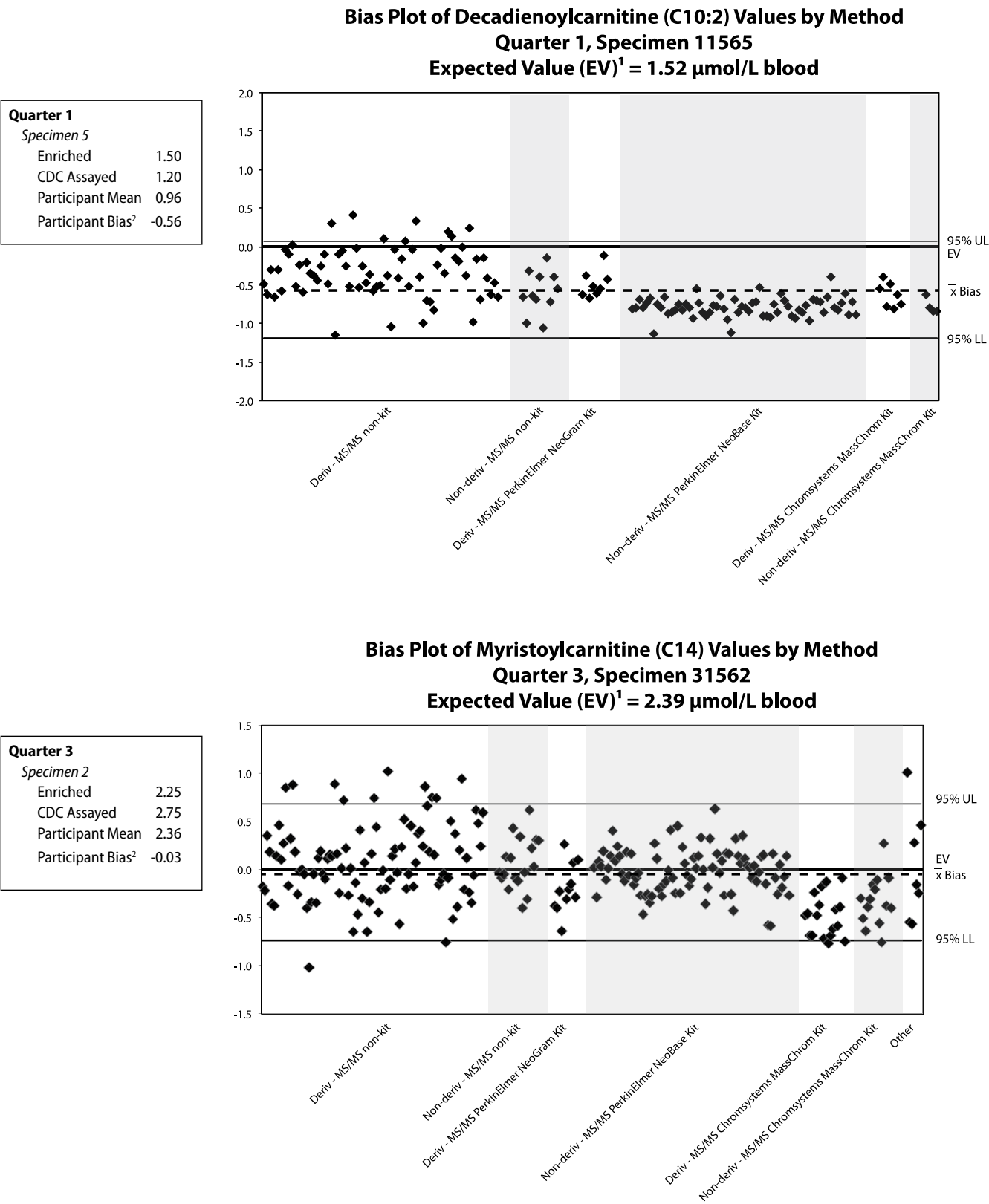


FIGURES 31-32. Reproducibility of Results by Method: Decanoylcarnitine (C10) and Decenoylcarnitine (C10:1)



¹EV is the sum of the endogenous and enrichment values. The solid line represents perfect agreement with the EV or zero bias.
²Participant bias (X) is the mean value of all participants' assayed values minus EV; represented by the broken line. Participant bias (X) excludes outlier values.
The 95% confidence interval is shown.
³AV is the CDC assayed value. The solid line represents perfect agreement with the AV or zero bias.

FIGURES 33-34. Reproducibility of Results by Method: Decadienoylcarnitine (C10:2) and Myristoylcarnitine (C14)



¹EV is the sum of the endogenous and enrichment values. The solid line represents perfect agreement with the EV or zero bias.

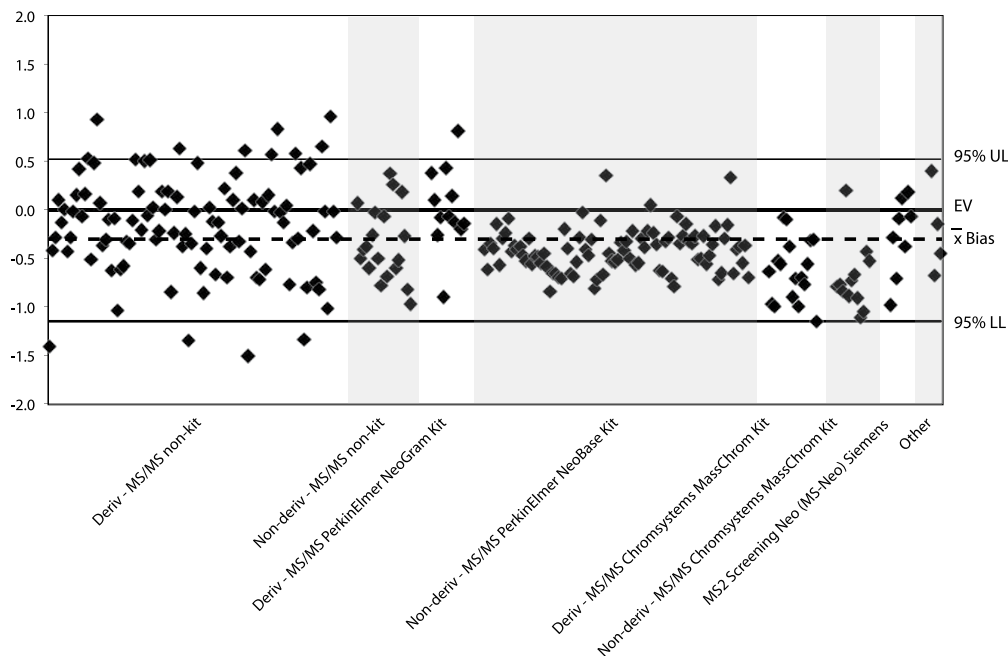
²Participant bias (X) is the mean value of all participants' assayed values minus EV; represented by the broken line. Participant bias (X) excludes outlier values. The 95% confidence interval is shown.

³AV is the CDC assayed value. The solid line represents perfect agreement with the AV or zero bias.

FIGURES 35-36. Reproducibility of Results by Method: Tetradecenoylcarnitine (C14:1) and Palmitoylcarnitine (C16)

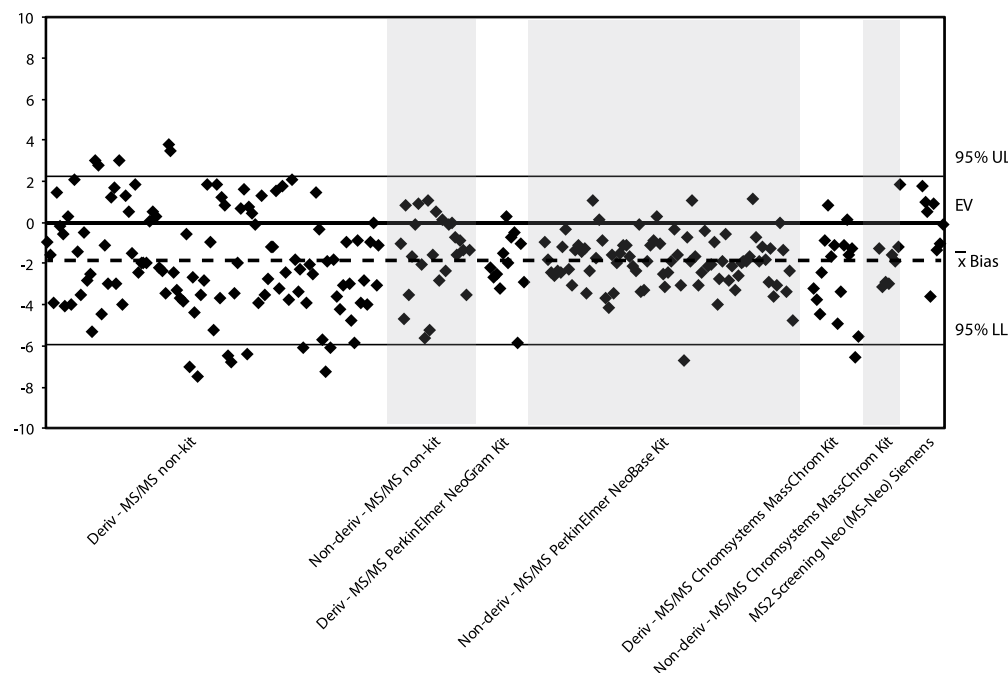
Bias Plot of Tetradecenoylcarnitine (C14:1) Values by Method
Quarter 3, Specimen 31562
Expected Value (EV)¹ = 2.30 μ mol/L blood

| | |
|-------------------------------|-------|
| Quarter 3 | |
| <i>Specimen 2</i> | |
| Enriched | 2.25 |
| CDC Assayed | 2.54 |
| Participant Mean | 1.99 |
| Participant Bias ² | -0.31 |



Bias Plot of Palmitoylcarnitine (C16) Values by Method
Quarter 1, Specimen 11564
Expected Value (EV)¹ = 16.69 μ mol/L blood

| | |
|-------------------------------|-------|
| Quarter 1 | |
| <i>Specimen 4</i> | |
| Enriched | 16.00 |
| CDC Assayed | 15.07 |
| Participant Mean | 14.84 |
| Participant Bias ² | -1.85 |

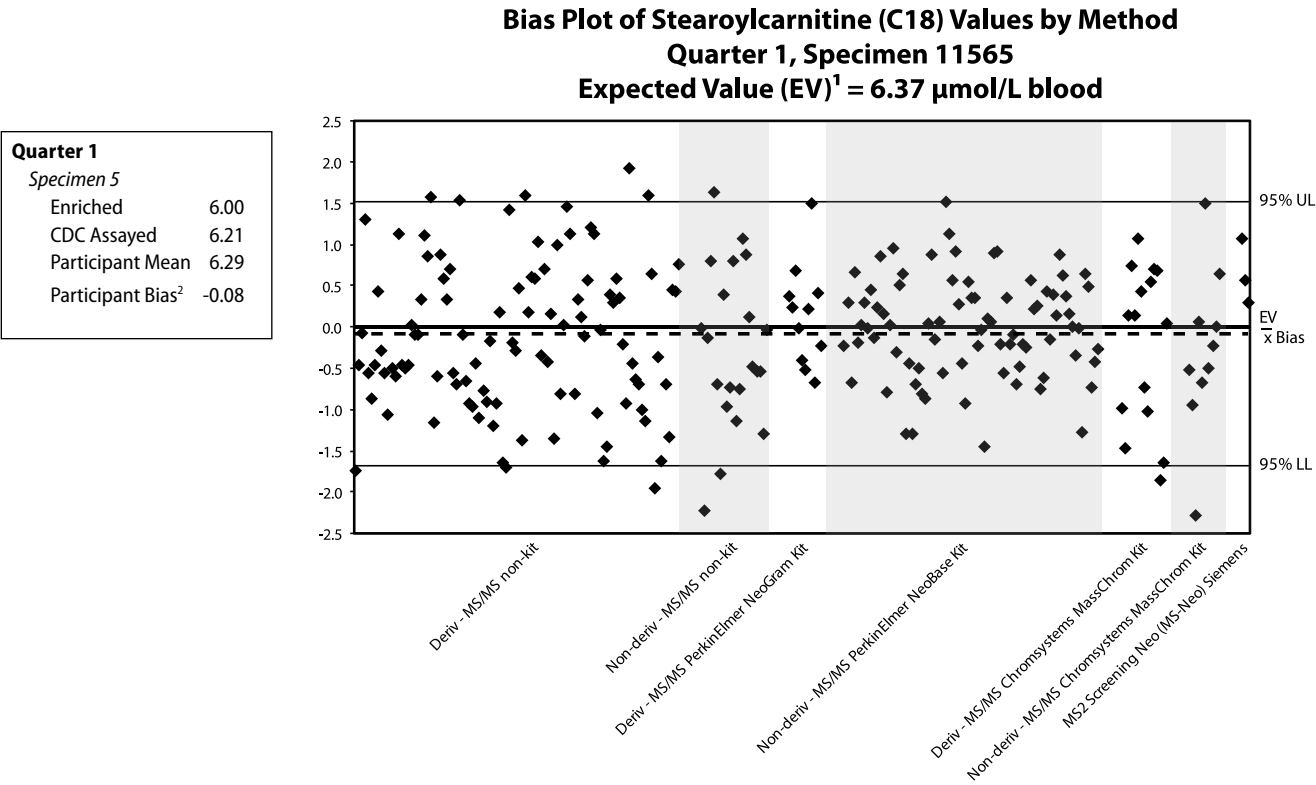
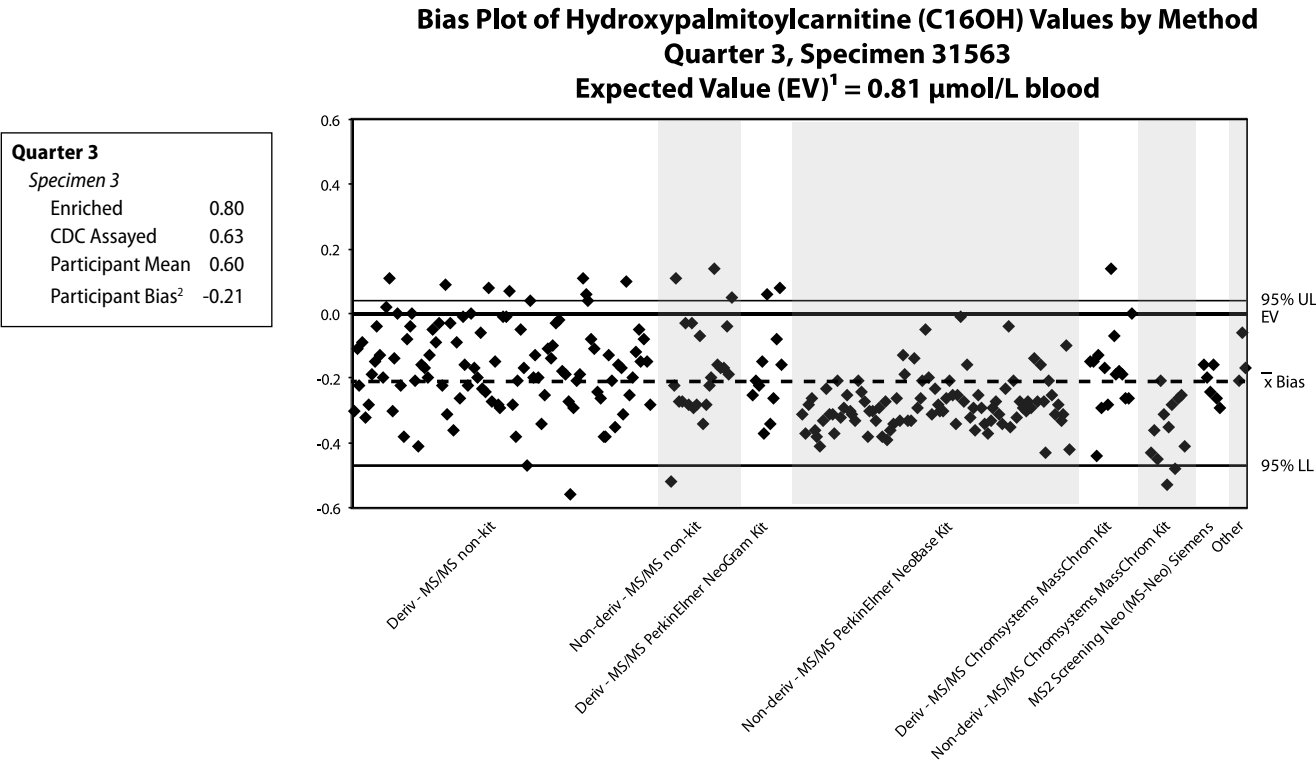


¹EV is the sum of the endogenous and enrichment values. The solid line represents perfect agreement with the EV or zero bias.

²Participant bias (X) is the mean value of all participants' assayed values minus EV; represented by the broken line. Participant bias (X) excludes outlier values. The 95% confidence interval is shown.

³AV is the CDC assayed value. The solid line represents perfect agreement with the AV or zero bias.

FIGURES 37-38. Reproducibility of Results by Method: Hydroxypalmitoylcarnitine (C16OH) and Stearoylcarnitine (C18)

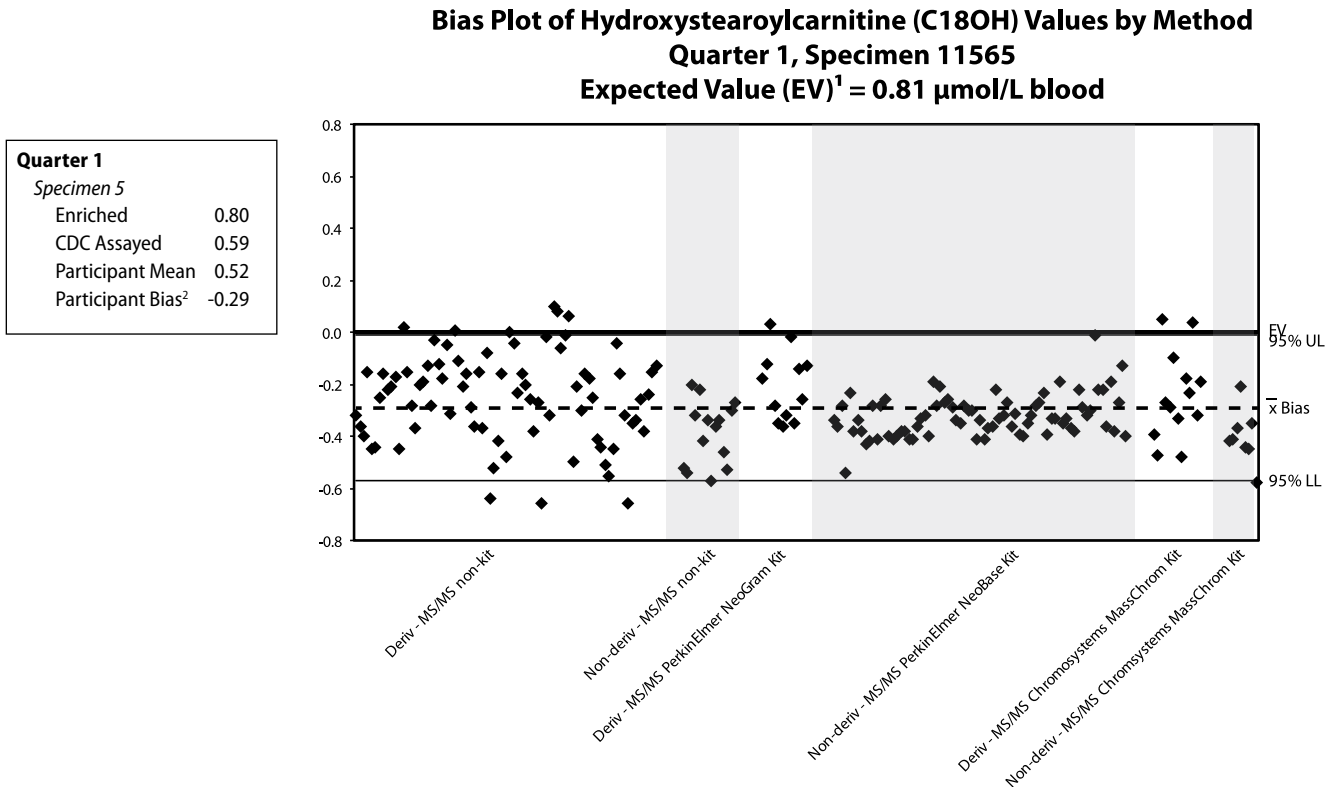
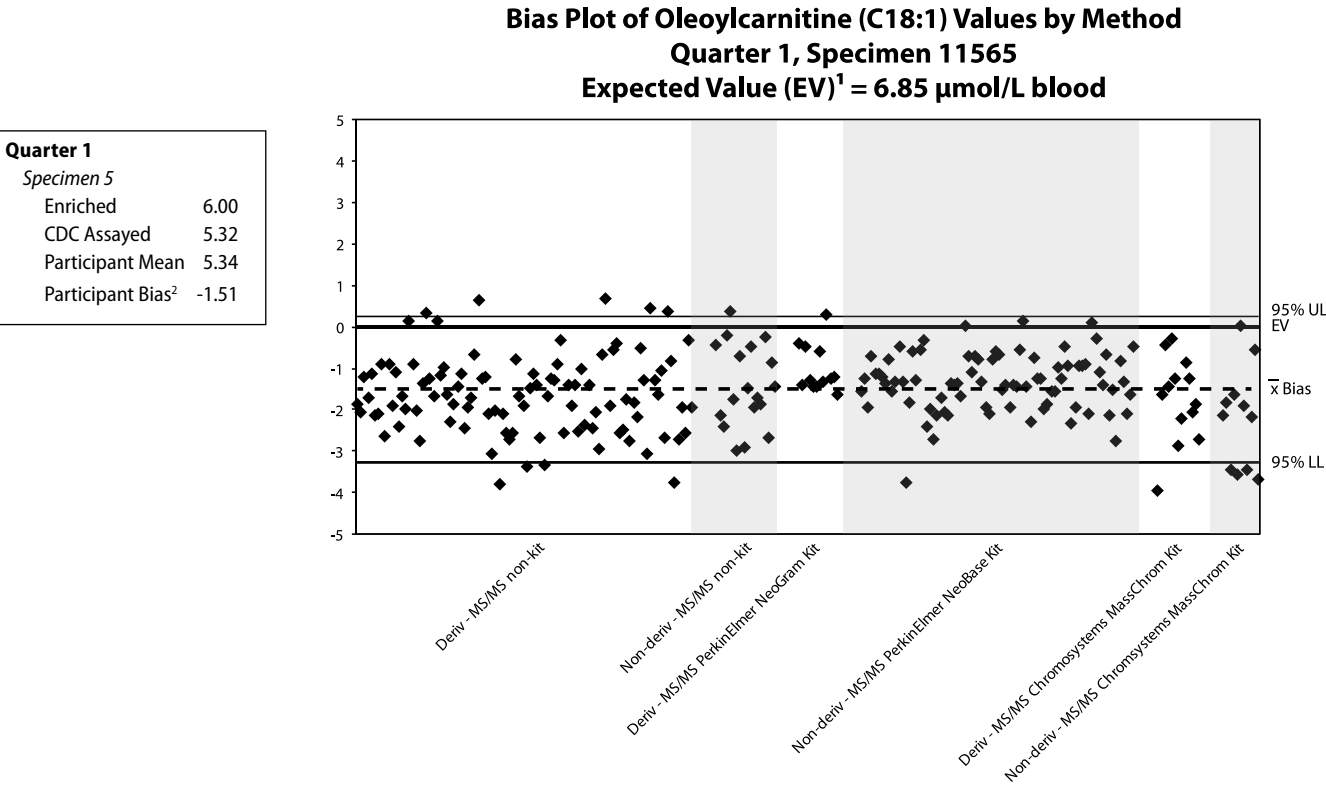


¹EV is the sum of the endogenous and enrichment values. The solid line represents perfect agreement with the EV or zero bias.

²Participant bias (X) is the mean value of all participants' assayed values minus EV; represented by the broken line. Participant bias (X) excludes outlier values. The 95% confidence interval is shown.

³AV is the CDC assayed value. The solid line represents perfect agreement with the AV or zero bias.

FIGURES 39-40. Reproducibility of Results by Method: Oleoylcarnitine (C18:1) and Hydroxystearoylcarnitine (C18OH)



¹EV is the sum of the endogenous and enrichment values. The solid line represents perfect agreement with the EV or zero bias.
²Participant bias (X) is the mean value of all participants' assayed values minus EV; represented by the broken line. Participant bias (X) excludes outlier values.
The 95% confidence interval is shown.
³AV is the CDC assayed value. The solid line represents perfect agreement with the AV or zero bias.

QUALITY CONTROL

The QC program helps laboratories maintain high levels of technical proficiency and continuity, particularly during lot-to-lot changes in commercial assay systems or reagents. The QC materials, which supplement the participants' method- or kit-control materials, allow participants to monitor long-term assay stability. QC materials are distributed semiannually.

QC MATERIALS AND METHODS

NSQAP certifies QC analysis materials for homogeneity, accuracy, stability, and suitability for newborn screening assays. We distribute QC analysis materials (DBS cards), instructions for storage, analysis, and certification sheets in each shipment. Download QC certification sheets and data report forms from our website at: http://www.cdc.gov/labstandards/nsqap_resources.html

QC materials are produced by combining blood from multiple donors. The RBCs are washed several times, combined with purified serum to achieve a 50% hematocrit, and then lysed. Each lot within a set of QC shipments contains a different analyte concentration of the following: T₄, TSH, 17OHP, IRT, TGal, GALT, amino acids (alanine, Arg, Cit, Leu, Met, Phe, SUAC, Tyr, Val), and acylcarnitines (C0, C2, C3, C3DC, C4, C4OH, C5, C5DC, C5OH, C6, C8, C10, C12, C14, C16, C16OH, C18, C18OH), and XALD.

- Purified analyte standards are used for most QC material enrichments, with the exception of TSH, for which the Third International Reference Preparation (81/565) is used.
- T₄ QC materials are enriched with calculated amounts of T₄ after T₄ depletion of the base serum.
- TGal materials are enriched with galactose and galactose-1-phosphate, allowing measurement of both free galactose (galactose alone) and total galactose (free galactose plus galactose present as TGal).
- GALT QC materials are made using a 50/50 saline/serum solution combined with compatible washed RBCs and then heat-treating the pool.

To ensure laboratories receive representative sheets of QC materials from each lot, we use a system to randomize blood spot cards from across the production batch.

QC DATA HANDLING

For each semiannual QC event, data points from five independent runs of each QC analyte lot level are compiled and tabulated.

Tables 17a–17jj show the reported QC data. The tables show the analyte by series of QC lots, number of measurements (N), mean values, within-laboratory standard deviations (SD), and total SDs by kit or analytic method. In addition, we use a weighted linear-regression analysis to examine the comparability by method of reported versus enriched concentrations. We calculate linear regressions (Y-intercept and slope) by method for all analytic values within an analyte QC series. Values outside the 99% CI (outliers) are excluded from the calculations.

Tables 17a–17jj show data for method-related differences in analytic recoveries and method biases. For regression analyses, we calculated the within-laboratory SD component of the total SD and used the reported QC data from multiple analytic runs. We calculated the Y-intercept and slope in each table, using all analyte concentrations within a lot series (e.g., lots 1425, 1426, 1427, 1428). Because only three or four concentrations of QC materials are available for each analyte, a bias in any one pool can markedly influence the slope and intercept. The Y-intercept provides one measure of the endogenous concentration level for an analyte. For amino acids and acylcarnitines, participants measure the endogenous concentrations by analyzing the non-enriched QC lots; for most methods, the Y-intercepts and measured endogenous levels were similar. Ideally, the slope should be 1.0. Slope deviations might relate to analytic (dose-response) ranges for calibration curves or to poor recoveries for one or more specimens in a three- or four-specimen QC set. Because the endogenous concentration is the same for all QC lots within a series, it should not affect the slope of the regression line among methods. Generally, slope values substantially different from 1.0 indicate that a method has an analytic bias.

In certain circumstances, where no unit conversion factor exists to allow for direct comparison of enrichment values to observed concentrations, we provide basic peer group statistics to assist in laboratory self assessment.

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3. Clinical and Laboratory Standards Institute. Blood collection on filter paper for newborn screening programs: Approved Standard—Sixth Edition. CLSI Document NBS01-A6. Wayne, PA: Clinical and Laboratory Standards Institute; 2014.

**Table 17a. 2015 Quality Control Data Summaries of Statistical Analyses
17 α -HYDROXYPROGESTERONE (ng 17OHP/mL serum)**

Lot 1351 - Enriched 25.0 ng/mL serum

| METHOD | N | Mean | Average Within Lab SD | Total SD | Y- Intercept* | Slope |
|-----------------------------------|-----|------|-----------------------|----------|---------------|-------|
| Siemens Healthcare Diagnostics | 30 | 21.9 | 1.7 | 3.5 | 5.9 | 0.7 |
| Neo-Genesis Accuwell | 30 | 23.5 | 3.0 | 5.7 | -2.0 | 1.0 |
| Delfia | 140 | 19.0 | 2.4 | 5.1 | -2.2 | 0.9 |
| Delfia Neonatal 17-OHP (A024) | 89 | 17.9 | 2.3 | 3.3 | -2.4 | 0.8 |
| AutoDelfia | 262 | 20.4 | 2.4 | 3.8 | -0.2 | 0.9 |
| AutoDelfia Neonatal 17-OHP (B024) | 345 | 20.5 | 2.1 | 3.0 | 0.5 | 0.8 |
| Bio-Rad Quantase | 90 | 21.4 | 2.9 | 5.3 | 3.0 | 0.8 |
| TecnoSuma UMELISA | 20 | 23.8 | 2.6 | 2.7 | -5.6 | 1.2 |
| LC-MS/MS | 39 | 21.8 | 1.9 | 3.5 | 1.0 | 0.8 |
| PerkinElmer GSP Neonatal | 320 | 21.4 | 1.9 | 2.3 | 1.6 | 0.8 |
| In House | 20 | 24.1 | 6.3 | 6.3 | 2.8 | 0.8 |

Lot 1352 - Enriched 50.0 ng/mL serum

| METHOD | N | Mean | Average Within Lab SD | Total SD | Y- Intercept* | Slope |
|-----------------------------------|-----|------|-----------------------|----------|---------------|-------|
| Siemens Healthcare Diagnostics | 30 | 43.0 | 3.0 | 7.0 | 5.9 | 0.7 |
| Neo-Genesis Accuwell | 29 | 47.0 | 6.1 | 6.4 | -2.0 | 1.0 |
| Delfia | 140 | 40.6 | 3.7 | 8.7 | -2.2 | 0.9 |
| Delfia Neonatal 17-OHP (A024) | 89 | 38.8 | 4.8 | 7.2 | -2.4 | 0.8 |
| AutoDelfia | 263 | 44.7 | 3.9 | 8.4 | -0.2 | 0.9 |
| AutoDelfia Neonatal 17-OHP (B024) | 345 | 43.0 | 3.8 | 6.1 | 0.5 | 0.8 |
| Bio-Rad Quantase | 90 | 47.7 | 4.9 | 15.6 | 3.0 | 0.8 |
| TecnoSuma UMELISA | 20 | 57.0 | 6.6 | 12.0 | -5.6 | 1.2 |
| LC-MS/MS | 40 | 43.2 | 3.8 | 5.9 | 1.0 | 0.8 |
| PerkinElmer GSP Neonatal | 324 | 44.1 | 3.3 | 4.5 | 1.6 | 0.8 |
| In House | 20 | 42.1 | 4.9 | 9.3 | 2.8 | 0.8 |

Lot 1353 - Enriched 100.0 ng/mL serum

| METHOD | N | Mean | Average Within Lab SD | Total SD | Y- Intercept* | Slope |
|-----------------------------------|-----|-------|-----------------------|----------|---------------|-------|
| Siemens Healthcare Diagnostics | 30 | 75.0 | 4.9 | 13.7 | 5.9 | 0.7 |
| Neo-Genesis Accuwell | 30 | 97.9 | 16.2 | 19.8 | -2.0 | 1.0 |
| Delfia | 144 | 83.0 | 9.3 | 23.9 | -2.2 | 0.9 |
| Delfia Neonatal 17-OHP (A024) | 90 | 79.3 | 11.3 | 18.1 | -2.4 | 0.8 |
| AutoDelfia | 252 | 85.9 | 8.9 | 15.1 | -0.2 | 0.9 |
| AutoDelfia Neonatal 17-OHP (B024) | 341 | 83.0 | 8.6 | 12.5 | 0.5 | 0.8 |
| Bio-Rad Quantase | 78 | 84.5 | 8.9 | 18.9 | 3.0 | 0.8 |
| TecnoSuma UMELISA | 20 | 115.6 | 7.7 | 18.3 | -5.6 | 1.2 |
| LC-MS/MS | 40 | 84.7 | 4.8 | 9.9 | 1.0 | 0.8 |
| PerkinElmer GSP Neonatal | 319 | 83.8 | 7.2 | 8.9 | 1.6 | 0.8 |
| In House | 20 | 84.6 | 6.2 | 23.3 | 2.8 | 0.8 |

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

2015 Quality Control Data Summaries of Statistical Analyses

17 α -HYDROXYPROGESTERONE (ng 17OHP/mL serum)

Lot 1551 - Enriched 25.0 ng/mL serum

| METHOD | N | Mean | Average Within Lab SD | Total SD | Y- Intercept* | Slope |
|-----------------------------------|-----|------|-----------------------|----------|---------------|-------|
| Siemens Healthcare Diagnostics | 30 | 29.6 | 2.4 | 3.6 | 5.8 | 1.0 |
| Neo-Genesis Accuwell | 30 | 26.6 | 2.8 | 3.1 | -2.6 | 1.1 |
| Delfia | 217 | 22.8 | 2.4 | 4.4 | -0.6 | 0.9 |
| Delfia Neonatal 17-OHP (A024) | 80 | 22.7 | 2.9 | 5.0 | -0.4 | 0.9 |
| AutoDelfia | 217 | 23.8 | 2.0 | 2.7 | -0.7 | 1.0 |
| AutoDelfia Neonatal 17-OHP (B024) | 368 | 23.8 | 2.4 | 4.3 | -1.3 | 1.0 |
| Bio-Rad Quantase | 77 | 22.5 | 3.2 | 7.7 | 1.5 | 0.9 |
| TecnoSuma UMELISA | 10 | 26.5 | 1.3 | 1.3 | 1.7 | 1.0 |
| LC-MS/MS | 60 | 24.8 | 2.8 | 6.5 | 2.9 | 0.9 |
| PerkinElmer GSP Neonatal | 351 | 25.0 | 2.0 | 2.8 | 0.4 | 1.0 |
| In House | 19 | 28.6 | 3.6 | 3.6 | 7.4 | 0.9 |

Lot 1552 - Enriched 50.0 ng/mL serum

| METHOD | N | Mean | Average Within Lab SD | Total SD | Y- Intercept* | Slope |
|-----------------------------------|-----|------|-----------------------|----------|---------------|-------|
| Siemens Healthcare Diagnostics | 30 | 54.4 | 4.0 | 8.7 | 5.8 | 1.0 |
| Neo-Genesis Accuwell | 30 | 48.4 | 4.7 | 6.5 | -2.6 | 1.1 |
| Delfia | 214 | 44.4 | 4.6 | 7.3 | -0.6 | 0.9 |
| Delfia Neonatal 17-OHP (A024) | 76 | 44.1 | 4.6 | 10.0 | -0.4 | 0.9 |
| AutoDelfia | 213 | 46.6 | 4.1 | 4.8 | -0.7 | 1.0 |
| AutoDelfia Neonatal 17-OHP (B024) | 361 | 46.8 | 4.0 | 7.9 | -1.3 | 1.0 |
| Bio-Rad Quantase | 78 | 45.7 | 6.2 | 17.3 | 1.5 | 0.9 |
| TecnoSuma UMELISA | 10 | 49.7 | 3.7 | 3.7 | 1.7 | 1.0 |
| LC-MS/MS | 60 | 47.4 | 4.0 | 11.5 | 2.9 | 0.9 |
| PerkinElmer GSP Neonatal | 347 | 47.9 | 3.5 | 4.2 | 0.4 | 1.0 |
| In House | 18 | 54.5 | 3.8 | 4.9 | 7.4 | 0.9 |

Lot 1553 - Enriched 100.0 ng/mL serum

| METHOD | N | Mean | Average Within Lab SD | Total SD | Y- Intercept* | Slope |
|-----------------------------------|-----|-------|-----------------------|----------|---------------|-------|
| Siemens Healthcare Diagnostics | 30 | 102.0 | 8.4 | 16.6 | 5.8 | 1.0 |
| Neo-Genesis Accuwell | 30 | 106.9 | 11.1 | 13.6 | -2.6 | 1.1 |
| Delfia | 217 | 91.2 | 10.0 | 15.9 | -0.6 | 0.9 |
| Delfia Neonatal 17-OHP (A024) | 75 | 90.4 | 9.9 | 19.6 | -0.4 | 0.9 |
| AutoDelfia | 222 | 95.5 | 9.2 | 12.9 | -0.7 | 1.0 |
| AutoDelfia Neonatal 17-OHP (B024) | 367 | 97.0 | 9.7 | 18.2 | -1.3 | 1.0 |
| Bio-Rad Quantase | 77 | 87.7 | 15.7 | 35.0 | 1.5 | 0.9 |
| TecnoSuma UMELISA | 10 | 99.3 | 9.3 | 9.3 | 1.7 | 1.0 |
| LC-MS/MS | 60 | 91.3 | 5.6 | 23.8 | 2.9 | 0.9 |
| PerkinElmer GSP Neonatal | 349 | 96.9 | 7.9 | 11.6 | 0.4 | 1.0 |
| In House | 20 | 96.8 | 7.2 | 28.9 | 7.4 | 0.9 |

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

**Table 17b. 2015 Quality Control Data Summaries of Statistical Analyses
THYROID-STIMULATING HORMONE ($\mu\text{IU TSH/mL serum}$)**

Lot 1411 - Enriched 25.0 $\mu\text{IU/mL}$ serum

| METHOD | N | Mean | Average Within Lab SD | Total SD | Y- Intercept* | Slope |
|----------------------------------|-----|------|-----------------------|----------|---------------|-------|
| Siemens Healthcare Diagnostics | 20 | 35.4 | 4.2 | 5.1 | -1.0 | 1.4 |
| Neo-Genesis Accuwell | 40 | 25.2 | 4.3 | 4.9 | -0.4 | 1.1 |
| MP Biomedicals ELISA | 20 | 15.9 | 2.2 | 4.1 | -6.6 | 0.9 |
| Delfia | 427 | 26.3 | 2.8 | 5.3 | -0.7 | 1.1 |
| AutoDelfia | 862 | 28.0 | 2.5 | 4.5 | -0.2 | 1.1 |
| Ani Labsystems | 89 | 25.6 | 2.2 | 3.7 | -5.1 | 1.2 |
| Bio-Rad Quantase | 70 | 32.8 | 4.0 | 11.8 | 1.3 | 1.3 |
| TecnoSuma UMELISA | 29 | 32.9 | 4.0 | 4.5 | -2.5 | 1.4 |
| Bioclone ELISA | 10 | 25.7 | 0.9 | 0.9 | -0.3 | 1.1 |
| DiaSorin | 88 | 25.0 | 2.1 | 3.0 | 1.5 | 1.0 |
| Interscientific NeoMAP Multiplex | 50 | 24.6 | 1.7 | 2.3 | -3.0 | 1.1 |
| PerkinElmer GSP Neonatal | 431 | 26.7 | 2.2 | 2.9 | 0.0 | 1.1 |
| In House | 40 | 25.7 | 1.8 | 2.7 | 1.1 | 1.0 |

Lot 1412 - Enriched 40.0 $\mu\text{IU/mL}$ serum

| METHOD | N | Mean | Average Within Lab SD | Total SD | Y- Intercept* | Slope |
|----------------------------------|-----|------|-----------------------|----------|---------------|-------|
| Siemens Healthcare Diagnostics | 20 | 55.7 | 5.0 | 7.0 | -1.0 | 1.4 |
| Neo-Genesis Accuwell | 40 | 42.7 | 4.8 | 7.3 | -0.4 | 1.1 |
| MP Biomedicals ELISA | 20 | 26.6 | 3.2 | 7.6 | -6.6 | 0.9 |
| Delfia | 427 | 44.0 | 4.8 | 8.1 | -0.7 | 1.1 |
| AutoDelfia | 841 | 45.9 | 3.5 | 5.0 | -0.2 | 1.1 |
| Ani Labsystems | 88 | 43.4 | 4.1 | 6.2 | -5.1 | 1.2 |
| Bio-Rad Quantase | 70 | 54.2 | 5.5 | 21.8 | 1.3 | 1.3 |
| TecnoSuma UMELISA | 28 | 53.4 | 4.4 | 5.1 | -2.5 | 1.4 |
| Bioclone ELISA | 10 | 43.6 | 2.2 | 2.2 | -0.3 | 1.1 |
| DiaSorin | 90 | 40.0 | 3.6 | 6.6 | 1.5 | 1.0 |
| Interscientific NeoMAP Multiplex | 50 | 41.7 | 2.5 | 3.2 | -3.0 | 1.1 |
| PerkinElmer GSP Neonatal | 433 | 42.7 | 3.2 | 4.5 | 0.0 | 1.1 |
| In House | 40 | 41.3 | 3.1 | 5.2 | 1.1 | 1.0 |

Lot 1413 - Enriched 80.0 $\mu\text{IU/mL}$ serum

| METHOD | N | Mean | Average Within Lab SD | Total SD | Y- Intercept* | Slope |
|----------------------------------|-----|-------|-----------------------|----------|---------------|-------|
| Siemens Healthcare Diagnostics | 20 | 114.0 | 11.5 | 11.9 | -1.0 | 1.4 |
| Neo-Genesis Accuwell | 39 | 83.5 | 9.7 | 10.9 | -0.4 | 1.1 |
| MP Biomedicals ELISA | 20 | 62.7 | 8.0 | 19.2 | -6.6 | 0.9 |
| Delfia | 412 | 87.1 | 7.8 | 15.4 | -0.7 | 1.1 |
| AutoDelfia | 838 | 91.0 | 7.1 | 10.0 | -0.2 | 1.1 |
| Ani Labsystems | 88 | 92.6 | 6.3 | 12.6 | -5.1 | 1.2 |
| Bio-Rad Quantase | 70 | 104.5 | 11.5 | 47.6 | 1.3 | 1.3 |
| TecnoSuma UMELISA | 29 | 110.0 | 7.0 | 7.0 | -2.5 | 1.4 |
| Bioclone ELISA | 10 | 85.0 | 2.9 | 2.9 | -0.3 | 1.1 |
| DiaSorin | 89 | 77.6 | 5.3 | 11.2 | 1.5 | 1.0 |
| Interscientific NeoMAP Multiplex | 48 | 85.9 | 5.1 | 6.4 | -3.0 | 1.1 |
| PerkinElmer GSP Neonatal | 435 | 85.5 | 6.6 | 9.2 | 0.0 | 1.1 |
| In House | 40 | 80.7 | 5.2 | 15.4 | 1.1 | 1.0 |

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

2015 Quality Control Data Summaries of Statistical Analyses

THYROID-STIMULATING HORMONE ($\mu\text{IU TSH/mL serum}$)

Lot 1511 - Enriched 25.0 $\mu\text{IU/mL serum}$

| METHOD | N | Mean | Average Within Lab SD | Total SD | Y- Intercept* | Slope |
|----------------------------------|-----|------|-----------------------|----------|---------------|-------|
| Siemens Healthcare Diagnostics | 20 | 33.4 | 3.1 | 4.5 | -0.5 | 1.4 |
| Neo-Genesis Accuwell | 39 | 26.9 | 2.8 | 4.1 | -1.8 | 1.2 |
| MP Biomedicals ELISA | 20 | 20.5 | 1.8 | 4.0 | -2.9 | 1.0 |
| Delfia | 415 | 27.8 | 2.5 | 3.6 | -0.5 | 1.2 |
| AutoDelfia | 880 | 27.8 | 2.2 | 5.8 | -1.2 | 1.2 |
| Ani Labsystems | 80 | 26.9 | 2.1 | 2.7 | -1.9 | 1.2 |
| Bio-Rad Quantase | 70 | 23.7 | 2.1 | 9.0 | 0.8 | 0.9 |
| TecnoSuma UMELISA | 20 | 36.9 | 5.3 | 14.2 | -6.0 | 1.8 |
| Bioclone ELISA | 20 | 17.9 | 1.4 | 11.2 | 1.2 | 0.7 |
| DiaSorin | 79 | 29.5 | 3.0 | 3.9 | -1.8 | 1.3 |
| Interscientific NeoMAP Multiplex | 49 | 27.0 | 1.8 | 1.9 | 1.4 | 1.1 |
| PerkinElmer GSP Neonatal | 462 | 26.7 | 1.9 | 2.4 | -2.7 | 1.2 |
| In House | 49 | 29.0 | 2.4 | 4.1 | 0.0 | 1.2 |

Lot 1512 - Enriched 40.0 $\mu\text{IU/mL serum}$

| METHOD | N | Mean | Average Within Lab SD | Total SD | Y- Intercept* | Slope |
|----------------------------------|-----|------|-----------------------|----------|---------------|-------|
| Siemens Healthcare Diagnostics | 20 | 59.3 | 4.5 | 6.6 | -0.5 | 1.4 |
| Neo-Genesis Accuwell | 40 | 46.2 | 5.0 | 5.0 | -1.8 | 1.2 |
| MP Biomedicals ELISA | 20 | 38.2 | 3.8 | 3.8 | -2.9 | 1.0 |
| Delfia | 420 | 48.0 | 4.3 | 5.8 | -0.5 | 1.2 |
| AutoDelfia | 865 | 48.1 | 3.5 | 9.8 | -1.2 | 1.2 |
| Ani Labsystems | 76 | 48.7 | 3.5 | 3.6 | -1.9 | 1.2 |
| Bio-Rad Quantase | 70 | 38.0 | 3.6 | 15.1 | 0.8 | 0.9 |
| TecnoSuma UMELISA | 20 | 67.3 | 10.1 | 23.5 | -6.0 | 1.8 |
| Bioclone ELISA | 20 | 29.8 | 2.9 | 19.1 | 1.2 | 0.7 |
| DiaSorin | 76 | 54.0 | 5.4 | 6.6 | -1.8 | 1.3 |
| Interscientific NeoMAP Multiplex | 49 | 48.9 | 3.3 | 3.6 | 1.4 | 1.1 |
| PerkinElmer GSP Neonatal | 464 | 47.2 | 3.1 | 4.9 | -2.7 | 1.2 |
| In House | 49 | 46.5 | 3.0 | 4.3 | 0.0 | 1.2 |

Lot 1513 - Enriched 80.0 $\mu\text{IU/mL serum}$

| METHOD | N | Mean | Average Within Lab SD | Total SD | Y- Intercept* | Slope |
|----------------------------------|-----|-------|-----------------------|----------|---------------|-------|
| Siemens Healthcare Diagnostics | 20 | 113.2 | 8.5 | 10.5 | -0.5 | 1.4 |
| Neo-Genesis Accuwell | 40 | 92.0 | 7.3 | 7.4 | -1.8 | 1.2 |
| MP Biomedicals ELISA | 20 | 75.5 | 13.2 | 15.7 | -2.9 | 1.0 |
| Delfia | 418 | 93.2 | 8.9 | 11.9 | -0.5 | 1.2 |
| AutoDelfia | 877 | 94.3 | 6.9 | 19.9 | -1.2 | 1.2 |
| Ani Labsystems | 78 | 94.4 | 5.9 | 9.2 | -1.9 | 1.2 |
| Bio-Rad Quantase | 70 | 74.7 | 9.3 | 32.9 | 0.8 | 0.9 |
| TecnoSuma UMELISA | 20 | 135.8 | 23.2 | 64.7 | -6.0 | 1.8 |
| Bioclone ELISA | 20 | 56.5 | 5.3 | 37.7 | 1.2 | 0.7 |
| DiaSorin | 74 | 103.5 | 9.1 | 10.1 | -1.8 | 1.3 |
| Interscientific NeoMAP Multiplex | 49 | 89.5 | 7.2 | 8.0 | 1.4 | 1.1 |
| PerkinElmer GSP Neonatal | 465 | 94.1 | 6.5 | 8.7 | -2.7 | 1.2 |
| In House | 50 | 92.7 | 7.1 | 13.5 | 0.0 | 1.2 |

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis

**Table 17c. 2015 Quality Control Data Summaries of Statistical Analyses
THYROXINE ($\mu\text{g T}_4/\text{dL serum}$)**

Lot 1401 - Enriched 2.0 $\mu\text{g}/\text{dL}$ serum

| METHOD | N | Mean | Average Within Lab SD | Total SD | Y- Intercept* | Slope |
|----------------------------------|-----|------|-----------------------|----------|---------------|-------|
| Neo-Genesis Accuwell | 37 | 1.3 | 0.2 | 0.2 | -0.3 | 0.9 |
| Delfia | 175 | 1.8 | 0.3 | 0.4 | -0.2 | 1.0 |
| AutoDelfia | 411 | 1.9 | 0.3 | 0.3 | -0.1 | 1.0 |
| Interscientific NeoMAP Multiplex | 99 | 1.8 | 0.3 | 0.3 | -0.2 | 1.0 |
| PerkinElmer GSP Neonatal | 374 | 1.8 | 0.2 | 0.2 | -0.3 | 1.0 |

Lot 1402 - Enriched 7.0 $\mu\text{g}/\text{dL}$ serum

| METHOD | N | Mean | Average Within Lab SD | Total SD | Y- Intercept* | Slope |
|----------------------------------|-----|------|-----------------------|----------|---------------|-------|
| Neo-Genesis Accuwell | 40 | 6.4 | 1.0 | 2.1 | -0.3 | 0.9 |
| Delfia | 176 | 6.5 | 0.7 | 0.9 | -0.2 | 1.0 |
| AutoDelfia | 420 | 6.6 | 0.6 | 0.7 | -0.1 | 1.0 |
| Interscientific NeoMAP Multiplex | 99 | 6.3 | 0.5 | 0.5 | -0.2 | 1.0 |
| PerkinElmer GSP Neonatal | 380 | 6.8 | 0.7 | 0.7 | -0.3 | 1.0 |

Lot 1403 - Enriched 11.0 $\mu\text{g}/\text{dL}$ serum

| METHOD | N | Mean | Average Within Lab SD | Total SD | Y- Intercept* | Slope |
|----------------------------------|-----|------|-----------------------|----------|---------------|-------|
| Neo-Genesis Accuwell | 40 | 9.2 | 0.9 | 1.8 | -0.3 | 0.9 |
| Delfia | 174 | 10.6 | 0.9 | 1.5 | -0.2 | 1.0 |
| AutoDelfia | 420 | 10.6 | 1.0 | 1.1 | -0.1 | 1.0 |
| Interscientific NeoMAP Multiplex | 100 | 10.5 | 0.9 | 0.9 | -0.2 | 1.0 |
| PerkinElmer GSP Neonatal | 368 | 11.2 | 1.2 | 1.3 | -0.3 | 1.0 |

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

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Table 17d. 2015 Quality Control Data Summaries of Statistical Analyses
TOTAL GALACTOSE (mg TGal/dL blood)

Lot 1425 - Enriched 5.0 mg/dL blood

| METHOD | N | Mean | Average Within Lab SD | Total SD | Y- Intercept* | Slope |
|-------------------------------------|-----|------|-----------------------|----------|---------------|-------|
| Siemens Healthcare Diagnostics | 40 | 5.6 | 0.5 | 0.6 | 1.4 | 0.9 |
| Fluorometric Manual | 99 | 4.6 | 0.5 | 1.3 | 0.8 | 0.9 |
| Colorimetric | 64 | 6.3 | 0.9 | 1.5 | 1.3 | 1.1 |
| PerkinElmer Neonatal Kit | 255 | 5.2 | 0.6 | 1.0 | 1.4 | 0.8 |
| Neo-Genesis Accuwell | 29 | 6.6 | 0.5 | 1.4 | 0.6 | 1.2 |
| Bio-Rad Quantase | 129 | 6.8 | 1.2 | 1.7 | -0.9 | 1.4 |
| Interscientific Enzyme | 30 | 5.3 | 0.4 | 0.5 | 1.2 | 0.8 |
| Astoria-Pacific 50 Hour Reagent Kit | 97 | 6.7 | 0.5 | 0.7 | 1.6 | 1.0 |
| TecnoSuma UMTEST | 30 | 8.2 | 1.7 | 2.1 | 2.5 | 1.1 |

Lot 1426 - Enriched 10.0 mg/dL blood

| METHOD | N | Mean | Average Within Lab SD | Total SD | Y- Intercept* | Slope |
|-------------------------------------|-----|------|-----------------------|----------|---------------|-------|
| Siemens Healthcare Diagnostics | 40 | 11.0 | 0.6 | 0.6 | 1.4 | 0.9 |
| Fluorometric Manual | 96 | 9.4 | 0.7 | 2.0 | 0.8 | 0.9 |
| Colorimetric | 68 | 12.7 | 1.3 | 2.4 | 1.3 | 1.1 |
| PerkinElmer Neonatal Kit | 257 | 9.5 | 0.9 | 1.4 | 1.4 | 0.8 |
| Neo-Genesis Accuwell | 29 | 13.1 | 1.0 | 2.1 | 0.6 | 1.2 |
| Bio-Rad Quantase | 128 | 12.7 | 2.0 | 2.8 | -0.9 | 1.4 |
| Interscientific Enzyme | 30 | 9.1 | 1.0 | 1.0 | 1.2 | 0.8 |
| Astoria-Pacific 50 Hour Reagent Kit | 100 | 11.9 | 0.8 | 1.2 | 1.6 | 1.0 |
| TecnoSuma UMTEST | 30 | 12.6 | 1.4 | 3.0 | 2.5 | 1.1 |

Lot 1427 - Enriched 15.0 mg/dL blood

| METHOD | N | Mean | Average Within Lab SD | Total SD | Y- Intercept* | Slope |
|-------------------------------------|-----|------|-----------------------|----------|---------------|-------|
| Siemens Healthcare Diagnostics | 40 | 15.5 | 1.0 | 1.2 | 1.4 | 0.9 |
| Fluorometric Manual | 90 | 15.4 | 1.2 | 1.2 | 0.8 | 0.9 |
| Colorimetric | 70 | 18.2 | 2.0 | 3.6 | 1.3 | 1.1 |
| PerkinElmer Neonatal Kit | 257 | 13.6 | 1.3 | 2.1 | 1.4 | 0.8 |
| Neo-Genesis Accuwell | 30 | 18.3 | 1.3 | 2.4 | 0.6 | 1.2 |
| Bio-Rad Quantase | 130 | 19.3 | 2.3 | 4.4 | -0.9 | 1.4 |
| Interscientific Enzyme | 30 | 13.8 | 1.1 | 1.3 | 1.2 | 0.8 |
| Astoria-Pacific 50 Hour Reagent Kit | 99 | 16.9 | 1.1 | 2.1 | 1.6 | 1.0 |
| TecnoSuma UMTEST | 30 | 20.2 | 1.9 | 3.1 | 2.5 | 1.1 |

Lot 1428 - Enriched 30.0 mg/dL blood

| METHOD | N | Mean | Average Within Lab SD | Total SD | Y- Intercept* | Slope |
|-------------------------------------|-----|------|-----------------------|----------|---------------|-------|
| Siemens Healthcare Diagnostics | 40 | 29.0 | 2.1 | 10.1 | 1.4 | 0.9 |
| Fluorometric Manual | 100 | 26.9 | 1.8 | 6.4 | 0.8 | 0.9 |
| Colorimetric | 70 | 34.2 | 3.6 | 8.6 | 1.3 | 1.1 |
| PerkinElmer Neonatal Kit | 266 | 25.2 | 2.3 | 3.6 | 1.4 | 0.8 |
| Neo-Genesis Accuwell | 28 | 37.1 | 2.3 | 2.9 | 0.6 | 1.2 |
| Bio-Rad Quantase | 140 | 41.2 | 5.3 | 10.2 | -0.9 | 1.4 |
| Interscientific Enzyme | 30 | 25.5 | 2.2 | 2.5 | 1.2 | 0.8 |
| Astoria-Pacific 50 Hour Reagent Kit | 100 | 32.2 | 1.9 | 3.6 | 1.6 | 1.0 |
| TecnoSuma UMTEST | 30 | 35.5 | 2.8 | 6.1 | 2.5 | 1.1 |

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

2015 Quality Control Data Summaries of Statistical Analyses
TOTAL GALACTOSE (mg TGal/dL blood)

Lot 1521 - Enriched 5.0 mg/dL blood

| METHOD | N | Mean | Average Within Lab SD | Total SD | Y- Intercept* | Slope |
|-------------------------------------|-----|------|-----------------------|----------|---------------|-------|
| Siemens Healthcare Diagnostics | 40 | 5.4 | 0.4 | 0.5 | 1.6 | 0.8 |
| Fluorometric Manual | 99 | 5.1 | 0.7 | 1.2 | 0.4 | 1.0 |
| Colorimetric | 57 | 5.9 | 0.8 | 1.2 | 0.2 | 1.1 |
| PerkinElmer Neonatal Kit | 259 | 5.3 | 0.7 | 1.1 | 1.2 | 0.8 |
| Neo-Genesis Accuwell | 28 | 6.4 | 0.6 | 1.1 | 0.7 | 1.2 |
| Bio-Rad Quantase | 153 | 6.5 | 0.7 | 1.4 | 0.5 | 1.1 |
| Interscientific Enzyme | 39 | 6.1 | 0.6 | 0.7 | 1.7 | 0.8 |
| PerkinElmer GSP Neonatal | 105 | 5.5 | 0.4 | 0.7 | 1.0 | 0.9 |
| Astoria-Pacific 50 Hour Reagent Kit | 87 | 6.6 | 0.5 | 0.9 | 1.7 | 0.9 |
| TecnoSuma UMTEST | 18 | 7.7 | 0.4 | 0.4 | 1.7 | 1.1 |

Lot 1522 - Enriched 10.0 mg/dL blood

| METHOD | N | Mean | Average Within Lab SD | Total SD | Y- Intercept* | Slope |
|-------------------------------------|-----|------|-----------------------|----------|---------------|-------|
| Siemens Healthcare Diagnostics | 40 | 9.7 | 0.6 | 0.8 | 1.6 | 0.8 |
| Fluorometric Manual | 90 | 10.0 | 0.7 | 1.5 | 0.4 | 1.0 |
| Colorimetric | 60 | 11.3 | 1.4 | 2.9 | 0.2 | 1.1 |
| PerkinElmer Neonatal Kit | 263 | 8.9 | 1.0 | 1.6 | 1.2 | 0.8 |
| Neo-Genesis Accuwell | 30 | 12.9 | 1.1 | 3.2 | 0.7 | 1.2 |
| Bio-Rad Quantase | 149 | 11.0 | 1.3 | 2.2 | 0.5 | 1.1 |
| Interscientific Enzyme | 39 | 9.6 | 0.8 | 1.3 | 1.7 | 0.8 |
| PerkinElmer GSP Neonatal | 110 | 9.9 | 1.0 | 1.3 | 1.0 | 0.9 |
| Astoria-Pacific 50 Hour Reagent Kit | 90 | 10.9 | 0.8 | 1.3 | 1.7 | 0.9 |
| TecnoSuma UMTEST | 20 | 12.5 | 1.3 | 1.7 | 1.7 | 1.1 |

Lot 1523 - Enriched 15.0 mg/dL blood

| METHOD | N | Mean | Average Within Lab SD | Total SD | Y- Intercept* | Slope |
|-------------------------------------|-----|------|-----------------------|----------|---------------|-------|
| Siemens Healthcare Diagnostics | 40 | 13.9 | 0.9 | 1.2 | 1.6 | 0.8 |
| Fluorometric Manual | 90 | 15.0 | 1.2 | 1.8 | 0.4 | 1.0 |
| Colorimetric | 60 | 16.7 | 2.0 | 4.4 | 0.2 | 1.1 |
| PerkinElmer Neonatal Kit | 264 | 12.9 | 1.1 | 2.1 | 1.2 | 0.8 |
| Neo-Genesis Accuwell | 28 | 18.0 | 1.1 | 2.7 | 0.7 | 1.2 |
| Bio-Rad Quantase | 147 | 15.9 | 1.6 | 3.0 | 0.5 | 1.1 |
| Interscientific Enzyme | 40 | 13.8 | 0.8 | 2.4 | 1.7 | 0.8 |
| PerkinElmer GSP Neonatal | 108 | 13.7 | 1.2 | 1.5 | 1.0 | 0.9 |
| Astoria-Pacific 50 Hour Reagent Kit | 89 | 15.1 | 0.9 | 1.3 | 1.7 | 0.9 |
| TecnoSuma UMTEST | 20 | 18.8 | 1.9 | 4.1 | 1.7 | 1.1 |

Lot 1524 - Enriched 30.0 mg/dL blood

| METHOD | N | Mean | Average Within Lab SD | Total SD | Y- Intercept* | Slope |
|-------------------------------------|-----|------|-----------------------|----------|---------------|-------|
| Siemens Healthcare Diagnostics | 40 | 25.5 | 1.3 | 5.9 | 1.6 | 0.8 |
| Fluorometric Manual | 94 | 29.0 | 2.5 | 3.6 | 0.4 | 1.0 |
| Colorimetric | 60 | 33.5 | 3.3 | 10.0 | 0.2 | 1.1 |
| PerkinElmer Neonatal Kit | 261 | 24.7 | 2.0 | 3.5 | 1.2 | 0.8 |
| Neo-Genesis Accuwell | 30 | 35.9 | 2.9 | 6.2 | 0.7 | 1.2 |
| Bio-Rad Quantase | 151 | 33.0 | 3.1 | 7.2 | 0.5 | 1.1 |
| Interscientific Enzyme | 39 | 26.4 | 2.3 | 4.4 | 1.7 | 0.8 |
| PerkinElmer GSP Neonatal | 107 | 27.5 | 2.7 | 3.2 | 1.0 | 0.9 |
| Astoria-Pacific 50 Hour Reagent Kit | 88 | 29.5 | 1.5 | 3.1 | 1.7 | 0.9 |
| TecnoSuma UMTEST | 20 | 35.6 | 3.6 | 7.9 | 1.7 | 1.1 |

**Table 17e. 2015 Quality Control Data Summaries of Statistical Analyses
GALACTOSE-1-PHOSPHATE URIDYLTRANSFERASE (U GALT/g Hb)**

Lot 1431 - Assayed 1.3 U/g Hb

| METHOD | N | Mean | Average Within Lab SD | Total SD | Y- Intercept* | Slope |
|---|-----|------|-----------------------------|----------|---------------|-------|
| PerkinElmer Neonatal Kit | 295 | 1.3 | 0.3 | 0.5 | 0.2 | 0.7 |
| Astoria-Pacific Neonatal Microplate Reagent Kit | 40 | 0.6 | 0.1 | 0.2 | -0.6 | 0.7 |

Lot 1432 - Assayed 4.1 U/g Hb

| METHOD | N | Mean | Average Within Lab SD | Total SD | Y- Intercept* | Slope |
|---|-----|------|-----------------------------|----------|---------------|-------|
| PerkinElmer Neonatal Kit | 293 | 3.0 | 0.4 | 0.5 | 0.2 | 0.7 |
| Astoria-Pacific Neonatal Microplate Reagent Kit | 39 | 2.1 | 0.2 | 0.3 | -0.6 | 0.7 |

Lot 1433 - Assayed 9.5 U/g Hb

| METHOD | N | Mean | Average Within Lab SD | Total SD | Y- Intercept* | Slope |
|---|-----|------|-----------------------------|----------|---------------|-------|
| PerkinElmer Neonatal Kit | 295 | 7.2 | 0.9 | 1.2 | 0.2 | 0.7 |
| Astoria-Pacific Neonatal Microplate Reagent Kit | 40 | 6.6 | 0.7 | 1.0 | -0.6 | 0.7 |

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

Methods Reported in Units Other Than U/g Hb (>3 Participants)*

| Lot Number | Method | N | Mean | Avg Within Lab SD | All Lab SD | Min Concentration | Max Concentration |
|---------------|--|----|-------|-------------------------|------------------|----------------------|----------------------|
| 1431 | Astoria-Pacific 50 Hour Reagent Kit (μmol/L blood) | 70 | 14.7 | 1.9 | 3.9 | 8.1 | 23.2 |
| | Perkin Elmer GSP Neonatal (U/dL blood) | 70 | 0.5 | 0.2 | 1.0 | 0.0 | 2.5 |
| 1432 | Astoria-Pacific 50 Hour Reagent Kit (μmol/L blood) | 70 | 66.3 | 6.5 | 10.0 | 45.0 | 94.6 |
| | Perkin Elmer GSP Neonatal (U/dL blood) | 70 | 1.5 | 0.3 | 0.6 | 0.5 | 2.5 |
| 1433 | Astoria-Pacific 50 Hour Reagent Kit (μmol/L blood) | 70 | 193.0 | 28.9 | 44.4 | 90.0 | 303.4 |
| | Perkin Elmer GSP Neonatal (U/dL blood) | 70 | 8.2 | 0.7 | 1.3 | 5.3 | 10.2 |

*Outlier data was removed based on the 99% confidence interval

**Table 17e. 2015 Quality Control Data Summaries of Statistical Analyses
GALACTOSE-1-PHOSPHATE URIDYLTRANSFERASE (U GALT/g Hb)**

Lot 1531 - Assayed 1.4 U/g Hb

| METHOD | N | Mean | Average Within Lab SD | Total SD | Y- Intercept* | Slope |
|---|-----|------|-----------------------------|----------|---------------|-------|
| PerkinElmer Neonatal Kit | 261 | 1.3 | 0.3 | 0.4 | 0.2 | 0.7 |
| Astoria-Pacific Neonatal Microplate Reagent Kit | 70 | 0.7 | 0.1 | 0.2 | -0.4 | 0.7 |

Lot 1532 - Assayed 3.4 U/g Hb

| METHOD | N | Mean | Average Within Lab SD | Total SD | Y- Intercept* | Slope |
|---|-----|------|-----------------------------|----------|---------------|-------|
| PerkinElmer Neonatal Kit | 267 | 2.6 | 0.3 | 0.5 | 0.2 | 0.7 |
| Astoria-Pacific Neonatal Microplate Reagent Kit | 70 | 2.1 | 0.2 | 0.5 | -0.4 | 0.7 |

Lot 1533 - Assayed 7.7 U/g Hb

| METHOD | N | Mean | Average Within Lab SD | Total SD | Y- Intercept* | Slope |
|---|-----|------|-----------------------------|----------|---------------|-------|
| PerkinElmer Neonatal Kit | 277 | 5.9 | 0.6 | 0.9 | 0.2 | 0.7 |
| Astoria-Pacific Neonatal Microplate Reagent Kit | 70 | 5.3 | 0.6 | 1.0 | -0.4 | 0.7 |

Methods Reported in Units Other Than U/g Hb (>3 Participants)*

| Lot Number | Method | N | Mean | Avg Within Lab SD | All Lab SD | Min Concentration | Max Concentration |
|---------------|--|-----|-------|-------------------------|------------------|----------------------|----------------------|
| 1531 | Astoria-Pacific 50 Hour Reagent Kit (μmol/L blood) | 60 | 16.9 | 2.6 | 3.1 | 10.0 | 24.7 |
| | Perkin Elmer GSP Neonatal (U/dL blood) | 91 | 0.7 | 0.1 | 1.0 | 0.0 | 2.5 |
| 1532 | Astoria-Pacific 50 Hour Reagent Kit (μmol/L blood) | 60 | 63.8 | 8.5 | 13.4 | 36.0 | 87.3 |
| | Perkin Elmer GSP Neonatal (U/dL blood) | 100 | 1.7 | 0.3 | 0.6 | 0.2 | 2.8 |
| 1533 | Astoria-Pacific 50 Hour Reagent Kit (μmol/L blood) | 60 | 171.3 | 25.2 | 53.6 | 52.0 | 266.9 |
| | Perkin Elmer GSP Neonatal (U/dL blood) | 100 | 7.5 | 0.6 | 1.1 | 5.2 | 4.7 |

*Outlier data was removed based on the 99% confidence interval

Several laboratories reported their GALT results in either μmol/L blood or U/dL blood according to their analytic method. NSQAP's certified units for GALT are U/g hemoglobin. Due to the lack of a conversion factor between U/g hemoglobin and μmol/L blood or U/dL blood, the linear regression parameters cannot be calculated for these units of measure. Basic peer-group statistics are provided to assist in self-assessment under those circumstances.

**Table 17f. 2015 Quality Control Data Summaries of Statistical Analyses
IMMUNOREACTIVE TRYPSINOGEN (ng IRT/mL blood)**

Lot 1491 - Assayed 19.7 ng/mL blood

| METHOD | N | Mean | Average Within Lab SD | Total SD | Y- Intercept* | Slope |
|--------------------------|------|------|-----------------------------|----------|---------------|-------|
| MP Biomedicals ELISA | 89 | 24.3 | 3.0 | 8.1 | 29.7 | 1.1 |
| Delfia | 400 | 19.3 | 2.4 | 2.7 | 2.1 | 0.9 |
| AutoDelfia | 1410 | 19.5 | 1.7 | 2.0 | 2.0 | 1.0 |
| Bio-Rad Quantase | 40 | 50.4 | 5.0 | 21.7 | 58.2 | 0.9 |
| PerkinElmer GSP Neonatal | 647 | 19.6 | 1.4 | 1.5 | 0.4 | 1.0 |

Lot 1492 - Assayed 70.3 ng/mL blood

| METHOD | N | Mean | Average Within Lab SD | Total SD | Y- Intercept* | Slope |
|--------------------------|------|-------|-----------------------------|----------|---------------|-------|
| MP Biomedicals ELISA | 83 | 114.7 | 14.3 | 32.7 | 29.7 | 1.1 |
| Delfia | 412 | 67.8 | 6.5 | 7.8 | 2.1 | 0.9 |
| AutoDelfia | 1399 | 70.2 | 5.6 | 6.7 | 2.0 | 1.0 |
| Bio-Rad Quantase | 40 | 138.0 | 5.2 | 49.2 | 58.2 | 0.9 |
| PerkinElmer GSP Neonatal | 664 | 71.6 | 4.3 | 4.5 | 0.4 | 1.0 |

Lot 1493 - Assayed 145.6 ng/mL blood

| METHOD | N | Mean | Average Within Lab SD | Total SD | Y- Intercept* | Slope |
|--------------------------|------|-------|-----------------------------|----------|---------------|-------|
| MP Biomedicals ELISA | 88 | 237.9 | 41.2 | 83.3 | 29.7 | 1.1 |
| Delfia | 406 | 140.2 | 13.9 | 15.8 | 2.1 | 0.9 |
| AutoDelfia | 1367 | 143.5 | 9.5 | 10.6 | 2.0 | 1.0 |
| Bio-Rad Quantase | 40 | 217.7 | 7.9 | 66.7 | 58.2 | 0.9 |
| PerkinElmer GSP Neonatal | 663 | 148.8 | 8.8 | 9.8 | 0.4 | 1.0 |

Lot 1494 - Assayed 259.3 ng/mL blood

| METHOD | N | Mean | Average Within Lab SD | Total SD | Y- Intercept* | Slope |
|--------------------------|------|-------|-----------------------------|----------|---------------|-------|
| MP Biomedicals ELISA | 65 | 281.5 | 40.7 | 98.1 | 29.7 | 1.1 |
| Delfia | 408 | 242.8 | 22.0 | 27.1 | 2.1 | 0.9 |
| AutoDelfia | 1390 | 249.7 | 18.1 | 20.4 | 2.0 | 1.0 |
| Bio-Rad Quantase | 40 | 275.3 | 27.9 | 85.6 | 58.2 | 0.9 |
| PerkinElmer GSP Neonatal | 651 | 261.8 | 16.9 | 17.5 | 0.4 | 1.0 |

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Table 17g. 2015 Quality Control Data Summaries of Statistical Analyses
ALANINE ($\mu\text{mol Ala/L}$ blood)

Lot 1425 - Nonenriched 0 $\mu\text{mol/L}$ blood

| METHOD | N | Mean | Average Within Lab SD | Total SD | Y- Intercept* | Slope |
|--|-----|-------|--------------------------|----------|------------------|-------|
| Derivatized - MS/MS non-kit | 663 | 360.6 | 36.2 | 78.6 | 359.1 | 0.7 |
| Non-derivatized - MS/MS non-kit | 94 | 352.5 | 27.0 | 82.9 | 350.9 | 0.7 |
| Derivatized - MS/MS PE NeoGram Kit | 88 | 354.9 | 35.7 | 78.1 | 354.3 | 0.7 |
| Non-derivatized - MS/MS PE NeoBase Kit | 458 | 424.9 | 32.0 | 66.3 | 426.0 | 0.9 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 95 | 345.7 | 24.9 | 34.4 | 346.8 | 0.7 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 90 | 313.0 | 26.0 | 52.0 | 313.8 | 0.6 |
| Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens | 10 | 392.7 | 14.2 | 14.2 | 387.3 | 0.9 |

Lot 1426 - Enriched 200.0 $\mu\text{mol/L}$ blood

| METHOD | N | Mean | Average Within Lab SD | Total SD | Y- Intercept* | Slope |
|--|-----|-------|--------------------------|----------|------------------|-------|
| Derivatized - MS/MS non-kit | 658 | 497.6 | 45.7 | 95.5 | 359.1 | 0.7 |
| Non-derivatized - MS/MS non-kit | 94 | 483.8 | 43.1 | 113.9 | 350.9 | 0.7 |
| Derivatized - MS/MS PE NeoGram Kit | 90 | 507.3 | 56.3 | 117.7 | 354.3 | 0.7 |
| Non-derivatized - MS/MS PE NeoBase Kit | 461 | 605.8 | 46.2 | 94.8 | 426.0 | 0.9 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 97 | 487.5 | 37.5 | 56.5 | 346.8 | 0.7 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 88 | 440.0 | 42.1 | 80.3 | 313.8 | 0.6 |
| Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens | 10 | 542.0 | 19.4 | 19.4 | 387.3 | 0.9 |

Lot 1427 - Enriched 400.0 $\mu\text{mol/L}$ blood

| METHOD | N | Mean | Average Within Lab SD | Total SD | Y- Intercept* | Slope |
|--|-----|-------|--------------------------|----------|---------------|-------|
| Derivatized - MS/MS non-kit | 654 | 626.4 | 57.2 | 123.7 | 359.1 | 0.7 |
| Non-derivatized - MS/MS non-kit | 94 | 615.0 | 39.3 | 134.2 | 350.9 | 0.7 |
| Derivatized - MS/MS PE NeoGram Kit | 90 | 641.3 | 59.5 | 152.4 | 354.3 | 0.7 |
| Non-derivatized - MS/MS PE NeoBase Kit | 466 | 766.1 | 58.3 | 120.4 | 426.0 | 0.9 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 95 | 615.6 | 41.7 | 65.3 | 346.8 | 0.7 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 90 | 561.4 | 36.0 | 105.1 | 313.8 | 0.6 |
| Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens | 10 | 753.6 | 25.1 | 25.1 | 387.3 | 0.9 |

Lot 1428 - Enriched 600.0 $\mu\text{mol/L}$ blood

| METHOD | N | Mean | Average Within Lab SD | Total SD | Y- Intercept* | Slope |
|--|-----|-------|--------------------------|----------|---------------|-------|
| Derivatized - MS/MS non-kit | 651 | 774.9 | 64.7 | 149.3 | 359.1 | 0.7 |
| Non-derivatized - MS/MS non-kit | 95 | 754.5 | 68.2 | 200.2 | 350.9 | 0.7 |
| Derivatized - MS/MS PE NeoGram Kit | 90 | 806.0 | 75.3 | 183.0 | 354.3 | 0.7 |
| Non-derivatized - MS/MS PE NeoBase Kit | 465 | 951.8 | 67.9 | 146.8 | 426.0 | 0.9 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 96 | 759.1 | 50.9 | 96.9 | 346.8 | 0.7 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 89 | 687.2 | 39.0 | 117.8 | 313.8 | 0.6 |
| Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens | 10 | 899.0 | 37.2 | 37.2 | 387.3 | 0.9 |

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

2015 Quality Control Data Summaries of Statistical Analyses ALANINE ($\mu\text{mol Ala/L blood}$)

Lot 1521 - Nonenriched 0 $\mu\text{mol/L blood}$

| METHOD | N | Mean | Average Within | | Y- Intercept* | Slope |
|--|-----|-------|----------------|----------|---------------|-------|
| | | | Lab SD | Total SD | | |
| Derivatized - MS/MS non-kit | 690 | 349.9 | 32.1 | 88.7 | 349.9 | 0.7 |
| Non-derivatized - MS/MS non-kit | 148 | 348.9 | 36.4 | 77.0 | 353.1 | 0.7 |
| Derivatized - MS/MS PE NeoGram Kit | 78 | 386.2 | 44.9 | 63.7 | 389.1 | 0.8 |
| Non-derivatized - MS/MS PE NeoBase Kit | 538 | 421.8 | 31.4 | 66.1 | 422.9 | 0.9 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 120 | 341.5 | 27.2 | 92.5 | 342.0 | 0.7 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 100 | 324.9 | 22.1 | 89.7 | 326.6 | 0.7 |
| Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens | 10 | 383.7 | 16.4 | 16.4 | 363.0 | 0.8 |

Lot 1522 - Enriched 200.0 $\mu\text{mol/L blood}$

| METHOD | N | Mean | Average Within | | Y- Intercept* | Slope |
|--|-----|-------|----------------|----------|---------------|-------|
| | | | Lab SD | Total SD | | |
| Derivatized - MS/MS non-kit | 679 | 492.7 | 43.5 | 112.4 | 349.9 | 0.7 |
| Non-derivatized - MS/MS non-kit | 149 | 499.6 | 57.0 | 124.8 | 353.1 | 0.7 |
| Derivatized - MS/MS PE NeoGram Kit | 78 | 542.4 | 56.3 | 94.8 | 389.1 | 0.8 |
| Non-derivatized - MS/MS PE NeoBase Kit | 539 | 602.8 | 42.6 | 91.9 | 422.9 | 0.9 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 119 | 477.3 | 34.2 | 124.7 | 342.0 | 0.7 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 100 | 470.1 | 32.1 | 132.3 | 326.6 | 0.7 |
| Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens | 10 | 500.0 | 24.1 | 24.1 | 363.0 | 0.8 |

Lot 1523 - Enriched 400.0 $\mu\text{mol/L blood}$

| METHOD | N | Mean | Average Within | | Y- Intercept* | Slope |
|--|-----|-------|----------------|----------|---------------|-------|
| | | | Lab SD | Total SD | | |
| Derivatized - MS/MS non-kit | 677 | 639.8 | 55.4 | 140.8 | 349.9 | 0.7 |
| Non-derivatized - MS/MS non-kit | 147 | 652.4 | 65.9 | 145.3 | 353.1 | 0.7 |
| Derivatized - MS/MS PE NeoGram Kit | 79 | 692.8 | 73.3 | 106.1 | 389.1 | 0.8 |
| Non-derivatized - MS/MS PE NeoBase Kit | 547 | 786.2 | 59.8 | 120.6 | 422.9 | 0.9 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 119 | 601.4 | 52.8 | 154.1 | 342.0 | 0.7 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 110 | 599.9 | 37.5 | 166.7 | 326.6 | 0.7 |
| Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens | 10 | 659.9 | 37.2 | 37.2 | 363.0 | 0.8 |

Lot 1428 - Enriched 600.0 $\mu\text{mol/L blood}$

| METHOD | N | Mean | Average Within | | Y- Intercept* | Slope |
|--|-----|-------|----------------|----------|---------------|-------|
| | | | Lab SD | Total SD | | |
| Derivatized - MS/MS non-kit | 685 | 780.2 | 74.9 | 178.2 | 349.9 | 0.7 |
| Non-derivatized - MS/MS non-kit | 150 | 781.2 | 72.4 | 192.8 | 353.1 | 0.7 |
| Derivatized - MS/MS PE NeoGram Kit | 80 | 837.4 | 93.1 | 166.2 | 389.1 | 0.8 |
| Non-derivatized - MS/MS PE NeoBase Kit | 548 | 960.3 | 68.9 | 136.8 | 422.9 | 0.9 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 119 | 740.5 | 52.5 | 176.0 | 342.0 | 0.7 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 110 | 744.0 | 44.3 | 199.7 | 326.6 | 0.7 |
| Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens | 10 | 858.1 | 46.5 | 46.5 | 363.0 | 0.8 |

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

Table 17h. 2015 Quality Control Data Summaries of Statistical Analyses
ARGININE ($\mu\text{mol Arg/L blood}$)

Lot 1425 - Nonenriched 0 $\mu\text{mol/L blood}$

| METHOD | N | Mean | Average Within | | Y- Intercept* | Slope |
|--|-----|------|----------------|----------|---------------|-------|
| | | | Lab SD | Total SD | | |
| Derivatized - MS/MS non-kit | 687 | 8.8 | 1.4 | 3.8 | 10.1 | 0.6 |
| Non-derivatized - MS/MS non-kit | 108 | 7.7 | 1.9 | 3.9 | 8.0 | 0.7 |
| Derivatized - MS/MS PE NeoGram Kit | 116 | 9.9 | 1.0 | 2.1 | 9.2 | 0.8 |
| Non-derivatized - MS/MS PE NeoBase Kit | 550 | 8.9 | 0.9 | 1.7 | 10.8 | 0.8 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 99 | 10.8 | 1.4 | 2.8 | 14.9 | 0.8 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 99 | 10.0 | 1.2 | 2.6 | 16.4 | 0.7 |
| Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens | 29 | 5.5 | 0.9 | 1.8 | 4.6 | 0.5 |

Lot 1426 - Enriched 200.0 $\mu\text{mol/L blood}$

| METHOD | N | Mean | Average Within | | Y- Intercept* | Slope |
|--|-----|-------|----------------|----------|---------------|-------|
| | | | Lab SD | Total SD | | |
| Derivatized - MS/MS non-kit | 711 | 74.1 | 8.2 | 28.2 | 10.1 | 0.6 |
| Non-derivatized - MS/MS non-kit | 119 | 77.1 | 6.9 | 18.7 | 8.0 | 0.7 |
| Derivatized - MS/MS PE NeoGram Kit | 116 | 90.9 | 6.7 | 16.8 | 9.2 | 0.8 |
| Non-derivatized - MS/MS PE NeoBase Kit | 560 | 96.2 | 6.2 | 10.6 | 10.8 | 0.8 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 99 | 100.0 | 13.2 | 23.1 | 14.9 | 0.8 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 97 | 90.5 | 7.7 | 18.0 | 16.4 | 0.7 |
| Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens | 30 | 48.7 | 3.0 | 3.7 | 4.6 | 0.5 |

Lot 1427 - Enriched 200.0 $\mu\text{mol/L blood}$

| METHOD | N | Mean | Average Within | | Y- Intercept* | Slope |
|--|-----|-------|----------------|----------|---------------|-------|
| | | | Lab SD | Total SD | | |
| Derivatized - MS/MS non-kit | 701 | 135.5 | 14.2 | 50.7 | 10.1 | 0.6 |
| Non-derivatized - MS/MS non-kit | 118 | 145.6 | 15.8 | 33.7 | 8.0 | 0.7 |
| Derivatized - MS/MS PE NeoGram Kit | 116 | 171.5 | 11.8 | 31.8 | 9.2 | 0.8 |
| Non-derivatized - MS/MS PE NeoBase Kit | 547 | 175.2 | 10.1 | 18.2 | 10.8 | 0.8 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 96 | 182.2 | 12.6 | 34.9 | 14.9 | 0.8 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 99 | 163.3 | 12.9 | 32.2 | 16.4 | 0.7 |
| Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens | 30 | 97.8 | 5.3 | 14.8 | 4.6 | 0.5 |

Lot 1428 - Enriched 600.0 $\mu\text{mol/L blood}$

| METHOD | N | Mean | Average Within | | Y- Intercept* | Slope |
|--|-----|-------|----------------|----------|---------------|-------|
| | | | Lab SD | Total SD | | |
| Derivatized - MS/MS non-kit | 690 | 196.1 | 18.5 | 74.3 | 10.1 | 0.6 |
| Non-derivatized - MS/MS non-kit | 119 | 214.3 | 21.7 | 48.5 | 8.0 | 0.7 |
| Derivatized - MS/MS PE NeoGram Kit | 119 | 256.2 | 18.3 | 47.5 | 9.2 | 0.8 |
| Non-derivatized - MS/MS PE NeoBase Kit | 553 | 257.3 | 15.2 | 28.6 | 10.8 | 0.8 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 96 | 254.2 | 17.0 | 56.0 | 14.9 | 0.8 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 91 | 215.0 | 14.1 | 39.8 | 16.4 | 0.7 |
| Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens | 30 | 142.5 | 11.1 | 24.2 | 4.6 | 0.5 |

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

2015 Quality Control Data Summaries of Statistical Analyses

ARGININE ($\mu\text{mol Arg/L blood}$)

Lot 1521 - Nonenriched 0 $\mu\text{mol/L blood}$

| METHOD | N | Mean | Average Within | | Y- Intercept* | Slope |
|--|-----|------|----------------|----------|---------------|-------|
| | | | Lab SD | Total SD | | |
| Derivatized - MS/MS non-kit | 734 | 7.3 | 1.5 | 3.5 | 7.1 | 0.7 |
| Non-derivatized - MS/MS non-kit | 150 | 5.4 | 1.2 | 3.0 | 5.1 | 0.7 |
| Derivatized - MS/MS PE NeoGram Kit | 107 | 6.5 | 1.1 | 1.4 | 5.1 | 0.7 |
| Non-derivatized - MS/MS PE NeoBase Kit | 629 | 6.5 | 1.2 | 2.2 | 5.8 | 0.8 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 119 | 8.6 | 1.3 | 2.3 | 10.4 | 0.9 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 101 | 5.2 | 1.1 | 1.6 | 7.7 | 0.7 |
| Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens | 38 | 4.8 | 1.3 | 3.7 | 3.2 | 0.5 |

Lot 1522 - Enriched 100.0 $\mu\text{mol/L blood}$

| METHOD | N | Mean | Average Within | | Y- Intercept* | Slope |
|--|-----|------|----------------|----------|---------------|-------|
| | | | Lab SD | Total SD | | |
| Derivatized - MS/MS non-kit | 777 | 71.3 | 9.4 | 27.1 | 7.1 | 0.7 |
| Non-derivatized - MS/MS non-kit | 158 | 77.1 | 8.4 | 18.7 | 5.1 | 0.7 |
| Derivatized - MS/MS PE NeoGram Kit | 109 | 77.2 | 8.2 | 14.9 | 5.1 | 0.7 |
| Non-derivatized - MS/MS PE NeoBase Kit | 628 | 86.9 | 5.9 | 12.9 | 5.8 | 0.8 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 120 | 97.9 | 8.2 | 18.9 | 10.4 | 0.9 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 104 | 82.8 | 7.3 | 12.1 | 7.7 | 0.7 |
| Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens | 40 | 47.2 | 4.7 | 6.4 | 3.2 | 0.5 |

Lot 1523 - Enriched 200.0 $\mu\text{mol/L blood}$

| METHOD | N | Mean | Average Within | | Y- Intercept* | Slope |
|--|-----|-------|----------------|----------|---------------|-------|
| | | | Lab SD | Total SD | | |
| Derivatized - MS/MS non-kit | 780 | 139.2 | 17.6 | 54.2 | 7.1 | 0.7 |
| Non-derivatized - MS/MS non-kit | 157 | 152.9 | 16.2 | 39.0 | 5.1 | 0.7 |
| Derivatized - MS/MS PE NeoGram Kit | 110 | 154.3 | 17.4 | 33.2 | 5.1 | 0.7 |
| Non-derivatized - MS/MS PE NeoBase Kit | 632 | 168.6 | 11.6 | 25.8 | 5.8 | 0.8 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 117 | 180.5 | 15.0 | 29.3 | 10.4 | 0.9 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 118 | 154.0 | 11.3 | 25.8 | 7.7 | 0.7 |
| Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens | 40 | 92.8 | 7.3 | 9.6 | 3.2 | 0.5 |

Lot 1524 - Enriched 300.0 $\mu\text{mol/L blood}$

| METHOD | N | Mean | Average Within | | Y- Intercept* | Slope |
|--|-----|-------|----------------|----------|---------------|-------|
| | | | Lab SD | Total SD | | |
| Derivatized - MS/MS non-kit | 773 | 202.2 | 25.8 | 80.1 | 7.1 | 0.7 |
| Non-derivatized - MS/MS non-kit | 156 | 223.7 | 24.3 | 56.7 | 5.1 | 0.7 |
| Derivatized - MS/MS PE NeoGram Kit | 107 | 228.7 | 24.4 | 42.3 | 5.1 | 0.7 |
| Non-derivatized - MS/MS PE NeoBase Kit | 626 | 251.6 | 17.9 | 36.4 | 5.8 | 0.8 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 120 | 263.8 | 24.2 | 48.6 | 10.4 | 0.9 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 120 | 222.7 | 15.7 | 40.5 | 7.7 | 0.7 |
| Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens | 40 | 141.5 | 11.2 | 19.4 | 3.2 | 0.5 |

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

**Table 17i. 2015 Quality Control Data Summaries of Statistical Analyses
CITRULLINE ($\mu\text{mol Cit/L blood}$)**

Lot 1425 - Nonenriched 0 $\mu\text{mol/L blood}$

| METHOD | N | Mean | Average Within | | Y- Intercept* | Slope |
|--|-----|------|----------------|----------|---------------|-------|
| | | | Lab SD | Total SD | | |
| Derivatized - MS/MS non-kit | 738 | 26.1 | 2.6 | 4.5 | 27.0 | 0.8 |
| Non-derivatized - MS/MS non-kit | 196 | 27.7 | 3.1 | 6.4 | 29.1 | 0.8 |
| Derivatized - MS/MS PE NeoGram Kit | 126 | 29.3 | 2.0 | 3.6 | 29.4 | 0.9 |
| Non-derivatized - MS/MS PE NeoBase Kit | 635 | 29.1 | 2.6 | 3.5 | 30.4 | 0.9 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 99 | 28.7 | 2.7 | 4.5 | 29.7 | 0.9 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 96 | 28.7 | 4.4 | 4.9 | 29.4 | 0.9 |
| Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens | 59 | 27.1 | 2.2 | 2.3 | 27.5 | 0.9 |

Lot 1426 - Enriched 25.0 $\mu\text{mol/L blood}$

| METHOD | N | Mean | Average Within | | Y- Intercept* | Slope |
|--|-----|------|----------------|----------|---------------|-------|
| | | | Lab SD | Total SD | | |
| Derivatized - MS/MS non-kit | 737 | 46.9 | 4.5 | 8.2 | 27.0 | 0.8 |
| Non-derivatized - MS/MS non-kit | 198 | 50.6 | 4.4 | 9.0 | 29.1 | 0.8 |
| Derivatized - MS/MS PE NeoGram Kit | 129 | 53.4 | 3.8 | 6.8 | 29.4 | 0.9 |
| Non-derivatized - MS/MS PE NeoBase Kit | 630 | 54.3 | 4.0 | 5.8 | 30.4 | 0.9 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 97 | 51.9 | 4.1 | 6.5 | 29.7 | 0.9 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 96 | 52.4 | 8.4 | 9.1 | 29.4 | 0.9 |
| Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens | 60 | 47.7 | 4.5 | 4.9 | 27.5 | 0.9 |

Lot 1427 - Enriched 100.0 $\mu\text{mol/L blood}$

| METHOD | N | Mean | Average Within | | Y- Intercept* | Slope |
|--|-----|-------|----------------|----------|---------------|-------|
| | | | Lab SD | Total SD | | |
| Derivatized - MS/MS non-kit | 746 | 106.4 | 9.4 | 18.6 | 27.0 | 0.8 |
| Non-derivatized - MS/MS non-kit | 197 | 114.6 | 10.0 | 18.0 | 29.1 | 0.8 |
| Derivatized - MS/MS PE NeoGram Kit | 128 | 118.4 | 6.4 | 14.6 | 29.4 | 0.9 |
| Non-derivatized - MS/MS PE NeoBase Kit | 635 | 122.3 | 8.1 | 12.9 | 30.4 | 0.9 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 95 | 115.6 | 7.7 | 11.6 | 29.7 | 0.9 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 98 | 118.1 | 11.8 | 17.7 | 29.4 | 0.9 |
| Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens | 60 | 115.1 | 8.6 | 12.3 | 27.5 | 0.9 |

Lot 1428 - Enriched 250.0 $\mu\text{mol/L blood}$

| METHOD | N | Mean | Average Within | | Y- Intercept* | Slope |
|--|-----|-------|----------------|----------|---------------|-------|
| | | | Lab SD | Total SD | | |
| Derivatized - MS/MS non-kit | 745 | 222.4 | 17.2 | 36.6 | 27.0 | 0.8 |
| Non-derivatized - MS/MS non-kit | 198 | 238.2 | 18.6 | 33.8 | 29.1 | 0.8 |
| Derivatized - MS/MS PE NeoGram Kit | 128 | 257.1 | 16.4 | 32.8 | 29.4 | 0.9 |
| Non-derivatized - MS/MS PE NeoBase Kit | 631 | 258.7 | 16.7 | 25.8 | 30.4 | 0.9 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 97 | 243.7 | 14.1 | 27.2 | 29.7 | 0.9 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 98 | 251.2 | 27.7 | 35.4 | 29.4 | 0.9 |
| Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens | 60 | 239.8 | 15.9 | 22.7 | 27.5 | 0.9 |

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

2015 Quality Control Data Summaries of Statistical Analyses CITRULLINE (μmol Cit/L blood)

Lot 1521 - Nonenriched 0 μmol/L blood

| METHOD | N | Mean | Average Within | | Y- Intercept* | Slope |
|--|-----|------|----------------|----------|---------------|-------|
| | | | Lab SD | Total SD | | |
| Derivatized - MS/MS non-kit | 799 | 26.3 | 2.7 | 5.7 | 27.2 | 0.8 |
| Non-derivatized - MS/MS non-kit | 240 | 29.1 | 3.6 | 5.1 | 30.8 | 0.9 |
| Derivatized - MS/MS PE NeoGram Kit | 109 | 30.1 | 2.8 | 3.9 | 30.2 | 0.9 |
| Non-derivatized - MS/MS PE NeoBase Kit | 685 | 30.1 | 2.9 | 4.2 | 31.4 | 0.9 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 118 | 30.8 | 2.8 | 3.8 | 32.0 | 0.9 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 116 | 30.9 | 3.1 | 4.4 | 32.0 | 0.9 |
| Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens | 50 | 27.4 | 2.8 | 3.2 | 28.0 | 0.8 |

Lot 1522 - Enriched 25.0 μmol/L blood

| METHOD | N | Mean | Average Within | | Y- Intercept* | Slope |
|--|-----|------|----------------|----------|---------------|-------|
| | | | Lab SD | Total SD | | |
| Derivatized - MS/MS non-kit | 799 | 46.6 | 4.4 | 9.8 | 27.2 | 0.8 |
| Non-derivatized - MS/MS non-kit | 245 | 52.4 | 5.0 | 8.3 | 30.8 | 0.9 |
| Derivatized - MS/MS PE NeoGram Kit | 107 | 51.0 | 4.4 | 6.6 | 30.2 | 0.9 |
| Non-derivatized - MS/MS PE NeoBase Kit | 689 | 54.7 | 4.5 | 6.7 | 31.4 | 0.9 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 118 | 54.5 | 4.2 | 7.5 | 32.0 | 0.9 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 119 | 53.9 | 4.3 | 7.3 | 32.0 | 0.9 |
| Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens | 49 | 47.8 | 3.1 | 4.1 | 28.0 | 0.8 |

Lot 1523 - Enriched 100.0 μmol/L blood

| METHOD | N | Mean | Average Within | | Y- Intercept* | Slope |
|--|-----|-------|----------------|----------|---------------|-------|
| | | | Lab SD | Total SD | | |
| Derivatized - MS/MS non-kit | 797 | 108.0 | 10.2 | 23.6 | 27.2 | 0.8 |
| Non-derivatized - MS/MS non-kit | 244 | 123.8 | 11.2 | 19.2 | 30.8 | 0.9 |
| Derivatized - MS/MS PE NeoGram Kit | 108 | 117.2 | 11.4 | 15.9 | 30.2 | 0.9 |
| Non-derivatized - MS/MS PE NeoBase Kit | 688 | 124.4 | 9.6 | 14.5 | 31.4 | 0.9 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 116 | 119.7 | 7.6 | 14.4 | 32.0 | 0.9 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 129 | 120.7 | 9.1 | 16.8 | 32.0 | 0.9 |
| Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens | 49 | 112.2 | 7.6 | 8.2 | 28.0 | 0.8 |

Lot 1524 - Enriched 250.0 μmol/L blood

| METHOD | N | Mean | Average Within | | Y- Intercept* | Slope |
|--|-----|-------|----------------|----------|---------------|-------|
| | | | Lab SD | Total SD | | |
| Derivatized - MS/MS non-kit | 790 | 223.3 | 21.4 | 46.3 | 27.2 | 0.8 |
| Non-derivatized - MS/MS non-kit | 250 | 251.9 | 22.9 | 40.2 | 30.8 | 0.9 |
| Derivatized - MS/MS PE NeoGram Kit | 108 | 244.2 | 23.9 | 37.9 | 30.2 | 0.9 |
| Non-derivatized - MS/MS PE NeoBase Kit | 684 | 259.5 | 18.0 | 28.5 | 31.4 | 0.9 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 118 | 249.0 | 17.2 | 26.1 | 32.0 | 0.9 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 127 | 249.2 | 17.6 | 35.0 | 32.0 | 0.9 |
| Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens | 50 | 232.7 | 15.5 | 25.6 | 28.0 | 0.8 |

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

**Table 17j. 2015 Quality Control Data Summaries of Statistical Analyses
LEUCINE ($\mu\text{mol Leu/L blood}$)**

Lot 1425 - Nonenriched 0 $\mu\text{mol/L blood}$

| METHOD | N | Mean | Average Within | | Y- Intercept* | Slope |
|--|-----|-------|----------------|----------|---------------|-------|
| | | | Lab SD | Total SD | | |
| Derivatized - MS/MS non-kit | 767 | 146.3 | 11.7 | 23.6 | 147.7 | 0.8 |
| Non-derivatized - MS/MS non-kit | 275 | 178.8 | 11.5 | 25.7 | 180.8 | 0.9 |
| Derivatized - MS/MS PE NeoGram Kit | 125 | 143.5 | 13.0 | 15.9 | 142.0 | 0.9 |
| Non-derivatized - MS/MS PE NeoBase Kit | 626 | 177.3 | 10.6 | 17.1 | 179.1 | 0.9 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 93 | 140.5 | 13.0 | 22.2 | 140.1 | 0.8 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 97 | 168.3 | 12.7 | 23.2 | 170.2 | 0.9 |
| Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens | 60 | 170.8 | 14.8 | 22.8 | 170.4 | 0.9 |

Lot 1426 - Enriched 100.0 $\mu\text{mol/L blood}$

| METHOD | N | Mean | Average Within | | Y- Intercept* | Slope |
|--|-----|-------|----------------|----------|---------------|-------|
| | | | Lab SD | Total SD | | |
| Derivatized - MS/MS non-kit | 765 | 232.3 | 18.8 | 31.8 | 147.7 | 0.8 |
| Non-derivatized - MS/MS non-kit | 261 | 274.3 | 19.6 | 42.2 | 180.8 | 0.9 |
| Derivatized - MS/MS PE NeoGram Kit | 127 | 235.6 | 19.7 | 26.8 | 142.0 | 0.9 |
| Non-derivatized - MS/MS PE NeoBase Kit | 628 | 273.0 | 16.8 | 28.1 | 179.1 | 0.9 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 95 | 222.3 | 18.7 | 27.9 | 140.1 | 0.8 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 95 | 258.7 | 14.9 | 29.3 | 170.2 | 0.9 |
| Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens | 56 | 264.9 | 17.2 | 26.8 | 170.4 | 0.9 |

Lot 1427 - Enriched 250.0 $\mu\text{mol/L blood}$

| METHOD | N | Mean | Average Within | | Y- Intercept* | Slope |
|--|-----|-------|----------------|----------|---------------|-------|
| | | | Lab SD | Total SD | | |
| Derivatized - MS/MS non-kit | 755 | 350.0 | 27.7 | 46.8 | 147.7 | 0.8 |
| Non-derivatized - MS/MS non-kit | 272 | 398.5 | 27.1 | 58.4 | 180.8 | 0.9 |
| Derivatized - MS/MS PE NeoGram Kit | 127 | 359.9 | 24.5 | 39.5 | 142.0 | 0.9 |
| Non-derivatized - MS/MS PE NeoBase Kit | 623 | 400.6 | 24.3 | 38.7 | 179.1 | 0.9 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 94 | 327.7 | 26.3 | 33.1 | 140.1 | 0.8 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 99 | 384.1 | 25.1 | 51.5 | 170.2 | 0.9 |
| Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens | 60 | 402.6 | 41.2 | 62.8 | 170.4 | 0.9 |

Lot 1428 - Enriched 500.0 $\mu\text{mol/L blood}$

| METHOD | N | Mean | Average Within | | Y- Intercept* | Slope |
|--|-----|-------|----------------|----------|---------------|-------|
| | | | Lab SD | Total SD | | |
| Derivatized - MS/MS non-kit | 772 | 556.8 | 43.7 | 83.1 | 147.7 | 0.8 |
| Non-derivatized - MS/MS non-kit | 277 | 624.1 | 46.8 | 98.3 | 180.8 | 0.9 |
| Derivatized - MS/MS PE NeoGram Kit | 129 | 597.3 | 43.8 | 69.9 | 142.0 | 0.9 |
| Non-derivatized - MS/MS PE NeoBase Kit | 630 | 628.6 | 38.4 | 66.4 | 179.1 | 0.9 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 98 | 532.8 | 36.0 | 54.1 | 140.1 | 0.8 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 100 | 599.0 | 45.6 | 89.1 | 170.2 | 0.9 |
| Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens | 57 | 639.7 | 41.5 | 70.5 | 170.4 | 0.9 |

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

2015 Quality Control Data Summaries of Statistical Analyses LEUCINE (μmol Leu/L blood)

Lot 1521 - Nonenriched 0 μmol/L blood

| METHOD | N | Mean | Average Within | | Y- Intercept* | Slope |
|--|-----|-------|----------------|----------|---------------|-------|
| | | | Lab SD | Total SD | | |
| Derivatized - MS/MS non-kit | 808 | 142.7 | 12.3 | 26.7 | 143.0 | 0.9 |
| Non-derivatized - MS/MS non-kit | 326 | 169.8 | 11.9 | 20.1 | 170.4 | 0.9 |
| Derivatized - MS/MS PE NeoGram Kit | 107 | 139.3 | 11.6 | 14.3 | 139.0 | 0.9 |
| Non-derivatized - MS/MS PE NeoBase Kit | 681 | 169.2 | 9.6 | 16.5 | 168.5 | 0.9 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 112 | 139.4 | 9.1 | 16.5 | 140.4 | 0.8 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 130 | 168.0 | 9.2 | 25.9 | 169.9 | 0.8 |
| Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens | 50 | 169.4 | 10.6 | 25.7 | 167.8 | 0.9 |

Lot 1522 - Enriched 100.0 μmol/L blood

| METHOD | N | Mean | Average Within | | Y- Intercept* | Slope |
|--|-----|-------|----------------|----------|---------------|-------|
| | | | Lab SD | Total SD | | |
| Derivatized - MS/MS non-kit | 811 | 230.4 | 18.1 | 35.6 | 143.0 | 0.9 |
| Non-derivatized - MS/MS non-kit | 324 | 260.9 | 18.2 | 29.5 | 170.4 | 0.9 |
| Derivatized - MS/MS PE NeoGram Kit | 110 | 227.1 | 18.4 | 26.1 | 139.0 | 0.9 |
| Non-derivatized - MS/MS PE NeoBase Kit | 675 | 259.8 | 15.8 | 25.7 | 168.5 | 0.9 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 115 | 219.0 | 17.2 | 25.4 | 140.4 | 0.8 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 126 | 258.6 | 13.0 | 33.8 | 169.9 | 0.8 |
| Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens | 50 | 261.2 | 12.7 | 31.9 | 167.8 | 0.9 |

Lot 1523 - Enriched 250.0 μmol/L blood

| METHOD | N | Mean | Average Within | | Y- Intercept* | Slope |
|--|-----|-------|----------------|----------|---------------|-------|
| | | | Lab SD | Total SD | | |
| Derivatized - MS/MS non-kit | 827 | 360.3 | 31.4 | 53.7 | 143.0 | 0.9 |
| Non-derivatized - MS/MS non-kit | 321 | 390.1 | 26.7 | 45.0 | 170.4 | 0.9 |
| Derivatized - MS/MS PE NeoGram Kit | 109 | 359.0 | 35.9 | 38.5 | 139.0 | 0.9 |
| Non-derivatized - MS/MS PE NeoBase Kit | 674 | 389.0 | 25.4 | 39.2 | 168.5 | 0.9 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 116 | 328.0 | 21.6 | 28.9 | 140.4 | 0.8 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 134 | 372.4 | 20.4 | 44.9 | 169.9 | 0.8 |
| Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens | 50 | 392.8 | 22.6 | 51.7 | 167.8 | 0.9 |

Lot 1524 - Enriched 500.0 μmol/L blood

| METHOD | N | Mean | Average Within | | Y- Intercept* | Slope |
|--|-----|-------|----------------|----------|---------------|-------|
| | | | Lab SD | Total SD | | |
| Derivatized - MS/MS non-kit | 819 | 577.8 | 46.1 | 92.6 | 143.0 | 0.9 |
| Non-derivatized - MS/MS non-kit | 325 | 613.9 | 41.2 | 82.2 | 170.4 | 0.9 |
| Derivatized - MS/MS PE NeoGram Kit | 109 | 580.3 | 56.5 | 67.7 | 139.0 | 0.9 |
| Non-derivatized - MS/MS PE NeoBase Kit | 670 | 619.0 | 41.2 | 58.5 | 168.5 | 0.9 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 115 | 520.9 | 34.7 | 45.9 | 140.4 | 0.8 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 129 | 586.3 | 31.0 | 49.2 | 169.9 | 0.8 |
| Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens | 50 | 630.4 | 38.5 | 84.6 | 167.8 | 0.9 |

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

**Table 17k. 2015 Quality Control Data Summaries of Statistical Analyses
METHIONINE ($\mu\text{mol Met/L blood}$)**

Lot 1425 - Nonenriched 0 $\mu\text{mol/L blood}$

| METHOD | N | Mean | Average Within | | Y- Intercept* | Slope |
|--|-----|------|----------------|----------|---------------|-------|
| | | | Lab SD | Total SD | | |
| Derivatized - MS/MS non-kit | 779 | 23.6 | 3.1 | 4.9 | 23.6 | 0.8 |
| Non-derivatized - MS/MS non-kit | 281 | 22.0 | 1.8 | 3.6 | 21.5 | 0.8 |
| Derivatized - MS/MS PE NeoGram Kit | 116 | 24.5 | 2.9 | 3.5 | 24.9 | 0.8 |
| Non-derivatized - MS/MS PE NeoBase Kit | 623 | 22.1 | 1.6 | 2.9 | 21.1 | 0.8 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 99 | 18.4 | 2.9 | 5.0 | 16.8 | 0.6 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 96 | 18.6 | 2.2 | 3.4 | 18.7 | 0.7 |
| Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens | 59 | 22.5 | 1.6 | 1.9 | 20.5 | 0.9 |

Lot 1426 - Enriched 50.0 $\mu\text{mol/L blood}$

| METHOD | N | Mean | Average Within | | Y- Intercept* | Slope |
|--|-----|------|----------------|----------|---------------|-------|
| | | | Lab SD | Total SD | | |
| Derivatized - MS/MS non-kit | 764 | 64.1 | 5.7 | 9.4 | 23.6 | 0.8 |
| Non-derivatized - MS/MS non-kit | 272 | 62.9 | 4.6 | 12.1 | 21.5 | 0.8 |
| Derivatized - MS/MS PE NeoGram Kit | 116 | 67.4 | 6.8 | 8.7 | 24.9 | 0.8 |
| Non-derivatized - MS/MS PE NeoBase Kit | 625 | 63.2 | 4.2 | 8.0 | 21.1 | 0.8 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 97 | 48.5 | 7.8 | 14.5 | 16.8 | 0.6 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 98 | 54.7 | 4.4 | 9.6 | 18.7 | 0.7 |
| Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens | 58 | 61.9 | 4.3 | 5.2 | 20.5 | 0.9 |

Lot 1427 - Enriched 150.0 $\mu\text{mol/L blood}$

| METHOD | N | Mean | Average Within | | Y- Intercept* | Slope |
|--|-----|-------|----------------|----------|---------------|-------|
| | | | Lab SD | Total SD | | |
| Derivatized - MS/MS non-kit | 769 | 143.6 | 12.4 | 22.1 | 23.6 | 0.8 |
| Non-derivatized - MS/MS non-kit | 280 | 142.2 | 9.1 | 24.8 | 21.5 | 0.8 |
| Derivatized - MS/MS PE NeoGram Kit | 119 | 149.4 | 12.3 | 17.6 | 24.9 | 0.8 |
| Non-derivatized - MS/MS PE NeoBase Kit | 626 | 141.1 | 9.4 | 17.6 | 21.1 | 0.8 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 97 | 107.2 | 14.3 | 32.4 | 16.8 | 0.6 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 99 | 126.1 | 16.5 | 25.6 | 18.7 | 0.7 |
| Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens | 58 | 146.5 | 10.4 | 13.3 | 20.5 | 0.9 |

Lot 1428 - Enriched 250.0 $\mu\text{mol/L blood}$

| METHOD | N | Mean | Average Within | | Y- Intercept* | Slope |
|--|-----|-------|----------------|----------|---------------|-------|
| | | | Lab SD | Total SD | | |
| Derivatized - MS/MS non-kit | 769 | 224.7 | 17.6 | 33.5 | 23.6 | 0.8 |
| Non-derivatized - MS/MS non-kit | 279 | 227.9 | 15.0 | 41.8 | 21.5 | 0.8 |
| Derivatized - MS/MS PE NeoGram Kit | 119 | 233.7 | 19.4 | 28.8 | 24.9 | 0.8 |
| Non-derivatized - MS/MS PE NeoBase Kit | 631 | 229.8 | 14.6 | 29.2 | 21.1 | 0.8 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 99 | 177.0 | 23.5 | 47.9 | 16.8 | 0.6 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 100 | 198.2 | 18.8 | 32.5 | 18.7 | 0.7 |
| Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens | 60 | 235.8 | 11.6 | 17.6 | 20.5 | 0.9 |

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

2015 Quality Control Data Summaries of Statistical Analyses

METHIONINE (μmol Met/L blood)

Lot 1521 - Nonenriched 0 μmol/L blood

| METHOD | N | Mean | Average Within | | Y- Intercept* | Slope |
|--|-----|------|----------------|----------|---------------|-------|
| | | | Lab SD | Total SD | | |
| Derivatized - MS/MS non-kit | 810 | 22.0 | 2.5 | 4.1 | 21.5 | 0.8 |
| Non-derivatized - MS/MS non-kit | 316 | 18.5 | 2.0 | 3.4 | 17.7 | 0.8 |
| Derivatized - MS/MS PE NeoGram Kit | 107 | 21.9 | 3.1 | 3.4 | 22.6 | 0.8 |
| Non-derivatized - MS/MS PE NeoBase Kit | 689 | 16.8 | 1.5 | 2.5 | 15.8 | 0.8 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 119 | 16.3 | 2.7 | 5.5 | 15.5 | 0.6 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 119 | 14.8 | 1.4 | 2.7 | 13.4 | 0.7 |
| Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens | 50 | 20.5 | 1.5 | 2.1 | 19.1 | 0.8 |

Lot 1522 - Enriched 50.0 μmol/L blood

| METHOD | N | Mean | Average Within | | Y- Intercept* | Slope |
|--|-----|------|----------------|----------|---------------|-------|
| | | | Lab SD | Total SD | | |
| Derivatized - MS/MS non-kit | 805 | 62.2 | 5.7 | 9.9 | 21.5 | 0.8 |
| Non-derivatized - MS/MS non-kit | 307 | 58.5 | 5.0 | 9.8 | 17.7 | 0.8 |
| Derivatized - MS/MS PE NeoGram Kit | 110 | 63.6 | 7.3 | 9.1 | 22.6 | 0.8 |
| Non-derivatized - MS/MS PE NeoBase Kit | 672 | 55.0 | 3.7 | 7.3 | 15.8 | 0.8 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 120 | 44.1 | 6.2 | 16.1 | 15.5 | 0.6 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 120 | 48.7 | 3.3 | 8.3 | 13.4 | 0.7 |
| Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens | 48 | 59.8 | 3.4 | 5.7 | 19.1 | 0.8 |

Lot 1523 - Enriched 150.0 μmol/L blood

| METHOD | N | Mean | Average Within | | Y- Intercept* | Slope |
|--|-----|-------|----------------|----------|---------------|-------|
| | | | Lab SD | Total SD | | |
| Derivatized - MS/MS non-kit | 807 | 146.4 | 12.5 | 22.5 | 21.5 | 0.8 |
| Non-derivatized - MS/MS non-kit | 315 | 142.6 | 12.1 | 25.6 | 17.7 | 0.8 |
| Derivatized - MS/MS PE NeoGram Kit | 108 | 151.9 | 17.1 | 18.5 | 22.6 | 0.8 |
| Non-derivatized - MS/MS PE NeoBase Kit | 692 | 136.7 | 9.6 | 19.8 | 15.8 | 0.8 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 119 | 101.8 | 13.8 | 37.5 | 15.5 | 0.6 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 127 | 116.7 | 8.4 | 16.8 | 13.4 | 0.7 |
| Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens | 50 | 145.4 | 11.4 | 15.6 | 19.1 | 0.8 |

Lot 1524 - Enriched 250.0 μmol/L blood

| METHOD | N | Mean | Average Within | | Y- Intercept* | Slope |
|--|-----|-------|----------------|----------|---------------|-------|
| | | | Lab SD | Total SD | | |
| Derivatized - MS/MS non-kit | 808 | 229.1 | 19.7 | 36.9 | 21.5 | 0.8 |
| Non-derivatized - MS/MS non-kit | 318 | 226.1 | 18.2 | 39.9 | 17.7 | 0.8 |
| Derivatized - MS/MS PE NeoGram Kit | 109 | 230.0 | 24.9 | 31.5 | 22.6 | 0.8 |
| Non-derivatized - MS/MS PE NeoBase Kit | 684 | 217.9 | 15.6 | 30.2 | 15.8 | 0.8 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 120 | 161.3 | 21.0 | 58.5 | 15.5 | 0.6 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 130 | 192.0 | 14.0 | 32.3 | 13.4 | 0.7 |
| Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens | 48 | 230.7 | 12.5 | 23.6 | 19.1 | 0.8 |

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

Table 17I. 2015 Quality Control Data Summaries of Statistical Analyses
PHENYLALANINE (μmol Phe/L blood)

Lot 1425 - Nonenriched 0 μmol/L blood

| METHOD | N | Mean | Average Within Lab SD | Total SD | Y- Intercept* | Slope |
|--|-----|-------|-----------------------------|----------|---------------|-------|
| Fluorometric Manual | 108 | 106.7 | 11.6 | 27.1 | 105.3 | 1.1 |
| PerkinElmer Neonatal Kit | 222 | 83.3 | 10.6 | 13.4 | 82.9 | 0.9 |
| Ani Labsystems | 117 | 92.2 | 11.9 | 22.2 | 91.6 | 1.3 |
| Bio-Rad Quantase | 30 | 98.8 | 14.6 | 17.9 | 99.4 | 1.1 |
| Interscientific Enzyme | 40 | 75.7 | 4.1 | 7.0 | 67.4 | 1.0 |
| Astoria-Pacific 50 Hour Reagent Kit | 10 | 112.7 | 10.1 | 10.1 | 122.3 | 1.1 |
| HPLC | 10 | 79.7 | 4.2 | 4.2 | 76.5 | 1.0 |
| Derivatized - MS/MS non-kit | 844 | 74.1 | 5.8 | 10.2 | 74.0 | 0.9 |
| Non-derivatized - MS/MS non-kit | 345 | 77.8 | 5.5 | 11.6 | 78.3 | 1.0 |
| Derivatized - MS/MS PE NeoGram Kit | 156 | 78.3 | 6.3 | 9.8 | 76.7 | 1.0 |
| Non-derivatized - MS/MS PE NeoBase Kit | 640 | 75.6 | 4.9 | 7.5 | 76.1 | 0.9 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 81 | 77.6 | 6.2 | 13.5 | 80.3 | 0.9 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 98 | 84.7 | 6.3 | 10.2 | 84.6 | 1.0 |
| TecnoSuma UMTEST | 20 | 120.5 | 9.7 | 52.0 | 114.2 | 1.3 |
| Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens | 60 | 75.6 | 4.4 | 7.6 | 74.5 | 1.0 |

Lot 1426 - Enriched 100.0 μmol/L blood

| METHOD | N | Mean | Average Within Lab SD | Total SD | Y- Intercept* | Slope |
|--|-----|-------|-----------------------------|----------|---------------|-------|
| Fluorometric Manual | 108 | 213.0 | 19.5 | 32.6 | 105.3 | 1.1 |
| PerkinElmer Neonatal Kit | 221 | 170.8 | 14.8 | 21.9 | 82.9 | 0.9 |
| Ani Labsystems | 119 | 226.8 | 21.1 | 36.4 | 91.6 | 1.3 |
| Bio-Rad Quantase | 28 | 210.9 | 17.0 | 20.8 | 99.4 | 1.1 |
| Interscientific Enzyme | 39 | 151.9 | 8.1 | 50.0 | 67.4 | 1.0 |
| Astoria-Pacific 50 Hour Reagent Kit | 10 | 234.0 | 12.0 | 12.0 | 122.3 | 1.1 |
| HPLC | 10 | 172.2 | 9.4 | 9.4 | 76.5 | 1.0 |
| Derivatized - MS/MS non-kit | 836 | 164.4 | 12.4 | 21.9 | 74.0 | 0.9 |
| Non-derivatized - MS/MS non-kit | 338 | 177.2 | 10.1 | 24.2 | 78.3 | 1.0 |
| Derivatized - MS/MS PE NeoGram Kit | 157 | 174.0 | 11.4 | 20.2 | 76.7 | 1.0 |
| Non-derivatized - MS/MS PE NeoBase Kit | 640 | 170.9 | 11.3 | 17.2 | 76.1 | 0.9 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 87 | 171.6 | 16.0 | 31.9 | 80.3 | 0.9 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 98 | 188.2 | 15.4 | 24.5 | 84.6 | 1.0 |
| TecnoSuma UMTEST | 20 | 235.7 | 15.0 | 97.0 | 114.2 | 1.3 |
| Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens | 60 | 167.5 | 10.8 | 15.8 | 74.5 | 1.0 |

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

2015 Quality Control Data Summaries of Statistical Analyses

PHENYLALANINE (μmol Phe/L blood)

Lot 1427 - Enriched 200.0 μmol/L blood

| METHOD | N | Mean | Average Within Lab SD | Total SD | Y- Intercept* | Slope |
|--|-----|-------|-----------------------|----------|---------------|-------|
| Fluorometric Manual | 97 | 320.1 | 29.4 | 45.2 | 105.3 | 1.1 |
| PerkinElmer Neonatal Kit | 221 | 261.2 | 20.2 | 31.3 | 82.9 | 0.9 |
| Ani Labsystems | 120 | 352.5 | 25.6 | 58.9 | 91.6 | 1.3 |
| Bio-Rad Quantase | 30 | 317.9 | 15.8 | 26.3 | 99.4 | 1.1 |
| Interscientific Enzyme | 40 | 261.9 | 10.2 | 18.8 | 67.4 | 1.0 |
| Astoria-Pacific 50 Hour Reagent Kit | 10 | 350.6 | 21.5 | 21.5 | 122.3 | 1.1 |
| HPLC | 10 | 272.9 | 9.8 | 9.8 | 76.5 | 1.0 |
| Derivatized - MS/MS non-kit | 845 | 253.2 | 20.3 | 35.3 | 74.0 | 0.9 |
| Non-derivatized - MS/MS non-kit | 342 | 269.4 | 16.4 | 39.0 | 78.3 | 1.0 |
| Derivatized - MS/MS PE NeoGram Kit | 155 | 268.4 | 16.7 | 30.8 | 76.7 | 1.0 |
| Non-derivatized - MS/MS PE NeoBase Kit | 638 | 262.4 | 16.4 | 27.3 | 76.1 | 0.9 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 82 | 251.7 | 17.0 | 35.8 | 80.3 | 0.9 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 97 | 288.7 | 14.9 | 26.9 | 84.6 | 1.0 |
| TecnoSuma UMTEST | 20 | 375.6 | 16.9 | 91.0 | 114.2 | 1.3 |
| Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens | 60 | 267.4 | 18.4 | 22.4 | 74.5 | 1.0 |

Lot 1428 - Enriched 300.0 μmol/L blood

| METHOD | N | Mean | Average Within Lab SD | Total SD | Y- Intercept* | Slope |
|--|-----|-------|-----------------------|----------|---------------|-------|
| Fluorometric Manual | 108 | 433.2 | 43.4 | 53.3 | 105.3 | 1.1 |
| PerkinElmer Neonatal Kit | 219 | 349.2 | 28.8 | 46.0 | 82.9 | 0.9 |
| Ani Labsystems | 120 | 494.6 | 28.7 | 79.5 | 91.6 | 1.3 |
| Bio-Rad Quantase | 27 | 429.3 | 18.3 | 33.8 | 99.4 | 1.1 |
| Interscientific Enzyme | 30 | 364.7 | 10.5 | 20.8 | 67.4 | 1.0 |
| Astoria-Pacific 50 Hour Reagent Kit | 10 | 426.2 | 20.9 | 20.9 | 122.3 | 1.1 |
| HPLC | 10 | 377.1 | 15.3 | 15.3 | 76.5 | 1.0 |
| Derivatized - MS/MS non-kit | 853 | 344.5 | 25.2 | 52.5 | 74.0 | 0.9 |
| Non-derivatized - MS/MS non-kit | 346 | 370.0 | 24.0 | 56.0 | 78.3 | 1.0 |
| Derivatized - MS/MS PE NeoGram Kit | 155 | 372.9 | 27.9 | 44.6 | 76.7 | 1.0 |
| Non-derivatized - MS/MS PE NeoBase Kit | 636 | 357.1 | 21.4 | 35.0 | 76.1 | 0.9 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 83 | 339.7 | 24.0 | 62.5 | 80.3 | 0.9 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 98 | 394.0 | 23.8 | 32.2 | 84.6 | 1.0 |
| TecnoSuma UMTEST | 20 | 509.6 | 42.8 | 121.1 | 114.2 | 1.3 |
| Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens | 59 | 360.7 | 17.6 | 26.9 | 74.5 | 1.0 |

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

2015 Quality Control Data Summaries of Statistical Analyses
PHENYLALANINE (μmol Phe/L blood)

Lot 1521 - Nonenriched 0 μmol/L blood

| METHOD | N | Mean | Average Within Lab SD | Total SD | Y- Intercept* | Slope |
|--|-----|-------|-----------------------------|----------|---------------|-------|
| Fluorometric Manual | 79 | 93.9 | 8.9 | 18.3 | 90.7 | 1.1 |
| PerkinElmer Neonatal Kit | 155 | 75.1 | 9.4 | 11.3 | 74.9 | 0.9 |
| Ani Labsystems | 79 | 82.3 | 9.2 | 12.8 | 81.0 | 1.3 |
| Bio-Rad Quantase | 29 | 84.2 | 10.9 | 10.9 | 82.7 | 1.1 |
| Interscientific Enzyme | 30 | 78.1 | 3.8 | 3.8 | 70.9 | 1.0 |
| Astoria-Pacific 50 Hour Reagent Kit | 10 | 100.9 | 3.5 | 3.5 | 97.7 | 1.1 |
| HPLC | 10 | 81.8 | 4.0 | 4.0 | 84.2 | 0.9 |
| Derivatized - MS/MS non-kit | 888 | 71.4 | 5.8 | 11.0 | 70.8 | 0.9 |
| Non-derivatized - MS/MS non-kit | 384 | 74.5 | 5.1 | 9.8 | 74.8 | 1.0 |
| Derivatized - MS/MS PE NeoGram Kit | 119 | 73.8 | 7.5 | 11.0 | 73.2 | 1.0 |
| Non-derivatized - MS/MS PE NeoBase Kit | 708 | 71.1 | 4.4 | 7.7 | 69.9 | 0.9 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 110 | 68.7 | 5.8 | 8.0 | 68.8 | 0.9 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 119 | 79.9 | 4.7 | 8.5 | 80.3 | 1.0 |
| TecnoSuma UMTEST | 10 | 74.6 | 9.9 | 9.9 | 69.8 | 1.1 |
| Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens | 50 | 74.3 | 5.1 | 7.1 | 73.0 | 1.0 |

Lot 1522 - Enriched 100.0 μmol/L blood

| METHOD | N | Mean | Average Within Lab SD | Total SD | Y- Intercept* | Slope |
|--|-----|-------|-----------------------------|----------|---------------|-------|
| Fluorometric Manual | 77 | 197.6 | 17.4 | 19.4 | 90.7 | 1.1 |
| PerkinElmer Neonatal Kit | 159 | 165.4 | 20.1 | 25.9 | 74.9 | 0.9 |
| Ani Labsystems | 79 | 212.0 | 16.2 | 30.8 | 81.0 | 1.3 |
| Bio-Rad Quantase | 30 | 191.2 | 26.0 | 38.1 | 82.7 | 1.1 |
| Interscientific Enzyme | 30 | 166.8 | 5.6 | 13.0 | 70.9 | 1.0 |
| Astoria-Pacific 50 Hour Reagent Kit | 10 | 196.2 | 6.1 | 6.1 | 97.7 | 1.1 |
| HPLC | 10 | 175.4 | 8.1 | 8.1 | 84.2 | 0.9 |
| Derivatized - MS/MS non-kit | 888 | 162.9 | 12.0 | 24.2 | 70.8 | 0.9 |
| Non-derivatized - MS/MS non-kit | 388 | 173.6 | 11.0 | 21.5 | 74.8 | 1.0 |
| Derivatized - MS/MS PE NeoGram Kit | 120 | 167.3 | 15.6 | 25.9 | 73.2 | 1.0 |
| Non-derivatized - MS/MS PE NeoBase Kit | 707 | 163.5 | 10.0 | 18.3 | 69.9 | 0.9 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 111 | 155.5 | 12.8 | 26.1 | 68.8 | 0.9 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 119 | 183.6 | 9.8 | 18.5 | 80.3 | 1.0 |
| TecnoSuma UMTEST | 10 | 173.4 | 20.0 | 20.0 | 69.8 | 1.1 |
| Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens | 50 | 168.8 | 8.7 | 17.6 | 73.0 | 1.0 |

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

2015 Quality Control Data Summaries of Statistical Analyses
PHENYLALANINE (μmol Phe/L blood)

Lot 1523 - Enriched 200.0 μmol/L blood

| METHOD | N | Mean | Average Within Lab SD | Total SD | Y- Intercept* | Slope |
|--|-----|-------|-----------------------------|----------|---------------|-------|
| Fluorometric Manual | 68 | 318.0 | 28.3 | 32.1 | 90.7 | 1.1 |
| PerkinElmer Neonatal Kit | 150 | 244.7 | 21.1 | 33.3 | 74.9 | 0.9 |
| Ani Labsystems | 80 | 337.4 | 27.3 | 53.0 | 81.0 | 1.3 |
| Bio-Rad Quantase | 29 | 286.0 | 21.8 | 25.7 | 82.7 | 1.1 |
| Interscientific Enzyme | 30 | 264.4 | 6.2 | 27.8 | 70.9 | 1.0 |
| Astoria-Pacific 50 Hour Reagent Kit | 10 | 320.0 | 8.8 | 8.8 | 97.7 | 1.1 |
| HPLC | 10 | 274.4 | 15.7 | 15.7 | 84.2 | 0.9 |
| Derivatized - MS/MS non-kit | 889 | 254.3 | 19.5 | 39.8 | 70.8 | 0.9 |
| Non-derivatized - MS/MS non-kit | 384 | 271.2 | 17.7 | 31.4 | 74.8 | 1.0 |
| Derivatized - MS/MS PE NeoGram Kit | 119 | 263.5 | 27.9 | 39.3 | 73.2 | 1.0 |
| Non-derivatized - MS/MS PE NeoBase Kit | 709 | 254.1 | 16.5 | 27.2 | 69.9 | 0.9 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 110 | 237.0 | 16.8 | 37.7 | 68.8 | 0.9 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 119 | 278.6 | 17.5 | 29.4 | 80.3 | 1.0 |
| TecnoSuma UMTEST | 10 | 291.3 | 48.0 | 48.0 | 69.8 | 1.1 |
| Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens | 50 | 263.2 | 15.0 | 26.5 | 73.0 | 1.0 |

Lot 1524 - Enriched 300.0 μmol/L blood

| METHOD | N | Mean | Average Within Lab SD | Total SD | Y- Intercept* | Slope |
|--|-----|-------|-----------------------------|----------|---------------|-------|
| Fluorometric Manual | 80 | 429.5 | 31.3 | 62.1 | 90.7 | 1.1 |
| PerkinElmer Neonatal Kit | 155 | 342.0 | 33.5 | 47.8 | 74.9 | 0.9 |
| Ani Labsystems | 80 | 475.9 | 38.3 | 74.2 | 81.0 | 1.3 |
| Bio-Rad Quantase | 29 | 406.7 | 20.9 | 25.9 | 82.7 | 1.1 |
| Interscientific Enzyme | 28 | 385.2 | 7.8 | 11.8 | 70.9 | 1.0 |
| Astoria-Pacific 50 Hour Reagent Kit | 10 | 417.3 | 15.3 | 15.3 | 97.7 | 1.1 |
| HPLC | 10 | 353.5 | 18.5 | 18.5 | 84.2 | 0.9 |
| Derivatized - MS/MS non-kit | 893 | 348.9 | 27.8 | 56.6 | 70.8 | 0.9 |
| Non-derivatized - MS/MS non-kit | 388 | 369.6 | 24.8 | 47.6 | 74.8 | 1.0 |
| Derivatized - MS/MS PE NeoGram Kit | 120 | 358.8 | 39.1 | 55.8 | 73.2 | 1.0 |
| Non-derivatized - MS/MS PE NeoBase Kit | 708 | 353.1 | 23.3 | 37.5 | 69.9 | 0.9 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 111 | 325.9 | 25.2 | 58.2 | 68.8 | 0.9 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 119 | 384.6 | 22.8 | 47.6 | 80.3 | 1.0 |
| TecnoSuma UMTEST | 10 | 404.5 | 36.1 | 36.1 | 69.8 | 1.1 |
| Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens | 50 | 363.9 | 23.1 | 37.8 | 73.0 | 1.0 |

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

**Table 17m. 2015 Quality Control Data Summaries of Statistical Analyses
SUCCINYLACETONE (µmol SUAC/L blood)**

Lot 1425 - Nonenriched 0 µmol/L blood

| METHOD | N | Mean | Average Within Lab SD | Total SD | Y- Intercept* | Slope |
|--|-----|------|-----------------------------|----------|---------------|-------|
| Derivatized - MS/MS non-kit | 237 | 0.7 | 0.2 | 0.5 | 0.8 | 0.5 |
| Non-derivatized - MS/MS non-kit | 68 | 1.0 | 0.3 | 0.9 | 1.1 | 0.5 |
| Non-derivatized - MS/MS PE NeoBase Kit | 395 | 0.5 | 0.1 | 0.3 | 0.5 | 0.2 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 40 | 0.5 | 0.2 | 0.4 | 0.6 | 0.4 |

Lot 1426 - Enriched 2.5 µmol/L blood

| METHOD | N | Mean | Average Within Lab SD | Total SD | Y- Intercept* | Slope |
|--|-----|------|-----------------------------|----------|---------------|-------|
| Derivatized - MS/MS non-kit | 233 | 2.1 | 0.3 | 1.2 | 0.8 | 0.5 |
| Non-derivatized - MS/MS non-kit | 70 | 2.4 | 0.4 | 0.9 | 1.1 | 0.5 |
| Non-derivatized - MS/MS PE NeoBase Kit | 395 | 1.0 | 0.2 | 0.3 | 0.5 | 0.2 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 38 | 1.6 | 0.2 | 0.2 | 0.6 | 0.4 |

Lot 1427 - Enriched 7.5 µmol/L blood

| METHOD | N | Mean | Average Within Lab SD | Total SD | Y- Intercept* | Slope |
|--|-----|------|-----------------------------|----------|---------------|-------|
| Derivatized - MS/MS non-kit | 238 | 5.0 | 0.6 | 2.8 | 0.8 | 0.5 |
| Non-derivatized - MS/MS non-kit | 70 | 4.9 | 0.7 | 1.8 | 1.1 | 0.5 |
| Non-derivatized - MS/MS PE NeoBase Kit | 393 | 2.0 | 0.3 | 0.7 | 0.5 | 0.2 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 38 | 3.6 | 0.4 | 0.5 | 0.6 | 0.4 |

Lot 1428 - Enriched 15.0 µmol/L blood

| METHOD | N | Mean | Average Within Lab SD | Total SD | Y- Intercept* | Slope |
|--|-----|------|-----------------------------|----------|---------------|-------|
| Derivatized - MS/MS non-kit | 237 | 8.8 | 1.0 | 4.9 | 0.8 | 0.5 |
| Non-derivatized - MS/MS non-kit | 70 | 8.8 | 1.2 | 3.7 | 1.1 | 0.5 |
| Non-derivatized - MS/MS PE NeoBase Kit | 389 | 3.5 | 0.4 | 1.1 | 0.5 | 0.2 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 39 | 6.2 | 0.5 | 1.3 | 0.6 | 0.4 |

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

2015 Quality Control Data Summaries of Statistical Analyses SUCCINYLACETONE (μmol SUAC/L blood)

Lot 1521 - Nonenriched 0 μmol/L blood

| METHOD | N | Mean | Average Within Lab SD | Total SD | Y- Intercept* | Slope |
|--|-----|------|-----------------------|----------|---------------|-------|
| Derivatized - MS/MS non-kit | 241 | 0.7 | 0.2 | 0.5 | 0.9 | 0.5 |
| Non-derivatized - MS/MS non-kit | 76 | 0.9 | 0.3 | 0.8 | 1.0 | 0.4 |
| Non-derivatized - MS/MS PE NeoBase Kit | 390 | 0.5 | 0.1 | 0.3 | 0.5 | 0.2 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 70 | 0.5 | 0.1 | 0.3 | 0.6 | 0.4 |

Lot 1522 - Enriched 2.5 μmol/L blood

| METHOD | N | Mean | Average Within Lab SD | Total SD | Y- Intercept* | Slope |
|--|-----|------|-----------------------|----------|---------------|-------|
| Derivatized - MS/MS non-kit | 235 | 2.3 | 0.3 | 1.2 | 0.9 | 0.5 |
| Non-derivatized - MS/MS non-kit | 80 | 2.2 | 0.4 | 1.1 | 1.0 | 0.4 |
| Non-derivatized - MS/MS PE NeoBase Kit | 396 | 1.0 | 0.2 | 0.3 | 0.5 | 0.2 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 70 | 1.7 | 0.2 | 0.5 | 0.6 | 0.4 |

Lot 1523 - Enriched 7.5 μmol/L blood

| METHOD | N | Mean | Average Within Lab SD | Total SD | Y- Intercept* | Slope |
|--|-----|------|-----------------------|----------|---------------|-------|
| Derivatized - MS/MS non-kit | 240 | 5.0 | 0.7 | 2.8 | 0.9 | 0.5 |
| Non-derivatized - MS/MS non-kit | 80 | 4.3 | 0.7 | 2.4 | 1.0 | 0.4 |
| Non-derivatized - MS/MS PE NeoBase Kit | 404 | 2.0 | 0.3 | 0.7 | 0.5 | 0.2 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 70 | 3.5 | 0.4 | 0.8 | 0.6 | 0.4 |

Lot 1524 - Enriched 15.0 μmol/L blood

| METHOD | N | Mean | Average Within Lab SD | Total SD | Y- Intercept* | Slope |
|--|-----|------|-----------------------|----------|---------------|-------|
| Derivatized - MS/MS non-kit | 236 | 8.7 | 1.2 | 4.8 | 0.9 | 0.5 |
| Non-derivatized - MS/MS non-kit | 79 | 7.4 | 1.2 | 4.8 | 1.0 | 0.4 |
| Non-derivatized - MS/MS PE NeoBase Kit | 390 | 3.6 | 0.4 | 1.1 | 0.5 | 0.2 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 70 | 6.4 | 0.4 | 1.7 | 0.6 | 0.4 |

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

**Table 17n. 2015 Quality Control Data Summaries of Statistical Analyses
TYROSINE ($\mu\text{mol Tyr/L blood}$)**

Lot 1425 - Nonenriched 0 $\mu\text{mol/L blood}$

| METHOD | N | Mean | Average Within | | Y- Intercept* | Slope |
|--|-----|------|----------------|----------|---------------|-------|
| | | | Lab SD | Total SD | | |
| HPLC | 10 | 83.1 | 3.7 | 3.7 | 82.1 | 0.9 |
| Derivatized - MS/MS non-kit | 809 | 55.1 | 4.7 | 7.7 | 57.4 | 0.8 |
| Non-derivatized - MS/MS non-kit | 301 | 56.8 | 4.5 | 7.8 | 59.4 | 0.8 |
| Derivatized - MS/MS PE NeoGram Kit | 128 | 56.2 | 5.5 | 8.0 | 56.0 | 0.8 |
| Non-derivatized - MS/MS PE NeoBase Kit | 631 | 61.7 | 4.3 | 7.1 | 63.9 | 0.9 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 95 | 61.2 | 6.6 | 9.0 | 64.9 | 0.9 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 97 | 62.8 | 7.1 | 10.6 | 61.9 | 1.0 |
| Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens | 68 | 55.3 | 3.7 | 5.2 | 56.6 | 0.8 |

Lot 1426 - Enriched 200.0 $\mu\text{mol/L blood}$

| METHOD | N | Mean | Average Within | | Y- Intercept* | Slope |
|--|-----|-------|----------------|----------|---------------|-------|
| | | | Lab SD | Total SD | | |
| HPLC | 10 | 262.3 | 12.2 | 12.2 | 82.1 | 0.9 |
| Derivatized - MS/MS non-kit | 831 | 220.0 | 17.6 | 30.1 | 57.4 | 0.8 |
| Non-derivatized - MS/MS non-kit | 292 | 229.6 | 14.9 | 37.8 | 59.4 | 0.8 |
| Derivatized - MS/MS PE NeoGram Kit | 127 | 225.8 | 19.9 | 28.5 | 56.0 | 0.8 |
| Non-derivatized - MS/MS PE NeoBase Kit | 638 | 252.1 | 16.7 | 29.3 | 63.9 | 0.9 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 98 | 242.5 | 17.6 | 27.7 | 64.9 | 0.9 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 97 | 251.3 | 28.3 | 42.0 | 61.9 | 1.0 |
| Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens | 70 | 223.8 | 15.2 | 21.8 | 56.6 | 0.8 |

Lot 1427 - Enriched 400.0 $\mu\text{mol/L blood}$

| METHOD | N | Mean | Average Within | | Y- Intercept* | Slope |
|--|-----|-------|----------------|----------|---------------|-------|
| | | | Lab SD | Total SD | | |
| HPLC | 9 | 444.1 | 14.7 | 14.7 | 82.1 | 0.9 |
| Derivatized - MS/MS non-kit | 816 | 379.3 | 28.3 | 49.5 | 57.4 | 0.8 |
| Non-derivatized - MS/MS non-kit | 302 | 392.6 | 26.9 | 68.6 | 59.4 | 0.8 |
| Derivatized - MS/MS PE NeoGram Kit | 130 | 389.2 | 26.4 | 45.5 | 56.0 | 0.8 |
| Non-derivatized - MS/MS PE NeoBase Kit | 638 | 432.3 | 27.8 | 51.2 | 63.9 | 0.9 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 98 | 412.6 | 32.1 | 43.5 | 64.9 | 0.9 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 94 | 439.5 | 40.9 | 79.3 | 61.9 | 1.0 |
| Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens | 70 | 396.5 | 21.9 | 30.3 | 56.6 | 0.8 |

Lot 1428 - Enriched 600.0 $\mu\text{mol/L blood}$

| METHOD | N | Mean | Average Within | | Y- Intercept* | Slope |
|--|-----|-------|----------------|----------|---------------|-------|
| | | | Lab SD | Total SD | | |
| HPLC | 10 | 627.0 | 26.2 | 26.2 | 82.1 | 0.9 |
| Derivatized - MS/MS non-kit | 821 | 535.6 | 37.4 | 76.0 | 57.4 | 0.8 |
| Non-derivatized - MS/MS non-kit | 307 | 557.1 | 44.8 | 95.8 | 59.4 | 0.8 |
| Derivatized - MS/MS PE NeoGram Kit | 129 | 562.9 | 42.0 | 69.0 | 56.0 | 0.8 |
| Non-derivatized - MS/MS PE NeoBase Kit | 637 | 617.0 | 37.6 | 69.1 | 63.9 | 0.9 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 97 | 581.4 | 47.4 | 83.3 | 64.9 | 0.9 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 98 | 632.7 | 46.0 | 98.0 | 61.9 | 1.0 |
| Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens | 69 | 556.5 | 25.1 | 40.2 | 56.6 | 0.8 |

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

2015 Quality Control Data Summaries of Statistical Analyses TYROSINE ($\mu\text{mol Tyr/L blood}$)

Lot 1521 - Nonenriched 0 $\mu\text{mol/L blood}$

| METHOD | N | Mean | Average Within | | Y- Intercept* | Slope |
|--|-----|------|----------------|----------|---------------|-------|
| | | | Lab SD | Total SD | | |
| HPLC | 10 | 91.4 | 5.5 | 5.5 | 95.4 | 0.8 |
| Derivatized - MS/MS non-kit | 824 | 53.3 | 4.9 | 7.9 | 52.3 | 0.8 |
| Non-derivatized - MS/MS non-kit | 346 | 56.7 | 4.7 | 8.3 | 55.3 | 0.9 |
| Derivatized - MS/MS PE NeoGram Kit | 107 | 54.5 | 6.0 | 7.2 | 54.8 | 0.8 |
| Non-derivatized - MS/MS PE NeoBase Kit | 712 | 58.9 | 4.6 | 8.6 | 56.9 | 0.9 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 119 | 59.9 | 4.9 | 9.1 | 59.9 | 0.9 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 118 | 61.2 | 4.0 | 6.7 | 59.4 | 1.0 |
| Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens | 50 | 52.7 | 2.5 | 5.5 | 48.9 | 0.8 |

Lot 1522 - Enriched 200.0 $\mu\text{mol/L blood}$

| METHOD | N | Mean | Average Within | | Y- Intercept* | Slope |
|--|-----|-------|----------------|----------|---------------|-------|
| | | | Lab SD | Total SD | | |
| HPLC | 10 | 262.5 | 10.9 | 10.9 | 95.4 | 0.8 |
| Derivatized - MS/MS non-kit | 828 | 216.9 | 16.7 | 32.2 | 52.3 | 0.8 |
| Non-derivatized - MS/MS non-kit | 346 | 232.9 | 17.1 | 32.9 | 55.3 | 0.9 |
| Derivatized - MS/MS PE NeoGram Kit | 108 | 218.9 | 20.9 | 25.8 | 54.8 | 0.8 |
| Non-derivatized - MS/MS PE NeoBase Kit | 704 | 240.0 | 15.7 | 30.8 | 56.9 | 0.9 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 120 | 242.7 | 20.3 | 41.4 | 59.9 | 0.9 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 120 | 251.3 | 17.6 | 32.1 | 59.4 | 1.0 |
| Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens | 48 | 209.1 | 9.4 | 18.9 | 48.9 | 0.8 |

Lot 1523 - Enriched 400.0 $\mu\text{mol/L blood}$

| METHOD | N | Mean | Average Within | | Y- Intercept* | Slope |
|--|-----|-------|----------------|----------|---------------|-------|
| | | | Lab SD | Total SD | | |
| HPLC | 10 | 441.7 | 27.7 | 27.7 | 95.4 | 0.8 |
| Derivatized - MS/MS non-kit | 837 | 386.8 | 30.8 | 57.9 | 52.3 | 0.8 |
| Non-derivatized - MS/MS non-kit | 338 | 407.5 | 28.5 | 52.4 | 55.3 | 0.9 |
| Derivatized - MS/MS PE NeoGram Kit | 108 | 390.0 | 40.8 | 51.8 | 54.8 | 0.8 |
| Non-derivatized - MS/MS PE NeoBase Kit | 710 | 423.7 | 27.5 | 52.9 | 56.9 | 0.9 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 118 | 413.4 | 33.5 | 56.6 | 59.9 | 0.9 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 127 | 429.2 | 33.5 | 55.8 | 59.4 | 1.0 |
| Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens | 49 | 370.6 | 18.3 | 36.4 | 48.9 | 0.8 |

Lot 1524 - Enriched 600.0 $\mu\text{mol/L blood}$

| METHOD | N | Mean | Average Within | | Y- Intercept* | Slope |
|--|-----|-------|----------------|----------|---------------|-------|
| | | | Lab SD | Total SD | | |
| HPLC | 10 | 588.6 | 29.0 | 29.0 | 95.4 | 0.8 |
| Derivatized - MS/MS non-kit | 839 | 552.3 | 43.9 | 87.5 | 52.3 | 0.8 |
| Non-derivatized - MS/MS non-kit | 342 | 591.5 | 42.1 | 80.3 | 55.3 | 0.9 |
| Derivatized - MS/MS PE NeoGram Kit | 107 | 549.4 | 50.5 | 71.7 | 54.8 | 0.8 |
| Non-derivatized - MS/MS PE NeoBase Kit | 712 | 613.7 | 41.5 | 81.8 | 56.9 | 0.9 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 118 | 602.2 | 40.1 | 87.2 | 59.9 | 0.9 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 130 | 633.4 | 44.5 | 78.6 | 59.4 | 1.0 |
| Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens | 50 | 543.6 | 26.3 | 62.3 | 48.9 | 0.8 |

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

**Table 17o. 2015 Quality Control Data Summaries of Statistical Analyses
VALINE (μmol Val/L blood)**

Lot 1425 - Nonenriched 0 μmol/L blood

| METHOD | N | Mean | Average Within | | Y- Intercept* | Slope |
|--|-----|-------|----------------|----------|---------------|-------|
| | | | Lab SD | Total SD | | |
| Derivatized - MS/MS non-kit | 711 | 158.6 | 15.7 | 28.0 | 160.9 | 0.7 |
| Non-derivatized - MS/MS non-kit | 188 | 144.3 | 8.4 | 25.4 | 146.6 | 0.7 |
| Derivatized - MS/MS PE NeoGram Kit | 115 | 165.2 | 19.1 | 22.9 | 168.3 | 0.7 |
| Non-derivatized - MS/MS PE NeoBase Kit | 627 | 175.6 | 13.4 | 23.2 | 179.8 | 0.9 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 93 | 135.9 | 12.5 | 22.3 | 138.9 | 0.7 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 99 | 131.2 | 10.9 | 19.6 | 136.0 | 0.7 |
| Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens | 60 | 176.4 | 11.3 | 21.2 | 175.7 | 0.9 |

Lot 1426 - Enriched 200.0 μmol/L blood

| METHOD | N | Mean | Average Within | | Y- Intercept* | Slope |
|--|-----|-------|----------------|----------|---------------|-------|
| | | | Lab SD | Total SD | | |
| Derivatized - MS/MS non-kit | 717 | 305.8 | 28.6 | 52.7 | 160.9 | 0.7 |
| Non-derivatized - MS/MS non-kit | 186 | 294.8 | 19.2 | 50.0 | 146.6 | 0.7 |
| Derivatized - MS/MS PE NeoGram Kit | 118 | 323.1 | 38.8 | 48.2 | 168.3 | 0.7 |
| Non-derivatized - MS/MS PE NeoBase Kit | 630 | 365.9 | 29.1 | 51.9 | 179.8 | 0.9 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 99 | 281.2 | 33.4 | 57.0 | 138.9 | 0.7 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 99 | 272.0 | 19.8 | 46.9 | 136.0 | 0.7 |
| Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens | 59 | 354.5 | 23.9 | 45.4 | 175.7 | 0.9 |

Lot 1427 - Enriched 350.0 μmol/L blood

| METHOD | N | Mean | Average Within | | Y- Intercept* | Slope |
|--|-----|-------|----------------|----------|---------------|-------|
| | | | Lab SD | Total SD | | |
| Derivatized - MS/MS non-kit | 715 | 402.1 | 40.5 | 68.6 | 160.9 | 0.7 |
| Non-derivatized - MS/MS non-kit | 188 | 392.9 | 22.2 | 65.4 | 146.6 | 0.7 |
| Derivatized - MS/MS PE NeoGram Kit | 118 | 425.0 | 39.0 | 61.1 | 168.3 | 0.7 |
| Non-derivatized - MS/MS PE NeoBase Kit | 632 | 484.1 | 40.2 | 70.5 | 179.8 | 0.9 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 96 | 357.9 | 38.8 | 72.3 | 138.9 | 0.7 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 100 | 364.3 | 22.1 | 57.6 | 136.0 | 0.7 |
| Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens | 60 | 498.7 | 27.9 | 60.2 | 175.7 | 0.9 |

Lot 1428 - Enriched 500.0 μmol/L blood

| METHOD | N | Mean | Average Within | | Y- Intercept* | Slope |
|--|-----|-------|----------------|----------|---------------|-------|
| | | | Lab SD | Total SD | | |
| Derivatized - MS/MS non-kit | 716 | 509.8 | 45.1 | 83.2 | 160.9 | 0.7 |
| Non-derivatized - MS/MS non-kit | 189 | 503.0 | 33.6 | 89.8 | 146.6 | 0.7 |
| Derivatized - MS/MS PE NeoGram Kit | 117 | 538.5 | 55.8 | 80.9 | 168.3 | 0.7 |
| Non-derivatized - MS/MS PE NeoBase Kit | 627 | 621.1 | 46.9 | 84.4 | 179.8 | 0.9 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 96 | 472.5 | 42.8 | 91.3 | 138.9 | 0.7 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 97 | 454.6 | 24.6 | 73.0 | 136.0 | 0.7 |
| Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens | 60 | 629.7 | 34.2 | 66.2 | 175.7 | 0.9 |

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

2015 Quality Control Data Summaries of Statistical Analyses VALINE (μmol Val/L blood)

Lot 1521 - Nonenriched 0 μmol/L blood

| METHOD | N | Mean | Average Within | | Y- Intercept* | Slope |
|--|-----|-------|----------------|----------|---------------|-------|
| | | | Lab SD | Total SD | | |
| Derivatized - MS/MS non-kit | 771 | 164.1 | 15.8 | 30.2 | 160.2 | 0.7 |
| Non-derivatized - MS/MS non-kit | 238 | 147.1 | 11.4 | 29.6 | 145.5 | 0.7 |
| Derivatized - MS/MS PE NeoGram Kit | 97 | 173.7 | 21.1 | 26.6 | 169.9 | 0.7 |
| Non-derivatized - MS/MS PE NeoBase Kit | 686 | 172.8 | 13.5 | 23.8 | 166.7 | 0.9 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 110 | 143.4 | 18.4 | 35.7 | 140.6 | 0.6 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 100 | 124.8 | 8.2 | 13.8 | 121.6 | 0.7 |
| Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens | 48 | 186.0 | 10.3 | 20.3 | 180.3 | 0.9 |

Lot 1522 - Enriched 200.0 μmol/L blood

| METHOD | N | Mean | Average Within | | Y- Intercept* | Slope |
|--|-----|-------|----------------|----------|---------------|-------|
| | | | Lab SD | Total SD | | |
| Derivatized - MS/MS non-kit | 775 | 302.1 | 30.1 | 55.2 | 160.2 | 0.7 |
| Non-derivatized - MS/MS non-kit | 239 | 289.1 | 22.4 | 58.8 | 145.5 | 0.7 |
| Derivatized - MS/MS PE NeoGram Kit | 97 | 307.5 | 36.7 | 50.8 | 169.9 | 0.7 |
| Non-derivatized - MS/MS PE NeoBase Kit | 709 | 334.0 | 29.4 | 56.5 | 166.7 | 0.9 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 110 | 265.4 | 26.4 | 65.8 | 140.6 | 0.6 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 107 | 251.9 | 15.3 | 34.6 | 121.6 | 0.7 |
| Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens | 48 | 355.2 | 17.5 | 35.6 | 180.3 | 0.9 |

Lot 1523 - Enriched 350.0 μmol/L blood

| METHOD | N | Mean | Average Within | | Y- Intercept* | Slope |
|--|-----|-------|----------------|----------|---------------|-------|
| | | | Lab SD | Total SD | | |
| Derivatized - MS/MS non-kit | 790 | 418.1 | 42.4 | 84.2 | 160.2 | 0.7 |
| Non-derivatized - MS/MS non-kit | 237 | 405.7 | 32.6 | 84.4 | 145.5 | 0.7 |
| Derivatized - MS/MS PE NeoGram Kit | 100 | 427.6 | 50.5 | 69.7 | 169.9 | 0.7 |
| Non-derivatized - MS/MS PE NeoBase Kit | 684 | 471.8 | 37.1 | 67.2 | 166.7 | 0.9 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 109 | 359.2 | 42.6 | 88.7 | 140.6 | 0.6 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 119 | 354.2 | 25.0 | 50.5 | 121.6 | 0.7 |
| Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens | 48 | 491.5 | 30.0 | 50.0 | 180.3 | 0.9 |

Lot 1524 - Enriched 500.0 μmol/L blood

| METHOD | N | Mean | Average Within | | Y- Intercept* | Slope |
|--|-----|-------|----------------|----------|---------------|-------|
| | | | Lab SD | Total SD | | |
| Derivatized - MS/MS non-kit | 790 | 533.2 | 57.7 | 108.9 | 160.2 | 0.7 |
| Non-derivatized - MS/MS non-kit | 240 | 513.9 | 37.6 | 106.8 | 145.5 | 0.7 |
| Derivatized - MS/MS PE NeoGram Kit | 100 | 534.5 | 69.4 | 95.7 | 169.9 | 0.7 |
| Non-derivatized - MS/MS PE NeoBase Kit | 679 | 611.7 | 49.8 | 86.9 | 166.7 | 0.9 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 110 | 463.1 | 43.9 | 116.3 | 140.6 | 0.6 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 118 | 459.5 | 29.0 | 58.2 | 121.6 | 0.7 |
| Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens | 50 | 640.4 | 44.0 | 68.7 | 180.3 | 0.9 |

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

**Table 17p. 2015 Quality Control Data Summaries of Statistical Analyses
FREE CARNITINE ($\mu\text{mol C0/L blood}$)**

Lot 1465 - Nonenriched 0 $\mu\text{mol/L blood}$

| METHOD | N | Mean | Average Within | | Total SD | Y- Intercept* | Slope |
|--|-----|-------|----------------|--|----------|---------------|-------|
| | | | Lab SD | | | | |
| Derivatized - MS/MS non-kit | 846 | 16.46 | 1.67 | | 2.87 | 16.17 | 1.3 |
| Non-derivatized - MS/MS non-kit | 209 | 15.73 | 1.23 | | 2.91 | 15.47 | 1.1 |
| Derivatized - MS/MS PE NeoGram Kit | 130 | 21.19 | 1.82 | | 3.29 | 20.18 | 1.8 |
| Non-derivatized - MS/MS PE NeoBase Kit | 633 | 15.29 | 1.29 | | 1.94 | 15.09 | 1.0 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 106 | 14.84 | 1.76 | | 3.05 | 14.80 | 1.1 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 87 | 13.43 | 1.01 | | 1.71 | 13.71 | 0.9 |
| Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens | 60 | 16.13 | 0.79 | | 1.66 | 15.97 | 1.1 |

Lot 1466 - Enriched 10.0 $\mu\text{mol/L blood}$

| METHOD | N | Mean | Average Within | | Total SD | Y- Intercept* | Slope |
|--|-----|-------|----------------|--|----------|---------------|-------|
| | | | Lab SD | | | | |
| Derivatized - MS/MS non-kit | 847 | 28.71 | 2.71 | | 4.67 | 16.17 | 1.3 |
| Non-derivatized - MS/MS non-kit | 206 | 25.92 | 1.84 | | 4.12 | 15.47 | 1.1 |
| Derivatized - MS/MS PE NeoGram Kit | 128 | 37.58 | 2.79 | | 5.94 | 20.18 | 1.8 |
| Non-derivatized - MS/MS PE NeoBase Kit | 633 | 25.29 | 2.02 | | 3.08 | 15.09 | 1.0 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 110 | 26.00 | 2.86 | | 5.54 | 14.80 | 1.1 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 87 | 23.52 | 1.49 | | 3.14 | 13.71 | 0.9 |
| Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens | 60 | 26.83 | 2.13 | | 3.26 | 15.97 | 1.1 |

Lot 1467 - Enriched 20.0 $\mu\text{mol/L blood}$

| METHOD | N | Mean | Average Within | | Total SD | Y- Intercept* | Slope |
|--|-----|-------|----------------|--|----------|---------------|-------|
| | | | Lab SD | | | | |
| Derivatized - MS/MS non-kit | 833 | 41.50 | 3.90 | | 6.83 | 16.17 | 1.3 |
| Non-derivatized - MS/MS non-kit | 203 | 36.24 | 2.51 | | 5.70 | 15.47 | 1.1 |
| Derivatized - MS/MS PE NeoGram Kit | 129 | 56.03 | 4.46 | | 9.98 | 20.18 | 1.8 |
| Non-derivatized - MS/MS PE NeoBase Kit | 630 | 35.50 | 2.70 | | 4.04 | 15.09 | 1.0 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 108 | 37.49 | 3.48 | | 8.47 | 14.80 | 1.1 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 86 | 31.40 | 2.43 | | 4.88 | 13.71 | 0.9 |
| Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens | 60 | 37.28 | 2.04 | | 3.70 | 15.97 | 1.1 |

Lot 1468 - Enriched 30.0 $\mu\text{mol/L blood}$

| METHOD | N | Mean | Average Within | | Total SD | Y- Intercept* | Slope |
|--|-----|-------|----------------|--|----------|---------------|-------|
| | | | Lab SD | | | | |
| Derivatized - MS/MS non-kit | 850 | 54.96 | 4.76 | | 9.71 | 16.17 | 1.3 |
| Non-derivatized - MS/MS non-kit | 207 | 47.68 | 3.38 | | 8.54 | 15.47 | 1.1 |
| Derivatized - MS/MS PE NeoGram Kit | 130 | 76.46 | 5.95 | | 12.97 | 20.18 | 1.8 |
| Non-derivatized - MS/MS PE NeoBase Kit | 644 | 46.38 | 3.98 | | 6.16 | 15.09 | 1.0 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 108 | 48.68 | 4.70 | | 10.45 | 14.80 | 1.1 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 86 | 41.22 | 2.87 | | 6.61 | 13.71 | 0.9 |
| Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens | 60 | 48.91 | 3.11 | | 6.59 | 15.97 | 1.1 |

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

2015 Quality Control Data Summaries of Statistical Analyses FREE CARNITINE ($\mu\text{mol C0/L blood}$)

Lot 1561 - Nonenriched 0 $\mu\text{mol/L blood}$

| METHOD | N | Mean | Average Within Lab SD | Total SD | Y- Intercept* | Slope |
|--|-----|-------|--------------------------|----------|------------------|-------|
| Derivatized - MS/MS non-kit | 913 | 16.87 | 1.80 | 3.47 | 16.74 | 1.4 |
| Non-derivatized - MS/MS non-kit | 256 | 15.27 | 1.41 | 3.04 | 15.40 | 1.1 |
| Derivatized - MS/MS PE NeoGram Kit | 109 | 19.67 | 1.75 | 3.02 | 19.23 | 1.9 |
| Non-derivatized - MS/MS PE NeoBase Kit | 700 | 13.96 | 1.11 | 2.00 | 14.15 | 1.0 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 128 | 14.23 | 1.34 | 3.31 | 14.01 | 1.2 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 110 | 13.29 | 0.87 | 1.56 | 13.41 | 1.0 |
| Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens | 50 | 14.77 | 1.19 | 2.09 | 14.88 | 1.1 |

Lot 1562 - Enriched 10.0 $\mu\text{mol/L blood}$

| METHOD | N | Mean | Average Within Lab SD | Total SD | Y- Intercept* | Slope |
|--|-----|-------|--------------------------|----------|------------------|-------|
| Derivatized - MS/MS non-kit | 914 | 31.10 | 3.02 | 5.88 | 16.74 | 1.4 |
| Non-derivatized - MS/MS non-kit | 259 | 26.67 | 2.49 | 5.85 | 15.40 | 1.1 |
| Derivatized - MS/MS PE NeoGram Kit | 110 | 37.93 | 3.72 | 6.72 | 19.23 | 1.9 |
| Non-derivatized - MS/MS PE NeoBase Kit | 698 | 24.64 | 1.90 | 3.36 | 14.15 | 1.0 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 129 | 25.55 | 2.51 | 6.10 | 14.01 | 1.2 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 107 | 23.32 | 1.21 | 2.40 | 13.41 | 1.0 |
| Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens | 50 | 25.90 | 1.44 | 3.44 | 14.88 | 1.1 |

Lot 1563 - Enriched 20.0 $\mu\text{mol/L blood}$

| METHOD | N | Mean | Average Within Lab SD | Total SD | Y- Intercept* | Slope |
|--|-----|-------|--------------------------|----------|------------------|-------|
| Derivatized - MS/MS non-kit | 913 | 44.86 | 3.99 | 8.03 | 16.74 | 1.4 |
| Non-derivatized - MS/MS non-kit | 260 | 37.64 | 2.75 | 7.67 | 15.40 | 1.1 |
| Derivatized - MS/MS PE NeoGram Kit | 110 | 55.59 | 4.72 | 10.52 | 19.23 | 1.9 |
| Non-derivatized - MS/MS PE NeoBase Kit | 704 | 35.00 | 2.41 | 4.76 | 14.15 | 1.0 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 130 | 37.66 | 3.70 | 9.22 | 14.01 | 1.2 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 110 | 32.52 | 2.21 | 3.86 | 13.41 | 1.0 |
| Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens | 50 | 37.07 | 2.26 | 4.32 | 14.88 | 1.1 |

Lot 1564 - Enriched 30.0 $\mu\text{mol/L blood}$

| METHOD | N | Mean | Average Within Lab SD | Total SD | Y- Intercept* | Slope |
|--|-----|-------|--------------------------|----------|------------------|-------|
| Derivatized - MS/MS non-kit | 911 | 59.98 | 5.70 | 11.54 | 16.74 | 1.4 |
| Non-derivatized - MS/MS non-kit | 260 | 48.62 | 3.77 | 9.71 | 15.40 | 1.1 |
| Derivatized - MS/MS PE NeoGram Kit | 107 | 76.34 | 6.58 | 12.83 | 19.23 | 1.9 |
| Non-derivatized - MS/MS PE NeoBase Kit | 696 | 44.89 | 3.29 | 5.95 | 14.15 | 1.0 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 129 | 49.66 | 4.24 | 12.30 | 14.01 | 1.2 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 109 | 42.37 | 2.49 | 4.14 | 13.41 | 1.0 |
| Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens | 50 | 47.64 | 3.06 | 5.56 | 14.88 | 1.1 |

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

Table 17q. 2015 Quality Control Data Summaries of Statistical Analyses
ACETYLCARNITINE ($\mu\text{mol C2/L blood}$)

Lot 1465 - Nonenriched 0 $\mu\text{mol/L blood}$

| METHOD | N | Mean | Average Within | | Y- Intercept* | Slope |
|--|-----|-------|----------------|----------|---------------|-------|
| | | | Lab SD | Total SD | | |
| Derivatized - MS/MS non-kit | 813 | 11.52 | 1.34 | 2.99 | 11.76 | 0.9 |
| Non-derivatized - MS/MS non-kit | 200 | 9.05 | 0.71 | 1.75 | 9.17 | 1.0 |
| Derivatized - MS/MS PE NeoGram Kit | 130 | 14.44 | 1.05 | 2.86 | 14.40 | 0.6 |
| Non-derivatized - MS/MS PE NeoBase Kit | 640 | 8.38 | 0.56 | 0.94 | 8.49 | 0.9 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 105 | 11.18 | 1.32 | 2.40 | 11.39 | 0.9 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 87 | 7.50 | 0.58 | 1.06 | 7.68 | 0.8 |
| Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens | 60 | 11.06 | 0.62 | 1.83 | 11.08 | 1.1 |

Lot 1466 - Enriched 10.0 $\mu\text{mol/L blood}$

| METHOD | N | Mean | Average Within | | Y- Intercept* | Slope |
|--|-----|-------|----------------|----------|---------------|-------|
| | | | Lab SD | Total SD | | |
| Derivatized - MS/MS non-kit | 817 | 20.89 | 2.19 | 4.75 | 11.76 | 0.9 |
| Non-derivatized - MS/MS non-kit | 198 | 19.02 | 1.36 | 3.29 | 9.17 | 1.0 |
| Derivatized - MS/MS PE NeoGram Kit | 128 | 20.99 | 1.27 | 2.84 | 14.40 | 0.6 |
| Non-derivatized - MS/MS PE NeoBase Kit | 652 | 17.58 | 1.10 | 2.06 | 8.49 | 0.9 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 108 | 20.32 | 1.99 | 2.94 | 11.39 | 0.9 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 90 | 16.56 | 1.03 | 1.92 | 7.68 | 0.8 |
| Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens | 60 | 22.09 | 1.45 | 3.00 | 11.08 | 1.1 |

Lot 1467 - Enriched 20.0 $\mu\text{mol/L blood}$

| METHOD | N | Mean | Average Within | | Y- Intercept* | Slope |
|--|-----|-------|----------------|----------|---------------|-------|
| | | | Lab SD | Total SD | | |
| Derivatized - MS/MS non-kit | 814 | 29.33 | 2.91 | 5.72 | 11.76 | 0.9 |
| Non-derivatized - MS/MS non-kit | 196 | 27.90 | 1.89 | 4.85 | 9.17 | 1.0 |
| Derivatized - MS/MS PE NeoGram Kit | 127 | 26.74 | 1.62 | 3.36 | 14.40 | 0.6 |
| Non-derivatized - MS/MS PE NeoBase Kit | 646 | 26.44 | 1.67 | 2.95 | 8.49 | 0.9 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 110 | 28.28 | 2.51 | 4.05 | 11.39 | 0.9 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 86 | 23.74 | 1.61 | 2.98 | 7.68 | 0.8 |
| Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens | 60 | 32.91 | 2.11 | 3.65 | 11.08 | 1.1 |

Lot 1468 - Enriched 30.0 $\mu\text{mol/L blood}$

| METHOD | N | Mean | Average Within | | Y- Intercept* | Slope |
|--|-----|-------|----------------|----------|---------------|-------|
| | | | Lab SD | Total SD | | |
| Derivatized - MS/MS non-kit | 816 | 37.99 | 3.50 | 7.30 | 11.76 | 0.9 |
| Non-derivatized - MS/MS non-kit | 198 | 37.81 | 2.63 | 7.15 | 9.17 | 1.0 |
| Derivatized - MS/MS PE NeoGram Kit | 130 | 33.88 | 2.03 | 4.03 | 14.40 | 0.6 |
| Non-derivatized - MS/MS PE NeoBase Kit | 642 | 35.24 | 2.31 | 4.02 | 8.49 | 0.9 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 107 | 36.97 | 3.16 | 4.13 | 11.39 | 0.9 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 90 | 32.89 | 2.10 | 3.57 | 7.68 | 0.8 |
| Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens | 60 | 43.95 | 2.63 | 4.14 | 11.08 | 1.1 |

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

2015 Quality Control Data Summaries of Statistical Analyses ACETYLCARNITINE (µmol C2/L blood)

Lot 1561 - Nonenriched 0 µmol/L blood

| METHOD | N | Mean | Average Within | | Y- Intercept* | Slope |
|--|-----|-------|----------------|----------|---------------|-------|
| | | | Lab SD | Total SD | | |
| Derivatized - MS/MS non-kit | 890 | 12.98 | 1.63 | 3.48 | 12.73 | 1.0 |
| Non-derivatized - MS/MS non-kit | 250 | 11.24 | 0.97 | 1.96 | 10.88 | 1.1 |
| Derivatized - MS/MS PE NeoGram Kit | 106 | 14.44 | 1.47 | 2.18 | 14.52 | 0.7 |
| Non-derivatized - MS/MS PE NeoBase Kit | 674 | 9.07 | 0.54 | 1.00 | 8.74 | 0.9 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 121 | 10.74 | 0.75 | 1.73 | 10.28 | 0.9 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 110 | 8.69 | 0.65 | 1.22 | 8.51 | 0.9 |
| Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens | 50 | 11.05 | 0.58 | 0.76 | 10.68 | 1.1 |

Lot 1562 - Enriched 10.0 µmol/L blood

| METHOD | N | Mean | Average Within | | Y- Intercept* | Slope |
|--|-----|-------|----------------|----------|---------------|-------|
| | | | Lab SD | Total SD | | |
| Derivatized - MS/MS non-kit | 868 | 22.24 | 2.10 | 4.09 | 12.73 | 1.0 |
| Non-derivatized - MS/MS non-kit | 245 | 21.41 | 1.47 | 3.17 | 10.88 | 1.1 |
| Derivatized - MS/MS PE NeoGram Kit | 105 | 21.76 | 2.29 | 3.00 | 14.52 | 0.7 |
| Non-derivatized - MS/MS PE NeoBase Kit | 680 | 17.92 | 1.09 | 1.90 | 8.74 | 0.9 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 122 | 19.35 | 1.41 | 2.99 | 10.28 | 0.9 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 109 | 16.95 | 1.07 | 1.89 | 8.51 | 0.9 |
| Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens | 49 | 21.60 | 1.02 | 1.65 | 10.68 | 1.1 |

Lot 1563 - Enriched 20.0 µmol/L blood

| METHOD | N | Mean | Average Within | | Y- Intercept* | Slope |
|--|-----|-------|----------------|----------|---------------|-------|
| | | | Lab SD | Total SD | | |
| Derivatized - MS/MS non-kit | 880 | 31.48 | 2.98 | 6.24 | 12.73 | 1.0 |
| Non-derivatized - MS/MS non-kit | 246 | 32.31 | 2.50 | 5.00 | 10.88 | 1.1 |
| Derivatized - MS/MS PE NeoGram Kit | 105 | 27.72 | 2.10 | 3.57 | 14.52 | 0.7 |
| Non-derivatized - MS/MS PE NeoBase Kit | 685 | 26.99 | 1.58 | 2.82 | 8.74 | 0.9 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 121 | 27.93 | 1.99 | 3.51 | 10.28 | 0.9 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 106 | 25.21 | 1.49 | 2.92 | 8.51 | 0.9 |
| Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens | 50 | 33.24 | 1.98 | 2.39 | 10.68 | 1.1 |

Lot 1564 - Enriched 30.0 µmol/L blood

| METHOD | N | Mean | Average Within | | Y- Intercept* | Slope |
|--|-----|-------|----------------|----------|---------------|-------|
| | | | Lab SD | Total SD | | |
| Derivatized - MS/MS non-kit | 875 | 42.01 | 3.52 | 7.50 | 12.73 | 1.0 |
| Non-derivatized - MS/MS non-kit | 248 | 43.92 | 3.07 | 6.29 | 10.88 | 1.1 |
| Derivatized - MS/MS PE NeoGram Kit | 107 | 35.32 | 3.36 | 4.14 | 14.52 | 0.7 |
| Non-derivatized - MS/MS PE NeoBase Kit | 676 | 37.39 | 2.17 | 3.95 | 8.74 | 0.9 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 128 | 38.84 | 2.53 | 5.65 | 10.28 | 0.9 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 95 | 34.40 | 2.24 | 3.59 | 8.51 | 0.9 |
| Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens | 50 | 45.10 | 2.32 | 3.06 | 10.68 | 1.1 |

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

**Table 17r. 2015 Quality Control Data Summaries of Statistical Analyses
PROPIONYLCARNITINE ($\mu\text{mol C3/L blood}$)**

Lot 1465 - Nonenriched 0 $\mu\text{mol/L blood}$

| METHOD | N | Mean | Average Within | | Y- Intercept* | Slope |
|--|-----|------|----------------|----------|---------------|-------|
| | | | Lab SD | Total SD | | |
| Derivatized - MS/MS non-kit | 819 | 0.95 | 0.12 | 0.18 | 1.02 | 0.9 |
| Non-derivatized - MS/MS non-kit | 205 | 0.92 | 0.09 | 0.17 | 0.94 | 1.0 |
| Derivatized - MS/MS PE NeoGram Kit | 125 | 0.78 | 0.08 | 0.11 | 0.77 | 0.8 |
| Non-derivatized - MS/MS PE NeoBase Kit | 636 | 0.78 | 0.06 | 0.09 | 0.78 | 0.8 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 105 | 0.90 | 0.16 | 0.20 | 0.86 | 0.8 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 90 | 0.80 | 0.08 | 0.14 | 0.80 | 0.8 |
| Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens | 59 | 1.01 | 0.07 | 0.10 | 1.02 | 1.0 |

Lot 1466 - Enriched 3.0 $\mu\text{mol/L blood}$

| METHOD | N | Mean | Average Within | | Y- Intercept* | Slope |
|--|-----|------|----------------|----------|---------------|-------|
| | | | Lab SD | Total SD | | |
| Derivatized - MS/MS non-kit | 819 | 3.88 | 0.42 | 0.64 | 1.02 | 0.9 |
| Non-derivatized - MS/MS non-kit | 206 | 3.90 | 0.27 | 0.63 | 0.94 | 1.0 |
| Derivatized - MS/MS PE NeoGram Kit | 127 | 3.25 | 0.24 | 0.37 | 0.77 | 0.8 |
| Non-derivatized - MS/MS PE NeoBase Kit | 650 | 3.30 | 0.22 | 0.36 | 0.78 | 0.8 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 106 | 3.39 | 0.32 | 0.42 | 0.86 | 0.8 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 88 | 3.36 | 0.34 | 0.53 | 0.80 | 0.8 |
| Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens | 59 | 4.12 | 0.29 | 0.36 | 1.02 | 1.0 |

Lot 1467 - Enriched 7.5 $\mu\text{mol/L blood}$

| METHOD | N | Mean | Average Within | | Y- Intercept* | Slope |
|--|-----|------|----------------|----------|---------------|-------|
| | | | Lab SD | Total SD | | |
| Derivatized - MS/MS non-kit | 822 | 8.14 | 0.89 | 1.41 | 1.02 | 0.9 |
| Non-derivatized - MS/MS non-kit | 201 | 8.16 | 0.66 | 1.29 | 0.94 | 1.0 |
| Derivatized - MS/MS PE NeoGram Kit | 126 | 6.76 | 0.47 | 0.83 | 0.77 | 0.8 |
| Non-derivatized - MS/MS PE NeoBase Kit | 647 | 7.00 | 0.47 | 0.74 | 0.78 | 0.8 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 107 | 7.00 | 0.70 | 0.78 | 0.86 | 0.8 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 90 | 7.01 | 0.56 | 1.22 | 0.80 | 0.8 |
| Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens | 58 | 8.66 | 0.54 | 0.58 | 1.02 | 1.0 |

Lot 1468 - Enriched 12.0 $\mu\text{mol/L blood}$

| METHOD | N | Mean | Average Within | | Y- Intercept* | Slope |
|--|-----|-------|----------------|----------|---------------|-------|
| | | | Lab SD | Total SD | | |
| Derivatized - MS/MS non-kit | 829 | 12.20 | 1.26 | 2.14 | 1.02 | 0.9 |
| Non-derivatized - MS/MS non-kit | 202 | 12.57 | 1.01 | 2.25 | 0.94 | 1.0 |
| Derivatized - MS/MS PE NeoGram Kit | 129 | 10.61 | 0.85 | 1.21 | 0.77 | 0.8 |
| Non-derivatized - MS/MS PE NeoBase Kit | 645 | 10.82 | 0.68 | 1.15 | 0.78 | 0.8 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 107 | 10.97 | 1.07 | 1.37 | 0.86 | 0.8 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 89 | 10.94 | 0.78 | 1.59 | 0.80 | 0.8 |
| Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens | 58 | 13.32 | 0.76 | 0.85 | 1.02 | 1.0 |

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

2015 Quality Control Data Summaries of Statistical Analyses PROPIONYL CARNITINE ($\mu\text{mol C3/L blood}$)

Lot 1561 - Nonenriched 0 $\mu\text{mol/L blood}$

| METHOD | N | Mean | Average Within | | Y- Intercept* | Slope |
|--|-----|------|----------------|----------|---------------|-------|
| | | | Lab SD | Total SD | | |
| Derivatized - MS/MS non-kit | 894 | 1.02 | 0.12 | 0.19 | 0.90 | 1.0 |
| Non-derivatized - MS/MS non-kit | 251 | 1.01 | 0.10 | 0.17 | 0.91 | 1.1 |
| Derivatized - MS/MS PE NeoGram Kit | 103 | 0.78 | 0.08 | 0.11 | 0.68 | 0.8 |
| Non-derivatized - MS/MS PE NeoBase Kit | 704 | 0.82 | 0.06 | 0.10 | 0.71 | 0.9 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 117 | 0.92 | 0.11 | 0.12 | 0.77 | 1.0 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 110 | 0.86 | 0.08 | 0.15 | 0.70 | 0.9 |
| Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens | 47 | 1.03 | 0.04 | 0.08 | 0.89 | 1.1 |

Lot 1562 - Enriched 4.0 $\mu\text{mol/L blood}$

| METHOD | N | Mean | Average Within | | Y- Intercept* | Slope |
|--|-----|------|----------------|----------|---------------|-------|
| | | | Lab SD | Total SD | | |
| Derivatized - MS/MS non-kit | 893 | 5.04 | 0.51 | 0.85 | 0.90 | 1.0 |
| Non-derivatized - MS/MS non-kit | 244 | 5.11 | 0.40 | 0.82 | 0.91 | 1.1 |
| Derivatized - MS/MS PE NeoGram Kit | 103 | 4.08 | 0.42 | 0.57 | 0.68 | 0.8 |
| Non-derivatized - MS/MS PE NeoBase Kit | 709 | 4.24 | 0.28 | 0.49 | 0.71 | 0.9 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 117 | 4.49 | 0.38 | 0.50 | 0.77 | 1.0 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 107 | 4.32 | 0.27 | 0.57 | 0.70 | 0.9 |
| Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens | 49 | 5.37 | 0.26 | 0.53 | 0.89 | 1.1 |

Lot 1563 - Enriched 8.0 $\mu\text{mol/L blood}$

| METHOD | N | Mean | Average Within | | Y- Intercept* | Slope |
|--|-----|------|----------------|----------|---------------|-------|
| | | | Lab SD | Total SD | | |
| Derivatized - MS/MS non-kit | 901 | 8.91 | 0.89 | 1.45 | 0.90 | 1.0 |
| Non-derivatized - MS/MS non-kit | 251 | 9.39 | 0.78 | 1.66 | 0.91 | 1.1 |
| Derivatized - MS/MS PE NeoGram Kit | 103 | 7.04 | 0.56 | 1.28 | 0.68 | 0.8 |
| Non-derivatized - MS/MS PE NeoBase Kit | 704 | 7.59 | 0.45 | 0.83 | 0.71 | 0.9 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 116 | 8.06 | 0.62 | 0.83 | 0.77 | 1.0 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 106 | 7.77 | 0.48 | 1.17 | 0.70 | 0.9 |
| Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens | 50 | 9.64 | 0.48 | 0.87 | 0.89 | 1.1 |

Lot 1564 - Enriched 12.0 $\mu\text{mol/L blood}$

| METHOD | N | Mean | Average Within | | Y- Intercept* | Slope |
|--|-----|-------|----------------|----------|---------------|-------|
| | | | Lab SD | Total SD | | |
| Derivatized - MS/MS non-kit | 902 | 13.61 | 1.36 | 2.18 | 0.90 | 1.0 |
| Non-derivatized - MS/MS non-kit | 248 | 13.95 | 1.01 | 2.18 | 0.91 | 1.1 |
| Derivatized - MS/MS PE NeoGram Kit | 107 | 11.01 | 1.04 | 1.96 | 0.68 | 0.8 |
| Non-derivatized - MS/MS PE NeoBase Kit | 702 | 11.61 | 0.70 | 1.29 | 0.71 | 0.9 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 117 | 12.39 | 0.91 | 1.44 | 0.77 | 1.0 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 110 | 12.08 | 0.79 | 1.67 | 0.70 | 0.9 |
| Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens | 50 | 14.68 | 0.79 | 1.32 | 0.89 | 1.1 |

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

**Table 17s. 2015 Quality Control Data Summaries of Statistical Analyses
MALONYLCARNITINE ($\mu\text{mol C3DC/L blood}$)**

Lot 1465 - Nonenriched 0 $\mu\text{mol/L blood}$

| METHOD | N | Mean | Average Within Lab SD | Total SD | Y- Intercept* | Slope |
|--|-----|------|-----------------------------|----------|---------------|-------|
| Derivatized - MS/MS non-kit | 750 | 0.03 | 0.01 | 0.02 | 0.05 | 0.5 |
| Derivatized - MS/MS PE NeoGram Kit | 112 | 0.04 | 0.01 | 0.01 | 0.07 | 1.3 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 96 | 0.04 | 0.02 | 0.03 | 0.06 | 0.6 |

Lot 1466 - Enriched 0.5 $\mu\text{mol/L blood}$

| METHOD | N | Mean | Average Within Lab SD | Total SD | Y- Intercept* | Slope |
|--|-----|------|-----------------------------|----------|---------------|-------|
| Derivatized - MS/MS non-kit | 746 | 0.31 | 0.06 | 0.10 | 0.05 | 0.5 |
| Derivatized - MS/MS PE NeoGram Kit | 120 | 0.68 | 0.07 | 0.19 | 0.07 | 1.3 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 97 | 0.36 | 0.08 | 0.14 | 0.06 | 0.6 |

Lot 1467 - Enriched 1.5 $\mu\text{mol/L blood}$

| METHOD | N | Mean | Average Within Lab SD | Total SD | Y- Intercept* | Slope |
|--|-----|------|-----------------------------|----------|---------------|-------|
| Derivatized - MS/MS non-kit | 744 | 0.91 | 0.15 | 0.28 | 0.05 | 0.5 |
| Derivatized - MS/MS PE NeoGram Kit | 120 | 2.16 | 0.19 | 0.59 | 0.07 | 1.3 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 96 | 1.06 | 0.20 | 0.35 | 0.06 | 0.6 |

Lot 1468 - Enriched 3.0 $\mu\text{mol/L blood}$

| METHOD | N | Mean | Average Within Lab SD | Total SD | Y- Intercept* | Slope |
|--|-----|------|-----------------------------|----------|---------------|-------|
| Derivatized - MS/MS non-kit | 737 | 1.62 | 0.22 | 0.50 | 0.05 | 0.5 |
| Derivatized - MS/MS PE NeoGram Kit | 120 | 3.91 | 0.33 | 1.05 | 0.07 | 1.3 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 93 | 1.89 | 0.43 | 0.65 | 0.06 | 0.6 |

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

2015 Quality Control Data Summaries of Statistical Analyses MALONYLCARNITINE (μmol C3DC/L blood)

Lot 1561 - Nonenriched 0 μmol/L blood

| METHOD | N | Mean | Average Within | Total SD | Y- Intercept* | Slope |
|--|-----|------|----------------|----------|---------------|-------|
| | | | Lab SD | | | |
| Derivatized - MS/MS non-kit | 803 | 0.03 | 0.02 | 0.03 | 0.03 | 0.6 |
| Derivatized - MS/MS PE NeoGram Kit | 82 | 0.03 | 0.01 | 0.02 | 0.01 | 1.3 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 123 | 0.03 | 0.02 | 0.03 | 0.02 | 0.7 |

Lot 1562 - Enriched 0.5 μmol/L blood

| METHOD | N | Mean | Average Within | Total SD | Y- Intercept* | Slope |
|--|-----|------|----------------|----------|---------------|-------|
| | | | Lab SD | | | |
| Derivatized - MS/MS non-kit | 808 | 0.33 | 0.06 | 0.12 | 0.03 | 0.6 |
| Derivatized - MS/MS PE NeoGram Kit | 86 | 0.70 | 0.08 | 0.15 | 0.01 | 1.3 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 123 | 0.35 | 0.07 | 0.12 | 0.02 | 0.7 |

Lot 1563 - Enriched 1.5 μmol/L blood

| METHOD | N | Mean | Average Within | Total SD | Y- Intercept* | Slope |
|--|-----|------|----------------|----------|---------------|-------|
| | | | Lab SD | | | |
| Derivatized - MS/MS non-kit | 815 | 0.92 | 0.13 | 0.32 | 0.03 | 0.6 |
| Derivatized - MS/MS PE NeoGram Kit | 88 | 1.93 | 0.20 | 0.47 | 0.01 | 1.3 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 124 | 1.00 | 0.17 | 0.35 | 0.02 | 0.7 |

Lot 1564 - Enriched 3.0 μmol/L blood

| METHOD | N | Mean | Average Within | Total SD | Y- Intercept* | Slope |
|--|-----|------|----------------|----------|---------------|-------|
| | | | Lab SD | | | |
| Derivatized - MS/MS non-kit | 811 | 1.83 | 0.25 | 0.59 | 0.03 | 0.6 |
| Derivatized - MS/MS PE NeoGram Kit | 86 | 4.03 | 0.43 | 0.88 | 0.01 | 1.3 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 124 | 2.01 | 0.35 | 0.67 | 0.02 | 0.7 |

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

**Table 17t. 2015 Quality Control Data Summaries of Statistical Analyses
MALONYLCARNITINE + HYDROXYBUTYRYLCARNITINE
($\mu\text{mol C3DC}+\text{C4OH/L blood}$)**

Lot 1465 - Nonenriched 0 $\mu\text{mol/L}$ blood

| METHOD | N | Mean | Average Within Lab SD | Total SD | Y- Intercept* | Slope |
|--|-----|------|-----------------------------|----------|---------------|-------|
| Non-derivatized - MS/MS non-kit | 119 | 0.09 | 0.02 | 0.05 | 0.09 | 0.4 |
| Non-derivatized - MS/MS PE NeoBase Kit | 493 | 0.06 | 0.01 | 0.03 | 0.05 | 0.3 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 48 | 0.12 | 0.04 | 0.15 | 0.08 | 0.6 |

Lot 1466 - Enriched 1.0 $\mu\text{mol/L}$ blood

| METHOD | N | Mean | Average Within Lab SD | Total SD | Y- Intercept* | Slope |
|--|-----|------|-----------------------------|----------|---------------|-------|
| Non-derivatized - MS/MS non-kit | 118 | 0.55 | 0.08 | 0.26 | 0.09 | 0.4 |
| Non-derivatized - MS/MS PE NeoBase Kit | 479 | 0.39 | 0.04 | 0.11 | 0.05 | 0.3 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 50 | 0.78 | 0.14 | 0.88 | 0.08 | 0.6 |

Lot 1467 - Enriched 2.5 $\mu\text{mol/L}$ blood

| METHOD | N | Mean | Average Within Lab SD | Total SD | Y- Intercept* | Slope |
|--|-----|------|-----------------------------|----------|---------------|-------|
| Non-derivatized - MS/MS non-kit | 120 | 1.17 | 0.17 | 0.63 | 0.09 | 0.4 |
| Non-derivatized - MS/MS PE NeoBase Kit | 473 | 0.79 | 0.07 | 0.20 | 0.05 | 0.3 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 50 | 1.51 | 0.19 | 1.81 | 0.08 | 0.6 |

Lot 1468 - Enriched 5.5 $\mu\text{mol/L}$ blood

| METHOD | N | Mean | Average Within Lab SD | Total SD | Y- Intercept* | Slope |
|--|-----|------|-----------------------------|----------|---------------|-------|
| Non-derivatized - MS/MS non-kit | 120 | 2.50 | 0.31 | 1.35 | 0.09 | 0.4 |
| Non-derivatized - MS/MS PE NeoBase Kit | 479 | 1.78 | 0.14 | 0.41 | 0.05 | 0.3 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 50 | 3.65 | 0.70 | 4.33 | 0.08 | 0.6 |

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

2015 Quality Control Data Summaries of Statistical Analyses
MALONYLCARNITINE + HYDROXYBUTYRYLCARNITINE
($\mu\text{mol C3DC}+\text{C4OH/L blood}$)

Lot 1561 - Nonenriched 0 $\mu\text{mol/L blood}$

| METHOD | N | Mean | Average Within Lab SD | Total SD | Y- Intercept* | Slope |
|--|-----|------|-----------------------|----------|---------------|-------|
| Non-derivatized - MS/MS non-kit | 139 | 0.08 | 0.02 | 0.05 | 0.08 | 0.5 |
| Non-derivatized - MS/MS PE NeoBase Kit | 521 | 0.05 | 0.01 | 0.02 | 0.04 | 0.3 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 70 | 0.09 | 0.04 | 0.12 | 0.16 | 0.3 |

Lot 1562 - Enriched 1.0 $\mu\text{mol/L blood}$

| METHOD | N | Mean | Average Within Lab SD | Total SD | Y- Intercept* | Slope |
|--|-----|------|-----------------------|----------|---------------|-------|
| Non-derivatized - MS/MS non-kit | 136 | 0.60 | 0.09 | 0.34 | 0.08 | 0.5 |
| Non-derivatized - MS/MS PE NeoBase Kit | 531 | 0.39 | 0.03 | 0.14 | 0.04 | 0.3 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 65 | 0.49 | 0.04 | 0.76 | 0.16 | 0.3 |

Lot 1563 - Enriched 2.5 $\mu\text{mol/L blood}$

| METHOD | N | Mean | Average Within Lab SD | Total SD | Y- Intercept* | Slope |
|--|-----|------|-----------------------|----------|---------------|-------|
| Non-derivatized - MS/MS non-kit | 137 | 1.21 | 0.19 | 0.69 | 0.08 | 0.5 |
| Non-derivatized - MS/MS PE NeoBase Kit | 510 | 0.79 | 0.06 | 0.14 | 0.04 | 0.3 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 63 | 0.86 | 0.12 | 1.54 | 0.16 | 0.3 |

Lot 1564 - Enriched 5.5 $\mu\text{mol/L blood}$

| METHOD | N | Mean | Average Within Lab SD | Total SD | Y- Intercept* | Slope |
|--|-----|------|-----------------------|----------|---------------|-------|
| Non-derivatized - MS/MS non-kit | 134 | 2.73 | 0.32 | 1.52 | 0.08 | 0.5 |
| Non-derivatized - MS/MS PE NeoBase Kit | 509 | 1.83 | 0.12 | 0.30 | 0.04 | 0.3 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 60 | 1.60 | 0.25 | 0.43 | 0.16 | 0.3 |

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

**Table 17u. 2015 Quality Control Data Summaries of Statistical Analyses
BUTYRYLCARNITINE ($\mu\text{mol C4/L blood}$)**

Lot 1465 - Nonenriched 0 $\mu\text{mol/L blood}$

| METHOD | N | Mean | Average Within | | Y- Intercept* | Slope |
|--|-----|------|----------------|----------|---------------|-------|
| | | | Lab SD | Total SD | | |
| Derivatized - MS/MS non-kit | 803 | 0.14 | 0.03 | 0.05 | 0.14 | 0.8 |
| Non-derivatized - MS/MS non-kit | 173 | 0.13 | 0.02 | 0.02 | 0.14 | 0.8 |
| Derivatized - MS/MS PE NeoGram Kit | 122 | 0.15 | 0.04 | 0.04 | 0.13 | 0.7 |
| Non-derivatized - MS/MS PE NeoBase Kit | 621 | 0.13 | 0.02 | 0.04 | 0.12 | 0.8 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 101 | 0.14 | 0.05 | 0.09 | 0.11 | 0.7 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 87 | 0.12 | 0.02 | 0.04 | 0.11 | 0.8 |
| Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens | 30 | 0.13 | 0.01 | 0.01 | 0.14 | 0.9 |

Lot 1466 - Enriched 1.0 $\mu\text{mol/L blood}$

| METHOD | N | Mean | Average Within | | Y- Intercept* | Slope |
|--|-----|------|----------------|----------|---------------|-------|
| | | | Lab SD | Total SD | | |
| Derivatized - MS/MS non-kit | 814 | 0.97 | 0.12 | 0.18 | 0.14 | 0.8 |
| Non-derivatized - MS/MS non-kit | 168 | 1.00 | 0.10 | 0.12 | 0.14 | 0.8 |
| Derivatized - MS/MS PE NeoGram Kit | 129 | 0.85 | 0.13 | 0.15 | 0.13 | 0.7 |
| Non-derivatized - MS/MS PE NeoBase Kit | 621 | 0.90 | 0.06 | 0.11 | 0.12 | 0.8 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 108 | 0.88 | 0.13 | 0.18 | 0.11 | 0.7 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 90 | 0.89 | 0.09 | 0.14 | 0.11 | 0.8 |
| Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens | 30 | 1.01 | 0.06 | 0.06 | 0.14 | 0.9 |

Lot 1467 - Enriched 2.5 $\mu\text{mol/L blood}$

| METHOD | N | Mean | Average Within | | Y- Intercept* | Slope |
|--|-----|------|----------------|----------|---------------|-------|
| | | | Lab SD | Total SD | | |
| Derivatized - MS/MS non-kit | 812 | 2.16 | 0.22 | 0.35 | 0.14 | 0.8 |
| Non-derivatized - MS/MS non-kit | 168 | 2.24 | 0.22 | 0.27 | 0.14 | 0.8 |
| Derivatized - MS/MS PE NeoGram Kit | 127 | 1.94 | 0.23 | 0.29 | 0.13 | 0.7 |
| Non-derivatized - MS/MS PE NeoBase Kit | 627 | 2.05 | 0.14 | 0.24 | 0.12 | 0.8 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 107 | 1.84 | 0.24 | 0.34 | 0.11 | 0.7 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 88 | 1.92 | 0.18 | 0.30 | 0.11 | 0.8 |
| Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens | 30 | 2.31 | 0.14 | 0.15 | 0.14 | 0.9 |

Lot 1468 - Enriched 5.0 $\mu\text{mol/L blood}$

| METHOD | N | Mean | Average Within | | Y- Intercept* | Slope |
|--|-----|------|----------------|----------|---------------|-------|
| | | | Lab SD | Total SD | | |
| Derivatized - MS/MS non-kit | 833 | 4.23 | 0.43 | 0.68 | 0.14 | 0.8 |
| Non-derivatized - MS/MS non-kit | 178 | 4.32 | 0.40 | 0.71 | 0.14 | 0.8 |
| Derivatized - MS/MS PE NeoGram Kit | 127 | 3.78 | 0.45 | 0.52 | 0.13 | 0.7 |
| Non-derivatized - MS/MS PE NeoBase Kit | 629 | 4.05 | 0.30 | 0.48 | 0.12 | 0.8 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 107 | 3.84 | 0.40 | 0.69 | 0.11 | 0.7 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 89 | 3.90 | 0.35 | 0.45 | 0.11 | 0.8 |
| Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens | 28 | 4.43 | 0.20 | 0.22 | 0.14 | 0.9 |

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

2015 Quality Control Data Summaries of Statistical Analyses BUTYRYLCARNITINE (μmol C4/L blood)

Lot 1561 - Nonenriched 0 μmol/L blood

| METHOD | N | Mean | Average Within | | Y- Intercept* | Slope |
|--|-----|------|----------------|----------|---------------|-------|
| | | | Lab SD | Total SD | | |
| Derivatized - MS/MS non-kit | 885 | 0.11 | 0.03 | 0.05 | 0.03 | 1.0 |
| Non-derivatized - MS/MS non-kit | 214 | 0.10 | 0.02 | 0.02 | 0.02 | 1.0 |
| Derivatized - MS/MS PE NeoGram Kit | 90 | 0.12 | 0.04 | 0.05 | 0.04 | 0.8 |
| Non-derivatized - MS/MS PE NeoBase Kit | 670 | 0.10 | 0.02 | 0.03 | 0.03 | 0.9 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 122 | 0.10 | 0.03 | 0.03 | 0.02 | 0.8 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 101 | 0.08 | 0.01 | 0.01 | 0.02 | 0.9 |
| Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens | 40 | 0.09 | 0.01 | 0.02 | 0.03 | 1.0 |

Lot 1562 - Enriched 1.0 μmol/L blood

| METHOD | N | Mean | Average Within | | Y- Intercept* | Slope |
|--|-----|------|----------------|----------|---------------|-------|
| | | | Lab SD | Total SD | | |
| Derivatized - MS/MS non-kit | 884 | 1.00 | 0.12 | 0.18 | 0.03 | 1.0 |
| Non-derivatized - MS/MS non-kit | 227 | 1.00 | 0.10 | 0.16 | 0.02 | 1.0 |
| Derivatized - MS/MS PE NeoGram Kit | 99 | 0.87 | 0.16 | 0.17 | 0.04 | 0.8 |
| Non-derivatized - MS/MS PE NeoBase Kit | 674 | 0.92 | 0.07 | 0.11 | 0.03 | 0.9 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 128 | 0.85 | 0.11 | 0.15 | 0.02 | 0.8 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 104 | 0.87 | 0.06 | 0.08 | 0.02 | 0.9 |
| Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens | 40 | 1.00 | 0.05 | 0.13 | 0.03 | 1.0 |

Lot 1563 - Enriched 3.0 μmol/L blood

| METHOD | N | Mean | Average Within | | Y- Intercept* | Slope |
|--|-----|------|----------------|----------|---------------|-------|
| | | | Lab SD | Total SD | | |
| Derivatized - MS/MS non-kit | 882 | 2.73 | 0.28 | 0.44 | 0.03 | 1.0 |
| Non-derivatized - MS/MS non-kit | 230 | 2.87 | 0.22 | 0.43 | 0.02 | 1.0 |
| Derivatized - MS/MS PE NeoGram Kit | 97 | 2.31 | 0.36 | 0.42 | 0.04 | 0.8 |
| Non-derivatized - MS/MS PE NeoBase Kit | 658 | 2.57 | 0.18 | 0.26 | 0.03 | 0.9 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 130 | 2.41 | 0.25 | 0.41 | 0.02 | 0.8 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 105 | 2.44 | 0.17 | 0.23 | 0.02 | 0.9 |
| Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens | 40 | 2.81 | 0.16 | 0.31 | 0.03 | 1.0 |

Lot 1564 - Enriched 5.0 μmol/L blood

| METHOD | N | Mean | Average Within | | Y- Intercept* | Slope |
|--|-----|------|----------------|----------|---------------|-------|
| | | | Lab SD | Total SD | | |
| Derivatized - MS/MS non-kit | 906 | 4.98 | 0.48 | 0.83 | 0.03 | 1.0 |
| Non-derivatized - MS/MS non-kit | 230 | 5.10 | 0.42 | 0.73 | 0.02 | 1.0 |
| Derivatized - MS/MS PE NeoGram Kit | 100 | 4.25 | 0.67 | 0.83 | 0.04 | 0.8 |
| Non-derivatized - MS/MS PE NeoBase Kit | 670 | 4.62 | 0.30 | 0.50 | 0.03 | 0.9 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 129 | 4.33 | 0.42 | 0.71 | 0.02 | 0.8 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 108 | 4.40 | 0.32 | 0.40 | 0.02 | 0.9 |
| Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens | 40 | 5.00 | 0.27 | 0.58 | 0.03 | 1.0 |

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

**Table 17v. 2015 Quality Control Data Summaries of Statistical Analyses
HYDROXYBUTYRYLCARNITINE ($\mu\text{mol C40H/L blood}$)**

Lot 1465 - Nonenriched 0 $\mu\text{mol/L blood}$

| METHOD | N | Mean | Average Within Lab SD | Total SD | Y- Intercept* | Slope |
|--|-----|------|-----------------------------|----------|---------------|-------|
| Derivatized - MS/MS non-kit | 691 | 0.08 | 0.02 | 0.03 | 0.08 | 0.7 |
| Derivatized - MS/MS PE NeoGram Kit | 106 | 0.10 | 0.03 | 0.05 | 0.11 | 0.7 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 67 | 0.06 | 0.02 | 0.03 | 0.06 | 0.7 |

Lot 1466 - Enriched 0.5 $\mu\text{mol/L blood}$

| METHOD | N | Mean | Average Within Lab SD | Total SD | Y- Intercept* | Slope |
|--|-----|------|-----------------------------|----------|---------------|-------|
| Derivatized - MS/MS non-kit | 703 | 0.41 | 0.06 | 0.11 | 0.08 | 0.7 |
| Derivatized - MS/MS PE NeoGram Kit | 109 | 0.47 | 0.08 | 0.19 | 0.11 | 0.7 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 70 | 0.40 | 0.05 | 0.08 | 0.06 | 0.7 |

Lot 1467 - Enriched 1.0 $\mu\text{mol/L blood}$

| METHOD | N | Mean | Average Within Lab SD | Total SD | Y- Intercept* | Slope |
|--|-----|------|-----------------------------|----------|---------------|-------|
| Derivatized - MS/MS non-kit | 703 | 0.74 | 0.10 | 0.19 | 0.08 | 0.7 |
| Derivatized - MS/MS PE NeoGram Kit | 106 | 0.85 | 0.14 | 0.38 | 0.11 | 0.7 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 70 | 0.70 | 0.09 | 0.14 | 0.06 | 0.7 |

Lot 1468 - Enriched 2.5 $\mu\text{mol/L blood}$

| METHOD | N | Mean | Average Within Lab SD | Total SD | Y- Intercept* | Slope |
|--|-----|------|-----------------------------|----------|---------------|-------|
| Derivatized - MS/MS non-kit | 714 | 1.75 | 0.21 | 0.42 | 0.08 | 0.7 |
| Derivatized - MS/MS PE NeoGram Kit | 107 | 1.93 | 0.25 | 0.77 | 0.11 | 0.7 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 68 | 1.69 | 0.19 | 0.36 | 0.06 | 0.7 |

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

2015 Quality Control Data Summaries of Statistical Analyses
HYDROXYBUTYRYLCARNITINE (μmol C40H/L blood)

Lot 1561 - Nonenriched 0 μmol/L blood

| METHOD | N | Mean | Average Within Lab SD | Total SD | Y- Intercept* | Slope |
|--|-----|------|-----------------------------|----------|---------------|-------|
| Derivatized - MS/MS non-kit | 757 | 0.08 | 0.02 | 0.03 | 0.07 | 0.7 |
| Derivatized - MS/MS PE NeoGram Kit | 94 | 0.08 | 0.03 | 0.05 | 0.06 | 0.8 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 96 | 0.06 | 0.02 | 0.02 | 0.05 | 0.7 |

Lot 1562 - Enriched 0.5 μmol/L blood

| METHOD | N | Mean | Average Within Lab SD | Total SD | Y- Intercept* | Slope |
|--|-----|------|-----------------------------|----------|---------------|-------|
| Derivatized - MS/MS non-kit | 758 | 0.44 | 0.07 | 0.12 | 0.07 | 0.7 |
| Derivatized - MS/MS PE NeoGram Kit | 99 | 0.45 | 0.09 | 0.14 | 0.06 | 0.8 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 96 | 0.36 | 0.05 | 0.08 | 0.05 | 0.7 |

Lot 1563 - Enriched 1.0 μmol/L blood

| METHOD | N | Mean | Average Within Lab SD | Total SD | Y- Intercept* | Slope |
|--|-----|------|-----------------------------|----------|---------------|-------|
| Derivatized - MS/MS non-kit | 756 | 0.81 | 0.11 | 0.21 | 0.07 | 0.7 |
| Derivatized - MS/MS PE NeoGram Kit | 100 | 0.83 | 0.14 | 0.27 | 0.06 | 0.8 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 98 | 0.72 | 0.10 | 0.15 | 0.05 | 0.7 |

Lot 1564 - Enriched 2.5 μmol/L blood

| METHOD | N | Mean | Average Within Lab SD | Total SD | Y- Intercept* | Slope |
|--|-----|------|-----------------------------|----------|---------------|-------|
| Derivatized - MS/MS non-kit | 754 | 1.92 | 0.23 | 0.48 | 0.07 | 0.7 |
| Derivatized - MS/MS PE NeoGram Kit | 99 | 2.02 | 0.35 | 0.67 | 0.06 | 0.8 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 95 | 1.70 | 0.17 | 0.31 | 0.05 | 0.7 |

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

**Table 17w. 2015 Quality Control Data Summaries of Statistical Analyses
ISOVALERYLCARNITINE ($\mu\text{mol C5/L blood}$)**

Lot 1465 - Nonenriched 0 $\mu\text{mol/L blood}$

| METHOD | N | Mean | Average Within | | Y- Intercept* | Slope |
|--|-----|------|----------------|----------|---------------|-------|
| | | | Lab SD | Total SD | | |
| Derivatized - MS/MS non-kit | 846 | 0.09 | 0.02 | 0.03 | 0.10 | 0.8 |
| Non-derivatized - MS/MS non-kit | 232 | 0.08 | 0.01 | 0.02 | 0.09 | 0.9 |
| Derivatized - MS/MS PE NeoGram Kit | 127 | 0.08 | 0.02 | 0.03 | 0.08 | 0.8 |
| Non-derivatized - MS/MS PE NeoBase Kit | 638 | 0.07 | 0.01 | 0.01 | 0.08 | 0.8 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 113 | 0.10 | 0.03 | 0.05 | 0.10 | 0.9 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 86 | 0.07 | 0.01 | 0.03 | 0.07 | 0.8 |
| Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens | 58 | 0.08 | 0.01 | 0.02 | 0.09 | 0.9 |

Lot 1466 - Enriched 0.5 $\mu\text{mol/L blood}$

| METHOD | N | Mean | Average Within | | Y- Intercept* | Slope |
|--|-----|------|----------------|----------|---------------|-------|
| | | | Lab SD | Total SD | | |
| Derivatized - MS/MS non-kit | 848 | 0.53 | 0.06 | 0.10 | 0.10 | 0.8 |
| Non-derivatized - MS/MS non-kit | 246 | 0.56 | 0.05 | 0.07 | 0.09 | 0.9 |
| Derivatized - MS/MS PE NeoGram Kit | 126 | 0.49 | 0.07 | 0.08 | 0.08 | 0.8 |
| Non-derivatized - MS/MS PE NeoBase Kit | 635 | 0.52 | 0.04 | 0.07 | 0.08 | 0.8 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 118 | 0.56 | 0.07 | 0.12 | 0.10 | 0.9 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 90 | 0.50 | 0.05 | 0.10 | 0.07 | 0.8 |
| Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens | 60 | 0.58 | 0.04 | 0.05 | 0.09 | 0.9 |

Lot 1467 - Enriched 1.5 $\mu\text{mol/L blood}$

| METHOD | N | Mean | Average Within | | Y- Intercept* | Slope |
|--|-----|------|----------------|----------|---------------|-------|
| | | | Lab SD | Total SD | | |
| Derivatized - MS/MS non-kit | 846 | 1.32 | 0.14 | 0.23 | 0.10 | 0.8 |
| Non-derivatized - MS/MS non-kit | 243 | 1.40 | 0.11 | 0.17 | 0.09 | 0.9 |
| Derivatized - MS/MS PE NeoGram Kit | 127 | 1.23 | 0.15 | 0.19 | 0.08 | 0.8 |
| Non-derivatized - MS/MS PE NeoBase Kit | 638 | 1.31 | 0.09 | 0.16 | 0.08 | 0.8 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 115 | 1.35 | 0.18 | 0.24 | 0.10 | 0.9 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 89 | 1.19 | 0.11 | 0.22 | 0.07 | 0.8 |
| Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens | 60 | 1.46 | 0.07 | 0.10 | 0.09 | 0.9 |

Lot 1466 - Enriched 3.0 $\mu\text{mol/L blood}$

| METHOD | N | Mean | Average Within | | Y- Intercept* | Slope |
|--|-----|------|----------------|----------|---------------|-------|
| | | | Lab SD | Total SD | | |
| Derivatized - MS/MS non-kit | 851 | 2.59 | 0.25 | 0.42 | 0.10 | 0.8 |
| Non-derivatized - MS/MS non-kit | 245 | 2.77 | 0.20 | 0.31 | 0.09 | 0.9 |
| Derivatized - MS/MS PE NeoGram Kit | 128 | 2.47 | 0.25 | 0.36 | 0.08 | 0.8 |
| Non-derivatized - MS/MS PE NeoBase Kit | 638 | 2.59 | 0.18 | 0.31 | 0.08 | 0.8 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 119 | 2.71 | 0.31 | 0.44 | 0.10 | 0.9 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 90 | 2.44 | 0.19 | 0.44 | 0.07 | 0.8 |
| Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens | 58 | 2.88 | 0.15 | 0.22 | 0.09 | 0.9 |

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

2015 Quality Control Data Summaries of Statistical Analyses ISOVALERYLCARNITINE (µmol C5/L blood)

Lot 1561 - Nonenriched 0 µmol/L blood

| METHOD | N | Mean | Average Within | | Total SD | Y- Intercept* | Slope |
|--|-----|------|----------------|--|----------|---------------|-------|
| | | | Lab SD | | | | |
| Derivatized - MS/MS non-kit | 913 | 0.07 | 0.02 | | 0.03 | 0.07 | 0.9 |
| Non-derivatized - MS/MS non-kit | 289 | 0.06 | 0.01 | | 0.02 | 0.06 | 0.9 |
| Derivatized - MS/MS PE NeoGram Kit | 107 | 0.07 | 0.02 | | 0.02 | 0.07 | 0.8 |
| Non-derivatized - MS/MS PE NeoBase Kit | 685 | 0.06 | 0.01 | | 0.02 | 0.06 | 0.8 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 126 | 0.07 | 0.02 | | 0.03 | 0.06 | 0.9 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 113 | 0.06 | 0.01 | | 0.01 | 0.06 | 0.9 |
| Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens | 48 | 0.06 | 0.01 | | 0.01 | 0.06 | 1.0 |

Lot 1562 - Enriched 0.5 µmol/L blood

| METHOD | N | Mean | Average Within | | Total SD | Y- Intercept* | Slope |
|--|-----|------|----------------|--|----------|---------------|-------|
| | | | Lab SD | | | | |
| Derivatized - MS/MS non-kit | 906 | 0.52 | 0.07 | | 0.10 | 0.07 | 0.9 |
| Non-derivatized - MS/MS non-kit | 297 | 0.52 | 0.05 | | 0.09 | 0.06 | 0.9 |
| Derivatized - MS/MS PE NeoGram Kit | 105 | 0.45 | 0.07 | | 0.08 | 0.07 | 0.8 |
| Non-derivatized - MS/MS PE NeoBase Kit | 687 | 0.48 | 0.04 | | 0.06 | 0.06 | 0.8 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 123 | 0.51 | 0.08 | | 0.10 | 0.06 | 0.9 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 117 | 0.49 | 0.05 | | 0.07 | 0.06 | 0.9 |
| Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens | 48 | 0.54 | 0.02 | | 0.04 | 0.06 | 1.0 |

Lot 1563 - Enriched 1.5 µmol/L blood

| METHOD | N | Mean | Average Within | | Total SD | Y- Intercept* | Slope |
|--|-----|------|----------------|--|----------|---------------|-------|
| | | | Lab SD | | | | |
| Derivatized - MS/MS non-kit | 904 | 1.36 | 0.15 | | 0.24 | 0.07 | 0.9 |
| Non-derivatized - MS/MS non-kit | 288 | 1.47 | 0.12 | | 0.23 | 0.06 | 0.9 |
| Derivatized - MS/MS PE NeoGram Kit | 110 | 1.23 | 0.17 | | 0.23 | 0.07 | 0.8 |
| Non-derivatized - MS/MS PE NeoBase Kit | 686 | 1.31 | 0.10 | | 0.17 | 0.06 | 0.8 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 127 | 1.35 | 0.14 | | 0.19 | 0.06 | 0.9 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 117 | 1.34 | 0.09 | | 0.23 | 0.06 | 0.9 |
| Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens | 48 | 1.47 | 0.06 | | 0.10 | 0.06 | 1.0 |

Lot 1564 - Enriched 3.0 µmol/L blood

| METHOD | N | Mean | Average Within | | Total SD | Y- Intercept* | Slope |
|--|-----|------|----------------|--|----------|---------------|-------|
| | | | Lab SD | | | | |
| Derivatized - MS/MS non-kit | 911 | 2.67 | 0.27 | | 0.46 | 0.07 | 0.9 |
| Non-derivatized - MS/MS non-kit | 285 | 2.84 | 0.20 | | 0.42 | 0.06 | 0.9 |
| Derivatized - MS/MS PE NeoGram Kit | 107 | 2.38 | 0.37 | | 0.42 | 0.07 | 0.8 |
| Non-derivatized - MS/MS PE NeoBase Kit | 689 | 2.57 | 0.17 | | 0.28 | 0.06 | 0.8 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 128 | 2.72 | 0.31 | | 0.49 | 0.06 | 0.9 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 117 | 2.64 | 0.17 | | 0.40 | 0.06 | 0.9 |
| Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens | 50 | 2.91 | 0.18 | | 0.28 | 0.06 | 1.0 |

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

Table 17x. 2015 Quality Control Data Summaries of Statistical Analyses
GLUTARYLCARNITINE ($\mu\text{mol C5DC/L blood}$)

Lot 1465 - Nonenriched 0 $\mu\text{mol/L}$ blood

| METHOD | N | Mean | Average Within | | Y- Intercept* | Slope |
|--|-----|------|----------------|----------|---------------|-------|
| | | | Lab SD | Total SD | | |
| Derivatized - MS/MS non-kit | 843 | 0.02 | 0.01 | 0.02 | 0.03 | 0.7 |
| Non-derivatized - MS/MS non-kit | 229 | 0.04 | 0.01 | 0.02 | 0.07 | 1.0 |
| Derivatized - MS/MS PE NeoGram Kit | 117 | 0.03 | 0.01 | 0.01 | 0.04 | 1.0 |
| Non-derivatized - MS/MS PE NeoBase Kit | 562 | 0.05 | 0.01 | 0.02 | 0.07 | 1.0 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 101 | 0.04 | 0.02 | 0.05 | 0.02 | 1.3 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 83 | 0.06 | 0.03 | 0.04 | 0.08 | 1.3 |
| Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens | 56 | 0.07 | 0.01 | 0.01 | 0.08 | 1.1 |

Lot 1466 - Enriched 0.5 $\mu\text{mol/L}$ blood

| METHOD | N | Mean | Average Within | | Y- Intercept* | Slope |
|--|-----|------|----------------|----------|---------------|-------|
| | | | Lab SD | Total SD | | |
| Derivatized - MS/MS non-kit | 840 | 0.36 | 0.07 | 0.15 | 0.03 | 0.7 |
| Non-derivatized - MS/MS non-kit | 240 | 0.55 | 0.06 | 0.16 | 0.07 | 1.0 |
| Derivatized - MS/MS PE NeoGram Kit | 120 | 0.52 | 0.05 | 0.06 | 0.04 | 1.0 |
| Non-derivatized - MS/MS PE NeoBase Kit | 569 | 0.57 | 0.05 | 0.07 | 0.07 | 1.0 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 107 | 0.65 | 0.13 | 0.27 | 0.02 | 1.3 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 90 | 0.71 | 0.09 | 0.21 | 0.08 | 1.3 |
| Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens | 59 | 0.62 | 0.05 | 0.05 | 0.08 | 1.1 |

Lot 1467 - Enriched 1.0 $\mu\text{mol/L}$ blood

| METHOD | N | Mean | Average Within | | Y- Intercept* | Slope |
|--|-----|------|----------------|----------|---------------|-------|
| | | | Lab SD | Total SD | | |
| Derivatized - MS/MS non-kit | 840 | 0.70 | 0.12 | 0.31 | 0.03 | 0.7 |
| Non-derivatized - MS/MS non-kit | 236 | 1.05 | 0.11 | 0.31 | 0.07 | 1.0 |
| Derivatized - MS/MS PE NeoGram Kit | 123 | 1.04 | 0.09 | 0.14 | 0.04 | 1.0 |
| Non-derivatized - MS/MS PE NeoBase Kit | 585 | 1.10 | 0.09 | 0.15 | 0.07 | 1.0 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 109 | 1.25 | 0.28 | 0.53 | 0.02 | 1.3 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 89 | 1.36 | 0.25 | 0.46 | 0.08 | 1.3 |
| Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens | 60 | 1.16 | 0.07 | 0.08 | 0.08 | 1.1 |

Lot 1468 - Enriched 2.5 $\mu\text{mol/L}$ blood

| METHOD | N | Mean | Average Within | | Y- Intercept* | Slope |
|--|-----|------|----------------|----------|---------------|-------|
| | | | Lab SD | Total SD | | |
| Derivatized - MS/MS non-kit | 840 | 1.65 | 0.25 | 0.72 | 0.03 | 0.7 |
| Non-derivatized - MS/MS non-kit | 236 | 2.45 | 0.23 | 0.72 | 0.07 | 1.0 |
| Derivatized - MS/MS PE NeoGram Kit | 124 | 2.48 | 0.20 | 0.26 | 0.04 | 1.0 |
| Non-derivatized - MS/MS PE NeoBase Kit | 590 | 2.58 | 0.21 | 0.34 | 0.07 | 1.0 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 109 | 3.16 | 0.44 | 1.34 | 0.02 | 1.3 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 88 | 3.21 | 0.44 | 1.06 | 0.08 | 1.3 |
| Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens | 60 | 2.74 | 0.19 | 0.20 | 0.08 | 1.1 |

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

2015 Quality Control Data Summaries of Statistical Analyses GLUTARYLCARNITINE (µmol C5DC/L blood)

Lot 1561 - Nonenriched 0 µmol/L blood

| METHOD | N | Mean | Average Within | | Y- Intercept* | Slope |
|--|-----|------|----------------|----------|---------------|-------|
| | | | Lab SD | Total SD | | |
| Derivatized - MS/MS non-kit | 881 | 0.02 | 0.01 | 0.02 | 0.02 | 0.6 |
| Non-derivatized - MS/MS non-kit | 286 | 0.04 | 0.01 | 0.03 | 0.05 | 0.9 |
| Derivatized - MS/MS PE NeoGram Kit | 102 | 0.03 | 0.01 | 0.02 | 0.02 | 1.1 |
| Non-derivatized - MS/MS PE NeoBase Kit | 632 | 0.05 | 0.01 | 0.02 | 0.04 | 1.0 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 125 | 0.04 | 0.02 | 0.03 | 0.06 | 1.4 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 112 | 0.07 | 0.03 | 0.05 | 0.07 | 1.6 |
| Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens | 49 | 0.06 | 0.01 | 0.01 | 0.06 | 1.2 |

Lot 1562 - Enriched 0.5 µmol/L blood

| METHOD | N | Mean | Average Within | | Y- Intercept* | Slope |
|--|-----|------|----------------|----------|---------------|-------|
| | | | Lab SD | Total SD | | |
| Derivatized - MS/MS non-kit | 883 | 0.34 | 0.06 | 0.14 | 0.02 | 0.6 |
| Non-derivatized - MS/MS non-kit | 281 | 0.54 | 0.07 | 0.18 | 0.05 | 0.9 |
| Derivatized - MS/MS PE NeoGram Kit | 105 | 0.56 | 0.07 | 0.09 | 0.02 | 1.1 |
| Non-derivatized - MS/MS PE NeoBase Kit | 628 | 0.56 | 0.05 | 0.09 | 0.04 | 1.0 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 128 | 0.75 | 0.18 | 0.28 | 0.06 | 1.4 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 116 | 0.91 | 0.15 | 0.30 | 0.07 | 1.6 |
| Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens | 49 | 0.64 | 0.04 | 0.05 | 0.06 | 1.2 |

Lot 1563 - Enriched 1.0 µmol/L blood

| METHOD | N | Mean | Average Within | | Y- Intercept* | Slope |
|--|-----|------|----------------|----------|---------------|-------|
| | | | Lab SD | Total SD | | |
| Derivatized - MS/MS non-kit | 882 | 0.63 | 0.09 | 0.26 | 0.02 | 0.6 |
| Non-derivatized - MS/MS non-kit | 278 | 0.97 | 0.11 | 0.35 | 0.05 | 0.9 |
| Derivatized - MS/MS PE NeoGram Kit | 107 | 1.05 | 0.11 | 0.14 | 0.02 | 1.1 |
| Non-derivatized - MS/MS PE NeoBase Kit | 645 | 1.05 | 0.09 | 0.18 | 0.04 | 1.0 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 129 | 1.41 | 0.22 | 0.47 | 0.06 | 1.4 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 113 | 1.63 | 0.21 | 0.47 | 0.07 | 1.6 |
| Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens | 47 | 1.20 | 0.07 | 0.09 | 0.06 | 1.2 |

Lot 1564 - Enriched 2.5 µmol/L blood

| METHOD | N | Mean | Average Within | | Y- Intercept* | Slope |
|--|-----|------|----------------|----------|---------------|-------|
| | | | Lab SD | Total SD | | |
| Derivatized - MS/MS non-kit | 875 | 1.59 | 0.21 | 0.63 | 0.02 | 0.6 |
| Non-derivatized - MS/MS non-kit | 277 | 2.40 | 0.24 | 0.86 | 0.05 | 0.9 |
| Derivatized - MS/MS PE NeoGram Kit | 105 | 2.64 | 0.30 | 0.39 | 0.02 | 1.1 |
| Non-derivatized - MS/MS PE NeoBase Kit | 649 | 2.65 | 0.21 | 0.43 | 0.04 | 1.0 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 128 | 3.43 | 0.47 | 1.10 | 0.06 | 1.4 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 114 | 4.10 | 0.37 | 1.22 | 0.07 | 1.6 |
| Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens | 50 | 2.94 | 0.19 | 0.32 | 0.06 | 1.2 |

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

**Table 17y. 2015 Quality Control Data Summaries of Statistical Analyses
HYDROXYISOVALERYLCARNITINE (µmol C5OH/L blood)**

Lot 1465 - Nonenriched 0 µmol/L blood

| METHOD | N | Mean | Average Within | | Y- Intercept* | Slope |
|--|-----|------|----------------|----------|---------------|-------|
| | | | Lab SD | Total SD | | |
| Derivatized - MS/MS non-kit | 833 | 0.39 | 0.06 | 0.10 | 0.39 | 0.8 |
| Non-derivatized - MS/MS non-kit | 199 | 0.55 | 0.05 | 0.10 | 0.56 | 0.8 |
| Derivatized - MS/MS PE NeoGram Kit | 125 | 0.36 | 0.07 | 0.08 | 0.36 | 0.7 |
| Non-derivatized - MS/MS PE NeoBase Kit | 522 | 0.43 | 0.04 | 0.08 | 0.43 | 0.5 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 98 | 0.42 | 0.08 | 0.12 | 0.42 | 0.7 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 57 | 0.31 | 0.05 | 0.07 | 0.33 | 0.4 |
| Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens | 59 | 0.66 | 0.05 | 0.09 | 0.63 | 1.0 |

Lot 1466 - Enriched 0.5 µmol/L blood

| METHOD | N | Mean | Average Within | | Y- Intercept* | Slope |
|--|-----|------|----------------|----------|---------------|-------|
| | | | Lab SD | Total SD | | |
| Derivatized - MS/MS non-kit | 819 | 0.77 | 0.09 | 0.16 | 0.39 | 0.8 |
| Non-derivatized - MS/MS non-kit | 199 | 0.97 | 0.08 | 0.19 | 0.56 | 0.8 |
| Derivatized - MS/MS PE NeoGram Kit | 129 | 0.70 | 0.10 | 0.14 | 0.36 | 0.7 |
| Non-derivatized - MS/MS PE NeoBase Kit | 524 | 0.70 | 0.05 | 0.13 | 0.43 | 0.5 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 96 | 0.77 | 0.12 | 0.16 | 0.42 | 0.7 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 60 | 0.56 | 0.07 | 0.13 | 0.33 | 0.4 |
| Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens | 55 | 1.11 | 0.06 | 0.12 | 0.63 | 1.0 |

Lot 1467 - Enriched 1.5 µmol/L blood

| METHOD | N | Mean | Average Within | | Y- Intercept* | Slope |
|--|-----|------|----------------|----------|---------------|-------|
| | | | Lab SD | Total SD | | |
| Derivatized - MS/MS non-kit | 822 | 1.53 | 0.18 | 0.33 | 0.39 | 0.8 |
| Non-derivatized - MS/MS non-kit | 198 | 1.74 | 0.15 | 0.34 | 0.56 | 0.8 |
| Derivatized - MS/MS PE NeoGram Kit | 125 | 1.35 | 0.18 | 0.25 | 0.36 | 0.7 |
| Non-derivatized - MS/MS PE NeoBase Kit | 522 | 1.21 | 0.09 | 0.22 | 0.43 | 0.5 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 99 | 1.49 | 0.21 | 0.31 | 0.42 | 0.7 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 58 | 0.98 | 0.09 | 0.26 | 0.33 | 0.4 |
| Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens | 57 | 2.08 | 0.12 | 0.27 | 0.63 | 1.0 |

Lot 1468 - Enriched 2.5 µmol/L blood

| METHOD | N | Mean | Average Within | | Y- Intercept* | Slope |
|--|-----|------|----------------|----------|---------------|-------|
| | | | Lab SD | Total SD | | |
| Derivatized - MS/MS non-kit | 816 | 2.28 | 0.23 | 0.47 | 0.39 | 0.8 |
| Non-derivatized - MS/MS non-kit | 198 | 2.54 | 0.20 | 0.51 | 0.56 | 0.8 |
| Derivatized - MS/MS PE NeoGram Kit | 128 | 2.07 | 0.25 | 0.36 | 0.36 | 0.7 |
| Non-derivatized - MS/MS PE NeoBase Kit | 526 | 1.75 | 0.13 | 0.32 | 0.43 | 0.5 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 99 | 2.17 | 0.26 | 0.48 | 0.42 | 0.7 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 56 | 1.36 | 0.16 | 0.26 | 0.33 | 0.4 |
| Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens | 58 | 3.11 | 0.14 | 0.37 | 0.63 | 1.0 |

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

2015 Quality Control Data Summaries of Statistical Analyses
HYDROXYISOVALERYLCARNITINE (µmol C50H/L blood)

Lot 1561 - Nonenriched 0 µmol/L blood

| METHOD | N | Mean | Average Within | | Y- Intercept* | Slope |
|--|-----|------|----------------|----------|---------------|-------|
| | | | Lab SD | Total SD | | |
| Derivatized - MS/MS non-kit | 909 | 0.48 | 0.07 | 0.12 | 0.45 | 0.9 |
| Non-derivatized - MS/MS non-kit | 239 | 0.66 | 0.08 | 0.16 | 0.64 | 0.9 |
| Derivatized - MS/MS PE NeoGram Kit | 109 | 0.44 | 0.07 | 0.09 | 0.42 | 0.8 |
| Non-derivatized - MS/MS PE NeoBase Kit | 525 | 0.50 | 0.05 | 0.10 | 0.49 | 0.6 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 138 | 0.44 | 0.06 | 0.12 | 0.44 | 0.7 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 80 | 0.44 | 0.10 | 0.18 | 0.40 | 0.7 |
| Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens | 50 | 0.73 | 0.04 | 0.06 | 0.70 | 1.1 |

Lot 1562 - Enriched 1.0 µmol/L blood

| METHOD | N | Mean | Average Within | | Y- Intercept* | Slope |
|--|-----|------|----------------|----------|---------------|-------|
| | | | Lab SD | Total SD | | |
| Derivatized - MS/MS non-kit | 890 | 1.30 | 0.16 | 0.26 | 0.45 | 0.9 |
| Non-derivatized - MS/MS non-kit | 240 | 1.51 | 0.13 | 0.36 | 0.64 | 0.9 |
| Derivatized - MS/MS PE NeoGram Kit | 108 | 1.20 | 0.14 | 0.21 | 0.42 | 0.8 |
| Non-derivatized - MS/MS PE NeoBase Kit | 522 | 1.08 | 0.08 | 0.22 | 0.49 | 0.6 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 139 | 1.18 | 0.14 | 0.32 | 0.44 | 0.7 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 80 | 1.04 | 0.18 | 0.40 | 0.40 | 0.7 |
| Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens | 50 | 1.75 | 0.10 | 0.15 | 0.70 | 1.1 |

Lot 1563 - Enriched 2.0 µmol/L blood

| METHOD | N | Mean | Average Within | | Y- Intercept* | Slope |
|--|-----|------|----------------|----------|---------------|-------|
| | | | Lab SD | Total SD | | |
| Derivatized - MS/MS non-kit | 893 | 2.12 | 0.23 | 0.41 | 0.45 | 0.9 |
| Non-derivatized - MS/MS non-kit | 236 | 2.44 | 0.23 | 0.56 | 0.64 | 0.9 |
| Derivatized - MS/MS PE NeoGram Kit | 108 | 1.92 | 0.24 | 0.34 | 0.42 | 0.8 |
| Non-derivatized - MS/MS PE NeoBase Kit | 523 | 1.67 | 0.12 | 0.35 | 0.49 | 0.6 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 139 | 1.90 | 0.23 | 0.49 | 0.44 | 0.7 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 80 | 1.67 | 0.10 | 0.52 | 0.40 | 0.7 |
| Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens | 50 | 2.80 | 0.14 | 0.23 | 0.70 | 1.1 |

Lot 1564 - Enriched 3.0 µmol/L blood

| METHOD | N | Mean | Average Within | | Y- Intercept* | Slope |
|--|-----|------|----------------|----------|---------------|-------|
| | | | Lab SD | Total SD | | |
| Derivatized - MS/MS non-kit | 900 | 3.09 | 0.34 | 0.66 | 0.45 | 0.9 |
| Non-derivatized - MS/MS non-kit | 240 | 3.36 | 0.28 | 0.81 | 0.64 | 0.9 |
| Derivatized - MS/MS PE NeoGram Kit | 109 | 2.80 | 0.39 | 0.48 | 0.42 | 0.8 |
| Non-derivatized - MS/MS PE NeoBase Kit | 519 | 2.30 | 0.14 | 0.45 | 0.49 | 0.6 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 137 | 2.66 | 0.32 | 0.77 | 0.44 | 0.7 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 79 | 2.42 | 0.21 | 0.79 | 0.40 | 0.7 |
| Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens | 50 | 3.95 | 0.23 | 0.35 | 0.70 | 1.1 |

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

**Table 17z. 2015 Quality Control Data Summaries of Statistical Analyses
HEXANOYLCARNITINE ($\mu\text{mol C6/L blood}$)**

Lot 1465 - Nonenriched 0 $\mu\text{mol/L blood}$

| METHOD | N | Mean | Average Within | | Y- Intercept* | Slope |
|--|-----|------|----------------|----------|---------------|-------|
| | | | Lab SD | Total SD | | |
| Derivatized - MS/MS non-kit | 846 | 0.03 | 0.01 | 0.03 | 0.04 | 0.8 |
| Non-derivatized - MS/MS non-kit | 198 | 0.02 | 0.01 | 0.01 | 0.02 | 0.8 |
| Derivatized - MS/MS PE NeoGram Kit | 120 | 0.03 | 0.02 | 0.02 | 0.07 | 0.6 |
| Non-derivatized - MS/MS PE NeoBase Kit | 631 | 0.02 | 0.01 | 0.01 | 0.03 | 0.8 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 103 | 0.06 | 0.03 | 0.05 | 0.09 | 0.7 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 84 | 0.02 | 0.01 | 0.01 | 0.04 | 0.8 |
| Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens | 30 | 0.01 | 0.00 | 0.00 | 0.01 | 0.7 |

Lot 1466 - Enriched 0.5 $\mu\text{mol/L blood}$

| METHOD | N | Mean | Average Within | | Y- Intercept* | Slope |
|--|-----|------|----------------|----------|---------------|-------|
| | | | Lab SD | Total SD | | |
| Derivatized - MS/MS non-kit | 837 | 0.43 | 0.06 | 0.09 | 0.04 | 0.8 |
| Non-derivatized - MS/MS non-kit | 196 | 0.44 | 0.05 | 0.09 | 0.02 | 0.8 |
| Derivatized - MS/MS PE NeoGram Kit | 128 | 0.42 | 0.06 | 0.08 | 0.07 | 0.6 |
| Non-derivatized - MS/MS PE NeoBase Kit | 659 | 0.42 | 0.03 | 0.05 | 0.03 | 0.8 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 108 | 0.46 | 0.07 | 0.08 | 0.09 | 0.7 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 89 | 0.46 | 0.05 | 0.07 | 0.04 | 0.8 |
| Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens | 30 | 0.36 | 0.02 | 0.04 | 0.01 | 0.7 |

Lot 1467 - Enriched 1.0 $\mu\text{mol/L blood}$

| METHOD | N | Mean | Average Within | | Y- Intercept* | Slope |
|--|-----|------|----------------|----------|---------------|-------|
| | | | Lab SD | Total SD | | |
| Derivatized - MS/MS non-kit | 837 | 0.79 | 0.10 | 0.17 | 0.04 | 0.8 |
| Non-derivatized - MS/MS non-kit | 196 | 0.84 | 0.09 | 0.18 | 0.02 | 0.8 |
| Derivatized - MS/MS PE NeoGram Kit | 129 | 0.68 | 0.09 | 0.10 | 0.07 | 0.6 |
| Non-derivatized - MS/MS PE NeoBase Kit | 649 | 0.80 | 0.06 | 0.09 | 0.03 | 0.8 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 107 | 0.77 | 0.11 | 0.12 | 0.09 | 0.7 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 90 | 0.82 | 0.07 | 0.13 | 0.04 | 0.8 |
| Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens | 30 | 0.69 | 0.04 | 0.10 | 0.01 | 0.7 |

Lot 1468 - Enriched 2.5 $\mu\text{mol/L blood}$

| METHOD | N | Mean | Average Within | | Y- Intercept* | Slope |
|--|-----|------|----------------|----------|---------------|-------|
| | | | Lab SD | Total SD | | |
| Derivatized - MS/MS non-kit | 839 | 1.93 | 0.19 | 0.36 | 0.04 | 0.8 |
| Non-derivatized - MS/MS non-kit | 189 | 2.05 | 0.23 | 0.43 | 0.02 | 0.8 |
| Derivatized - MS/MS PE NeoGram Kit | 129 | 1.56 | 0.16 | 0.21 | 0.07 | 0.6 |
| Non-derivatized - MS/MS PE NeoBase Kit | 652 | 1.96 | 0.15 | 0.23 | 0.03 | 0.8 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 107 | 1.75 | 0.20 | 0.23 | 0.09 | 0.7 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 89 | 2.01 | 0.14 | 0.22 | 0.04 | 0.8 |
| Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens | 30 | 1.73 | 0.12 | 0.23 | 0.01 | 0.7 |

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

2015 Quality Control Data Summaries of Statistical Analyses HEXANOYL CARNITINE ($\mu\text{mol C6/L blood}$)

Lot 1561 - Nonenriched 0 $\mu\text{mol/L}$ whole blood

| METHOD | N | Mean | Average Within | | Total SD | Y- Intercept* | Slope |
|--|-----|------|----------------|--|----------|---------------|-------|
| | | | Lab SD | | | | |
| Derivatized - MS/MS non-kit | 881 | 0.03 | 0.01 | | 0.02 | 0.04 | 0.8 |
| Non-derivatized - MS/MS non-kit | 228 | 0.01 | 0.00 | | 0.01 | 0.02 | 0.9 |
| Derivatized - MS/MS PE NeoGram Kit | 101 | 0.03 | 0.02 | | 0.02 | 0.08 | 0.6 |
| Non-derivatized - MS/MS PE NeoBase Kit | 692 | 0.01 | 0.01 | | 0.01 | 0.03 | 0.8 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 128 | 0.04 | 0.01 | | 0.02 | 0.09 | 0.6 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 102 | 0.01 | 0.01 | | 0.01 | 0.02 | 0.9 |
| Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens | 37 | 0.01 | 0.00 | | 0.00 | 0.03 | 0.8 |

Lot 1562 - Enriched 0.5 $\mu\text{mol/L}$ blood

| METHOD | N | Mean | Average Within | | Total SD | Y- Intercept* | Slope |
|--|-----|------|----------------|--|----------|---------------|-------|
| | | | Lab SD | | | | |
| Derivatized - MS/MS non-kit | 901 | 0.48 | 0.06 | | 0.11 | 0.04 | 0.8 |
| Non-derivatized - MS/MS non-kit | 236 | 0.47 | 0.05 | | 0.09 | 0.02 | 0.9 |
| Derivatized - MS/MS PE NeoGram Kit | 106 | 0.41 | 0.07 | | 0.08 | 0.08 | 0.6 |
| Non-derivatized - MS/MS PE NeoBase Kit | 716 | 0.46 | 0.04 | | 0.05 | 0.03 | 0.8 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 129 | 0.45 | 0.07 | | 0.07 | 0.09 | 0.6 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 109 | 0.48 | 0.03 | | 0.05 | 0.02 | 0.9 |
| Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens | 40 | 0.45 | 0.03 | | 0.05 | 0.03 | 0.8 |

Lot 1563 - Enriched 1.0 $\mu\text{mol/L}$ blood

| METHOD | N | Mean | Average Within | | Total SD | Y- Intercept* | Slope |
|--|-----|------|----------------|--|----------|---------------|-------|
| | | | Lab SD | | | | |
| Derivatized - MS/MS non-kit | 894 | 0.86 | 0.10 | | 0.18 | 0.04 | 0.8 |
| Non-derivatized - MS/MS non-kit | 239 | 0.87 | 0.09 | | 0.16 | 0.02 | 0.9 |
| Derivatized - MS/MS PE NeoGram Kit | 107 | 0.66 | 0.09 | | 0.14 | 0.08 | 0.6 |
| Non-derivatized - MS/MS PE NeoBase Kit | 703 | 0.83 | 0.05 | | 0.09 | 0.03 | 0.8 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 125 | 0.72 | 0.08 | | 0.10 | 0.09 | 0.6 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 107 | 0.86 | 0.06 | | 0.09 | 0.02 | 0.9 |
| Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens | 40 | 0.82 | 0.06 | | 0.12 | 0.03 | 0.8 |

Lot 1562 - Enriched 2.5 $\mu\text{mol/L}$ blood

| METHOD | N | Mean | Average Within | | Total SD | Y- Intercept* | Slope |
|--|-----|------|----------------|--|----------|---------------|-------|
| | | | Lab SD | | | | |
| Derivatized - MS/MS non-kit | 896 | 2.14 | 0.23 | | 0.45 | 0.04 | 0.8 |
| Non-derivatized - MS/MS non-kit | 239 | 2.18 | 0.19 | | 0.40 | 0.02 | 0.9 |
| Derivatized - MS/MS PE NeoGram Kit | 107 | 1.46 | 0.17 | | 0.28 | 0.08 | 0.6 |
| Non-derivatized - MS/MS PE NeoBase Kit | 706 | 2.04 | 0.12 | | 0.20 | 0.03 | 0.8 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 126 | 1.61 | 0.21 | | 0.35 | 0.09 | 0.6 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 110 | 2.18 | 0.15 | | 0.32 | 0.02 | 0.9 |
| Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens | 40 | 2.02 | 0.14 | | 0.30 | 0.03 | 0.8 |

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

**Table 17aa. 2015 Quality Control Data Summaries of Statistical Analyses
OCTANOYLCARNITINE (µmol C8/L blood)**

Lot 1465 - Nonenriched 0 µmol/L blood

| METHOD | N | Mean | Average Within | | Total SD | Y- Intercept* | Slope |
|--|-----|------|----------------|--|----------|---------------|-------|
| | | | Lab SD | | | | |
| Derivatized - MS/MS non-kit | 865 | 0.03 | 0.01 | | 0.02 | 0.03 | 0.9 |
| Non-derivatized - MS/MS non-kit | 260 | 0.02 | 0.01 | | 0.01 | 0.01 | 1.0 |
| Derivatized - MS/MS PE NeoGram Kit | 119 | 0.02 | 0.02 | | 0.02 | 0.01 | 0.9 |
| Non-derivatized - MS/MS PE NeoBase Kit | 643 | 0.02 | 0.01 | | 0.01 | 0.01 | 0.9 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 101 | 0.03 | 0.02 | | 0.04 | 0.03 | 0.8 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 88 | 0.02 | 0.01 | | 0.01 | 0.01 | 0.8 |
| Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens | 56 | 0.03 | 0.01 | | 0.01 | 0.02 | 1.0 |

Lot 1466 - Enriched 0.5 µmol/L blood

| METHOD | N | Mean | Average Within | | Total SD | Y- Intercept* | Slope |
|--|-----|------|----------------|--|----------|---------------|-------|
| | | | Lab SD | | | | |
| Derivatized - MS/MS non-kit | 856 | 0.50 | 0.06 | | 0.11 | 0.03 | 0.9 |
| Non-derivatized - MS/MS non-kit | 262 | 0.50 | 0.04 | | 0.07 | 0.01 | 1.0 |
| Derivatized - MS/MS PE NeoGram Kit | 125 | 0.45 | 0.08 | | 0.09 | 0.01 | 0.9 |
| Non-derivatized - MS/MS PE NeoBase Kit | 640 | 0.47 | 0.04 | | 0.06 | 0.01 | 0.9 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 105 | 0.45 | 0.07 | | 0.08 | 0.03 | 0.8 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 87 | 0.42 | 0.04 | | 0.06 | 0.01 | 0.8 |
| Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens | 60 | 0.51 | 0.04 | | 0.05 | 0.02 | 1.0 |

Lot 1467 - Enriched 1.0 µmol/L blood

| METHOD | N | Mean | Average Within | | Total SD | Y- Intercept* | Slope |
|--|-----|------|----------------|--|----------|---------------|-------|
| | | | Lab SD | | | | |
| Derivatized - MS/MS non-kit | 857 | 0.95 | 0.12 | | 0.19 | 0.03 | 0.9 |
| Non-derivatized - MS/MS non-kit | 266 | 0.98 | 0.09 | | 0.15 | 0.01 | 1.0 |
| Derivatized - MS/MS PE NeoGram Kit | 126 | 0.86 | 0.12 | | 0.14 | 0.01 | 0.9 |
| Non-derivatized - MS/MS PE NeoBase Kit | 644 | 0.92 | 0.07 | | 0.10 | 0.01 | 0.9 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 108 | 0.86 | 0.11 | | 0.13 | 0.03 | 0.8 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 90 | 0.78 | 0.06 | | 0.10 | 0.01 | 0.8 |
| Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens | 59 | 0.99 | 0.06 | | 0.09 | 0.02 | 1.0 |

Lot 1468 - Enriched 2.5 µmol/L blood

| METHOD | N | Mean | Average Within | | Total SD | Y- Intercept* | Slope |
|--|-----|------|----------------|--|----------|---------------|-------|
| | | | Lab SD | | | | |
| Derivatized - MS/MS non-kit | 858 | 2.35 | 0.25 | | 0.41 | 0.03 | 0.9 |
| Non-derivatized - MS/MS non-kit | 267 | 2.45 | 0.20 | | 0.33 | 0.01 | 1.0 |
| Derivatized - MS/MS PE NeoGram Kit | 129 | 2.21 | 0.25 | | 0.33 | 0.01 | 0.9 |
| Non-derivatized - MS/MS PE NeoBase Kit | 642 | 2.35 | 0.17 | | 0.26 | 0.01 | 0.9 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 107 | 2.12 | 0.23 | | 0.30 | 0.03 | 0.8 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 87 | 2.04 | 0.16 | | 0.24 | 0.01 | 0.8 |
| Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens | 59 | 2.51 | 0.15 | | 0.17 | 0.02 | 1.0 |

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

2015 Quality Control Data Summaries of Statistical Analyses OCTANOYLCARNITINE (µmol C8/L blood)

Lot 1561 - Nonenriched 0 µmol/L blood

| METHOD | N | Mean | Average Within | | Y- Intercept* | Slope |
|--|-----|------|----------------|----------|---------------|-------|
| | | | Lab SD | Total SD | | |
| Derivatized - MS/MS non-kit | 909 | 0.03 | 0.01 | 0.02 | 0.03 | 1.0 |
| Non-derivatized - MS/MS non-kit | 305 | 0.02 | 0.01 | 0.01 | 0.02 | 1.0 |
| Derivatized - MS/MS PE NeoGram Kit | 104 | 0.02 | 0.01 | 0.02 | 0.03 | 0.9 |
| Non-derivatized - MS/MS PE NeoBase Kit | 711 | 0.01 | 0.01 | 0.01 | 0.01 | 1.0 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 128 | 0.02 | 0.01 | 0.01 | 0.03 | 0.9 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 115 | 0.02 | 0.01 | 0.01 | 0.01 | 0.9 |
| Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens | 50 | 0.02 | 0.01 | 0.01 | 0.02 | 1.1 |

Lot 1562 - Enriched 0.5 µmol/L blood

| METHOD | N | Mean | Average Within | | Y- Intercept* | Slope |
|--|-----|------|----------------|----------|---------------|-------|
| | | | Lab SD | Total SD | | |
| Derivatized - MS/MS non-kit | 898 | 0.57 | 0.07 | 0.11 | 0.03 | 1.0 |
| Non-derivatized - MS/MS non-kit | 315 | 0.54 | 0.05 | 0.07 | 0.02 | 1.0 |
| Derivatized - MS/MS PE NeoGram Kit | 105 | 0.51 | 0.08 | 0.09 | 0.03 | 0.9 |
| Non-derivatized - MS/MS PE NeoBase Kit | 700 | 0.52 | 0.04 | 0.05 | 0.01 | 1.0 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 124 | 0.48 | 0.06 | 0.07 | 0.03 | 0.9 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 118 | 0.47 | 0.03 | 0.05 | 0.01 | 0.9 |
| Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens | 50 | 0.61 | 0.03 | 0.09 | 0.02 | 1.1 |

Lot 1563 - Enriched 1.0 µmol/L blood

| METHOD | N | Mean | Average Within | | Y- Intercept* | Slope |
|--|-----|------|----------------|----------|---------------|-------|
| | | | Lab SD | Total SD | | |
| Derivatized - MS/MS non-kit | 889 | 1.05 | 0.12 | 0.18 | 0.03 | 1.0 |
| Non-derivatized - MS/MS non-kit | 304 | 1.04 | 0.09 | 0.13 | 0.02 | 1.0 |
| Derivatized - MS/MS PE NeoGram Kit | 110 | 0.94 | 0.14 | 0.17 | 0.03 | 0.9 |
| Non-derivatized - MS/MS PE NeoBase Kit | 701 | 0.98 | 0.07 | 0.10 | 0.01 | 1.0 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 123 | 0.89 | 0.10 | 0.12 | 0.03 | 0.9 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 117 | 0.89 | 0.06 | 0.10 | 0.01 | 0.9 |
| Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens | 49 | 1.14 | 0.07 | 0.18 | 0.02 | 1.1 |

Lot 1564 - Enriched 2.5 µmol/L blood

| METHOD | N | Mean | Average Within | | Y- Intercept* | Slope |
|--|-----|------|----------------|----------|---------------|-------|
| | | | Lab SD | Total SD | | |
| Derivatized - MS/MS non-kit | 889 | 2.61 | 0.25 | 0.41 | 0.03 | 1.0 |
| Non-derivatized - MS/MS non-kit | 307 | 2.61 | 0.19 | 0.28 | 0.02 | 1.0 |
| Derivatized - MS/MS PE NeoGram Kit | 110 | 2.34 | 0.35 | 0.39 | 0.03 | 0.9 |
| Non-derivatized - MS/MS PE NeoBase Kit | 712 | 2.48 | 0.14 | 0.24 | 0.01 | 1.0 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 125 | 2.17 | 0.21 | 0.29 | 0.03 | 0.9 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 120 | 2.27 | 0.15 | 0.26 | 0.01 | 0.9 |
| Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens | 50 | 2.87 | 0.19 | 0.45 | 0.02 | 1.1 |

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

**Table 17bb. 2015 Quality Control Data Summaries of Statistical Analyses
DECANOYL CARNITINE ($\mu\text{mol C10/L blood}$)**

Lot 1465 - Nonenriched 0 $\mu\text{mol/L blood}$

| METHOD | N | Mean | Average Within | | Y- Intercept* | Slope |
|--|-----|------|----------------|----------|---------------|-------|
| | | | Lab SD | Total SD | | |
| Derivatized - MS/MS non-kit | 813 | 0.02 | 0.01 | 0.02 | 0.00 | 1.0 |
| Non-derivatized - MS/MS non-kit | 245 | 0.02 | 0.01 | 0.01 | 0.00 | 1.0 |
| Derivatized - MS/MS PE NeoGram Kit | 124 | 0.02 | 0.01 | 0.02 | 0.00 | 0.7 |
| Non-derivatized - MS/MS PE NeoBase Kit | 649 | 0.02 | 0.01 | 0.01 | -0.01 | 0.9 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 97 | 0.02 | 0.01 | 0.02 | 0.00 | 0.7 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 85 | 0.02 | 0.01 | 0.01 | -0.01 | 0.8 |
| Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens | 57 | 0.02 | 0.01 | 0.01 | -0.01 | 1.1 |

Lot 1466 - Enriched 0.5 $\mu\text{mol/L blood}$

| METHOD | N | Mean | Average Within | | Y- Intercept* | Slope |
|--|-----|------|----------------|----------|---------------|-------|
| | | | Lab SD | Total SD | | |
| Derivatized - MS/MS non-kit | 833 | 0.48 | 0.07 | 0.12 | 0.00 | 1.0 |
| Non-derivatized - MS/MS non-kit | 246 | 0.52 | 0.04 | 0.09 | 0.00 | 1.0 |
| Derivatized - MS/MS PE NeoGram Kit | 127 | 0.37 | 0.06 | 0.07 | 0.00 | 0.7 |
| Non-derivatized - MS/MS PE NeoBase Kit | 644 | 0.42 | 0.04 | 0.06 | -0.01 | 0.9 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 105 | 0.38 | 0.06 | 0.08 | 0.00 | 0.7 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 87 | 0.38 | 0.04 | 0.05 | -0.01 | 0.8 |
| Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens | 60 | 0.55 | 0.04 | 0.12 | -0.01 | 1.1 |

Lot 1467 - Enriched 1.0 $\mu\text{mol/L blood}$

| METHOD | N | Mean | Average Within | | Y- Intercept* | Slope |
|--|-----|------|----------------|----------|---------------|-------|
| | | | Lab SD | Total SD | | |
| Derivatized - MS/MS non-kit | 829 | 0.93 | 0.13 | 0.22 | 0.00 | 1.0 |
| Non-derivatized - MS/MS non-kit | 244 | 0.98 | 0.10 | 0.19 | 0.00 | 1.0 |
| Derivatized - MS/MS PE NeoGram Kit | 128 | 0.72 | 0.11 | 0.13 | 0.00 | 0.7 |
| Non-derivatized - MS/MS PE NeoBase Kit | 650 | 0.81 | 0.07 | 0.10 | -0.01 | 0.9 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 107 | 0.70 | 0.10 | 0.14 | 0.00 | 0.7 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 86 | 0.71 | 0.06 | 0.11 | -0.01 | 0.8 |
| Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens | 60 | 1.06 | 0.08 | 0.18 | -0.01 | 1.1 |

Lot 1468 - Enriched 2.5 $\mu\text{mol/L blood}$

| METHOD | N | Mean | Average Within | | Y- Intercept* | Slope |
|--|-----|------|----------------|----------|---------------|-------|
| | | | Lab SD | Total SD | | |
| Derivatized - MS/MS non-kit | 836 | 2.40 | 0.29 | 0.53 | 0.00 | 1.0 |
| Non-derivatized - MS/MS non-kit | 248 | 2.58 | 0.23 | 0.48 | 0.00 | 1.0 |
| Derivatized - MS/MS PE NeoGram Kit | 126 | 1.86 | 0.20 | 0.28 | 0.00 | 0.7 |
| Non-derivatized - MS/MS PE NeoBase Kit | 638 | 2.15 | 0.15 | 0.26 | -0.01 | 0.9 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 107 | 1.86 | 0.23 | 0.33 | 0.00 | 0.7 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 89 | 1.94 | 0.14 | 0.23 | -0.01 | 0.8 |
| Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens | 60 | 2.78 | 0.21 | 0.39 | -0.01 | 1.1 |

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

2015 Quality Control Data Summaries of Statistical Analyses
DECANOYL Carnitine ($\mu\text{mol C10/L blood}$)

Lot 1561 - Nonenriched 0 $\mu\text{mol/L blood}$

| METHOD | N | Mean | Average Within | | Total SD | Y- Intercept* | Slope |
|--|-----|------|----------------|--|----------|---------------|-------|
| | | | Lab SD | | | | |
| Derivatized - MS/MS non-kit | 872 | 0.02 | 0.01 | | 0.02 | 0.02 | 1.0 |
| Non-derivatized - MS/MS non-kit | 284 | 0.02 | 0.01 | | 0.02 | 0.02 | 1.1 |
| Derivatized - MS/MS PE NeoGram Kit | 108 | 0.03 | 0.02 | | 0.03 | 0.02 | 0.8 |
| Non-derivatized - MS/MS PE NeoBase Kit | 715 | 0.02 | 0.01 | | 0.01 | 0.01 | 0.9 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 127 | 0.03 | 0.01 | | 0.02 | 0.03 | 0.7 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 116 | 0.02 | 0.01 | | 0.01 | 0.01 | 0.9 |
| Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens | 49 | 0.02 | 0.00 | | 0.01 | 0.01 | 1.3 |

Lot 1562 - Enriched 0.5 $\mu\text{mol/L blood}$

| METHOD | N | Mean | Average Within | | Total SD | Y- Intercept* | Slope |
|--|-----|------|----------------|--|----------|---------------|-------|
| | | | Lab SD | | | | |
| Derivatized - MS/MS non-kit | 876 | 0.55 | 0.07 | | 0.12 | 0.02 | 1.0 |
| Non-derivatized - MS/MS non-kit | 294 | 0.59 | 0.06 | | 0.09 | 0.02 | 1.1 |
| Derivatized - MS/MS PE NeoGram Kit | 106 | 0.42 | 0.07 | | 0.08 | 0.02 | 0.8 |
| Non-derivatized - MS/MS PE NeoBase Kit | 700 | 0.47 | 0.04 | | 0.06 | 0.01 | 0.9 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 125 | 0.37 | 0.05 | | 0.08 | 0.03 | 0.7 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 115 | 0.45 | 0.05 | | 0.09 | 0.01 | 0.9 |
| Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens | 50 | 0.63 | 0.06 | | 0.11 | 0.01 | 1.3 |

Lot 1563 - Enriched 1.0 $\mu\text{mol/L blood}$

| METHOD | N | Mean | Average Within | | Total SD | Y- Intercept* | Slope |
|--|-----|------|----------------|--|----------|---------------|-------|
| | | | Lab SD | | | | |
| Derivatized - MS/MS non-kit | 881 | 1.07 | 0.14 | | 0.22 | 0.02 | 1.0 |
| Non-derivatized - MS/MS non-kit | 283 | 1.16 | 0.11 | | 0.17 | 0.02 | 1.1 |
| Derivatized - MS/MS PE NeoGram Kit | 106 | 0.79 | 0.11 | | 0.15 | 0.02 | 0.8 |
| Non-derivatized - MS/MS PE NeoBase Kit | 716 | 0.92 | 0.06 | | 0.11 | 0.01 | 0.9 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 125 | 0.75 | 0.09 | | 0.16 | 0.03 | 0.7 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 117 | 0.92 | 0.08 | | 0.20 | 0.01 | 0.9 |
| Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens | 50 | 1.27 | 0.11 | | 0.21 | 0.01 | 1.3 |

Lot 1564 - Enriched 2.5 $\mu\text{mol/L blood}$

| METHOD | N | Mean | Average Within | | Total SD | Y- Intercept* | Slope |
|--|-----|------|----------------|--|----------|---------------|-------|
| | | | Lab SD | | | | |
| Derivatized - MS/MS non-kit | 884 | 2.63 | 0.28 | | 0.52 | 0.02 | 1.0 |
| Non-derivatized - MS/MS non-kit | 280 | 2.87 | 0.22 | | 0.38 | 0.02 | 1.1 |
| Derivatized - MS/MS PE NeoGram Kit | 107 | 2.04 | 0.28 | | 0.34 | 0.02 | 0.8 |
| Non-derivatized - MS/MS PE NeoBase Kit | 718 | 2.34 | 0.15 | | 0.26 | 0.01 | 0.9 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 124 | 1.76 | 0.17 | | 0.34 | 0.03 | 0.7 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 117 | 2.25 | 0.16 | | 0.44 | 0.01 | 0.9 |
| Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens | 50 | 3.14 | 0.28 | | 0.54 | 0.01 | 1.3 |

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

**Table 17cc. 2015 Quality Control Data Summaries of Statistical Analyses
DODECANOYL CARNITINE ($\mu\text{mol C12/L blood}$)**

Lot 1465 - Nonenriched 0 $\mu\text{mol/L blood}$

| METHOD | N | Mean | Average Within | | Y- Intercept* | Slope |
|--|-----|------|----------------|----------|---------------|-------|
| | | | Lab SD | Total SD | | |
| Derivatized - MS/MS non-kit | 745 | 0.03 | 0.02 | 0.03 | 0.05 | 0.9 |
| Non-derivatized - MS/MS non-kit | 162 | 0.01 | 0.00 | 0.01 | 0.02 | 0.9 |
| Derivatized - MS/MS PE NeoGram Kit | 128 | 0.03 | 0.02 | 0.02 | 0.04 | 0.8 |
| Non-derivatized - MS/MS PE NeoBase Kit | 595 | 0.01 | 0.00 | 0.00 | 0.00 | 0.8 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 105 | 0.07 | 0.03 | 0.06 | 0.11 | 0.9 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 85 | 0.01 | 0.01 | 0.01 | 0.00 | 0.7 |
| Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens | 40 | 0.01 | 0.00 | 0.00 | 0.02 | 0.9 |

Lot 1466 - Enriched 0.5 $\mu\text{mol/L blood}$

| METHOD | N | Mean | Average Within | | Y- Intercept* | Slope |
|--|-----|------|----------------|----------|---------------|-------|
| | | | Lab SD | Total SD | | |
| Derivatized - MS/MS non-kit | 761 | 0.48 | 0.09 | 0.14 | 0.05 | 0.9 |
| Non-derivatized - MS/MS non-kit | 161 | 0.45 | 0.04 | 0.09 | 0.02 | 0.9 |
| Derivatized - MS/MS PE NeoGram Kit | 125 | 0.45 | 0.07 | 0.09 | 0.04 | 0.8 |
| Non-derivatized - MS/MS PE NeoBase Kit | 604 | 0.41 | 0.04 | 0.05 | 0.00 | 0.8 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 104 | 0.51 | 0.09 | 0.14 | 0.11 | 0.9 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 88 | 0.38 | 0.04 | 0.05 | 0.00 | 0.7 |
| Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens | 40 | 0.48 | 0.04 | 0.07 | 0.02 | 0.9 |

Lot 1467 - Enriched 1.0 $\mu\text{mol/L blood}$

| METHOD | N | Mean | Average Within | | Y- Intercept* | Slope |
|--|-----|------|----------------|----------|---------------|-------|
| | | | Lab SD | Total SD | | |
| Derivatized - MS/MS non-kit | 756 | 0.94 | 0.15 | 0.26 | 0.05 | 0.9 |
| Non-derivatized - MS/MS non-kit | 158 | 0.87 | 0.09 | 0.17 | 0.02 | 0.9 |
| Derivatized - MS/MS PE NeoGram Kit | 127 | 0.89 | 0.11 | 0.17 | 0.04 | 0.8 |
| Non-derivatized - MS/MS PE NeoBase Kit | 616 | 0.80 | 0.07 | 0.09 | 0.00 | 0.8 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 105 | 1.05 | 0.19 | 0.33 | 0.11 | 0.9 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 88 | 0.71 | 0.06 | 0.13 | 0.00 | 0.7 |
| Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens | 40 | 0.96 | 0.09 | 0.11 | 0.02 | 0.9 |

Lot 1468 - Enriched 2.5 $\mu\text{mol/L blood}$

| METHOD | N | Mean | Average Within | | Y- Intercept* | Slope |
|--|-----|------|----------------|----------|---------------|-------|
| | | | Lab SD | Total SD | | |
| Derivatized - MS/MS non-kit | 773 | 2.22 | 0.29 | 0.53 | 0.05 | 0.9 |
| Non-derivatized - MS/MS non-kit | 160 | 2.14 | 0.23 | 0.43 | 0.02 | 0.9 |
| Derivatized - MS/MS PE NeoGram Kit | 125 | 2.09 | 0.24 | 0.30 | 0.04 | 0.8 |
| Non-derivatized - MS/MS PE NeoBase Kit | 609 | 2.04 | 0.15 | 0.22 | 0.00 | 0.8 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 102 | 2.20 | 0.25 | 0.41 | 0.11 | 0.9 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 87 | 1.84 | 0.12 | 0.18 | 0.00 | 0.7 |
| Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens | 40 | 2.31 | 0.21 | 0.21 | 0.02 | 0.9 |

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

2015 Quality Control Data Summaries of Statistical Analyses DODECANOYL CARNITINE (μmol C12/L blood)

Lot 1561 - Nonenriched 0 μmol/L blood

| METHOD | N | Mean | Average Within | | Y- Intercept* | Slope |
|--|-----|------|----------------|----------|---------------|-------|
| | | | Lab SD | Total SD | | |
| Derivatized - MS/MS non-kit | 780 | 0.03 | 0.01 | 0.03 | 0.02 | 1.0 |
| Non-derivatized - MS/MS non-kit | 202 | 0.01 | 0.00 | 0.01 | 0.01 | 1.0 |
| Derivatized - MS/MS PE NeoGram Kit | 100 | 0.04 | 0.02 | 0.03 | 0.02 | 0.9 |
| Non-derivatized - MS/MS PE NeoBase Kit | 650 | 0.01 | 0.00 | 0.01 | -0.01 | 0.9 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 124 | 0.05 | 0.02 | 0.03 | 0.04 | 0.9 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 106 | 0.01 | 0.00 | 0.01 | -0.01 | 0.9 |
| Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens | 36 | 0.01 | 0.00 | 0.00 | 0.00 | 1.1 |

Lot 1562 - Enriched 1.0 μmol/L blood

| METHOD | N | Mean | Average Within | | Y- Intercept* | Slope |
|--|-----|------|----------------|----------|---------------|-------|
| | | | Lab SD | Total SD | | |
| Derivatized - MS/MS non-kit | 791 | 0.98 | 0.14 | 0.25 | 0.02 | 1.0 |
| Non-derivatized - MS/MS non-kit | 190 | 1.01 | 0.12 | 0.22 | 0.01 | 1.0 |
| Derivatized - MS/MS PE NeoGram Kit | 99 | 0.94 | 0.14 | 0.15 | 0.02 | 0.9 |
| Non-derivatized - MS/MS PE NeoBase Kit | 669 | 0.92 | 0.06 | 0.09 | -0.01 | 0.9 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 125 | 0.95 | 0.11 | 0.22 | 0.04 | 0.9 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 104 | 0.85 | 0.06 | 0.09 | -0.01 | 0.9 |
| Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens | 39 | 1.06 | 0.06 | 0.13 | 0.00 | 1.1 |

Lot 1563 - Enriched 2.0 μmol/L blood

| METHOD | N | Mean | Average Within | | Y- Intercept* | Slope |
|--|-----|------|----------------|----------|---------------|-------|
| | | | Lab SD | Total SD | | |
| Derivatized - MS/MS non-kit | 793 | 1.89 | 0.23 | 0.46 | 0.02 | 1.0 |
| Non-derivatized - MS/MS non-kit | 190 | 2.02 | 0.22 | 0.49 | 0.01 | 1.0 |
| Derivatized - MS/MS PE NeoGram Kit | 100 | 1.83 | 0.25 | 0.30 | 0.02 | 0.9 |
| Non-derivatized - MS/MS PE NeoBase Kit | 659 | 1.82 | 0.11 | 0.16 | -0.01 | 0.9 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 124 | 1.82 | 0.16 | 0.32 | 0.04 | 0.9 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 106 | 1.68 | 0.13 | 0.21 | -0.01 | 0.9 |
| Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens | 40 | 2.13 | 0.15 | 0.29 | 0.00 | 1.1 |

Lot 1564 - Enriched 3.0 μmol/L blood

| METHOD | N | Mean | Average Within | | Y- Intercept* | Slope |
|--|-----|------|----------------|----------|---------------|-------|
| | | | Lab SD | Total SD | | |
| Derivatized - MS/MS non-kit | 792 | 2.94 | 0.35 | 0.68 | 0.02 | 1.0 |
| Non-derivatized - MS/MS non-kit | 190 | 3.01 | 0.29 | 0.62 | 0.01 | 1.0 |
| Derivatized - MS/MS PE NeoGram Kit | 98 | 2.81 | 0.39 | 0.43 | 0.02 | 0.9 |
| Non-derivatized - MS/MS PE NeoBase Kit | 667 | 2.83 | 0.18 | 0.26 | -0.01 | 0.9 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 122 | 2.78 | 0.29 | 0.48 | 0.04 | 0.9 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 105 | 2.62 | 0.18 | 0.27 | -0.01 | 0.9 |
| Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens | 40 | 3.24 | 0.19 | 0.46 | 0.00 | 1.1 |

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

**Table 17dd. 2015 Quality Control Data Summaries of Statistical Analyses
MYRISTOYL CARNITINE ($\mu\text{mol C14/L blood}$)**

Lot 1465 - Nonenriched 0 $\mu\text{mol/L}$ blood

| METHOD | N | Mean | Average Within | | Y- Intercept* | Slope |
|--|-----|------|----------------|----------|---------------|-------|
| | | | Lab SD | Total SD | | |
| Derivatized - MS/MS non-kit | 819 | 0.06 | 0.02 | 0.03 | 0.05 | 1.0 |
| Non-derivatized - MS/MS non-kit | 175 | 0.04 | 0.01 | 0.01 | 0.03 | 1.0 |
| Derivatized - MS/MS PE NeoGram Kit | 126 | 0.06 | 0.02 | 0.02 | 0.05 | 0.9 |
| Non-derivatized - MS/MS PE NeoBase Kit | 622 | 0.04 | 0.01 | 0.01 | 0.02 | 0.9 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 113 | 0.08 | 0.03 | 0.05 | 0.08 | 0.8 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 86 | 0.03 | 0.01 | 0.01 | 0.02 | 0.8 |
| Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens | 28 | 0.04 | 0.00 | 0.00 | 0.01 | 1.1 |

Lot 1466 - Enriched 0.5 $\mu\text{mol/L}$ blood

| METHOD | N | Mean | Average Within | | Y- Intercept* | Slope |
|--|-----|------|----------------|----------|---------------|-------|
| | | | Lab SD | Total SD | | |
| Derivatized - MS/MS non-kit | 820 | 0.53 | 0.07 | 0.10 | 0.05 | 1.0 |
| Non-derivatized - MS/MS non-kit | 179 | 0.53 | 0.05 | 0.07 | 0.03 | 1.0 |
| Derivatized - MS/MS PE NeoGram Kit | 125 | 0.50 | 0.07 | 0.08 | 0.05 | 0.9 |
| Non-derivatized - MS/MS PE NeoBase Kit | 628 | 0.48 | 0.04 | 0.05 | 0.02 | 0.9 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 118 | 0.49 | 0.08 | 0.08 | 0.08 | 0.8 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 90 | 0.43 | 0.04 | 0.08 | 0.02 | 0.8 |
| Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens | 30 | 0.54 | 0.03 | 0.04 | 0.01 | 1.1 |

Lot 1467 - Enriched 1.5 $\mu\text{mol/L}$ blood

| METHOD | N | Mean | Average Within | | Y- Intercept* | Slope |
|--|-----|------|----------------|----------|---------------|-------|
| | | | Lab SD | Total SD | | |
| Derivatized - MS/MS non-kit | 826 | 1.47 | 0.17 | 0.27 | 0.05 | 1.0 |
| Non-derivatized - MS/MS non-kit | 180 | 1.49 | 0.14 | 0.23 | 0.03 | 1.0 |
| Derivatized - MS/MS PE NeoGram Kit | 128 | 1.36 | 0.15 | 0.20 | 0.05 | 0.9 |
| Non-derivatized - MS/MS PE NeoBase Kit | 635 | 1.40 | 0.10 | 0.15 | 0.02 | 0.9 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 119 | 1.30 | 0.17 | 0.19 | 0.08 | 0.8 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 90 | 1.22 | 0.09 | 0.20 | 0.02 | 0.8 |
| Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens | 30 | 1.62 | 0.12 | 0.13 | 0.01 | 1.1 |

Lot 1468 - Enriched 3.0 $\mu\text{mol/L}$ blood

| METHOD | N | Mean | Average Within | | Y- Intercept* | Slope |
|--|-----|------|----------------|----------|---------------|-------|
| | | | Lab SD | Total SD | | |
| Derivatized - MS/MS non-kit | 824 | 2.94 | 0.34 | 0.51 | 0.05 | 1.0 |
| Non-derivatized - MS/MS non-kit | 179 | 3.02 | 0.26 | 0.44 | 0.03 | 1.0 |
| Derivatized - MS/MS PE NeoGram Kit | 127 | 2.73 | 0.28 | 0.41 | 0.05 | 0.9 |
| Non-derivatized - MS/MS PE NeoBase Kit | 626 | 2.81 | 0.20 | 0.30 | 0.02 | 0.9 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 114 | 2.54 | 0.25 | 0.34 | 0.08 | 0.8 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 88 | 2.51 | 0.14 | 0.34 | 0.02 | 0.8 |
| Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens | 30 | 3.30 | 0.29 | 0.30 | 0.01 | 1.1 |

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

2015 Quality Control Data Summaries of Statistical Analyses
MYRISTOYL CARNITINE ($\mu\text{mol C14/L blood}$)

Lot 1561 - Nonenriched 0 $\mu\text{mol/L blood}$

| METHOD | N | Mean | Average Within | | Y- Intercept* | Slope |
|--|-----|------|----------------|----------|---------------|-------|
| | | | Lab SD | Total SD | | |
| Derivatized - MS/MS non-kit | 870 | 0.06 | 0.02 | 0.03 | 0.06 | 1.0 |
| Non-derivatized - MS/MS non-kit | 226 | 0.05 | 0.01 | 0.01 | 0.04 | 1.0 |
| Derivatized - MS/MS PE NeoGram Kit | 108 | 0.07 | 0.02 | 0.02 | 0.05 | 0.9 |
| Non-derivatized - MS/MS PE NeoBase Kit | 684 | 0.04 | 0.01 | 0.01 | 0.03 | 0.9 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 118 | 0.07 | 0.02 | 0.03 | 0.07 | 0.8 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 107 | 0.03 | 0.01 | 0.01 | 0.03 | 0.8 |
| Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens | 40 | 0.04 | 0.01 | 0.01 | 0.04 | 1.0 |

Lot 1562 - Enriched 0.5 $\mu\text{mol/L blood}$

| METHOD | N | Mean | Average Within | | Y- Intercept* | Slope |
|--|-----|------|----------------|----------|---------------|-------|
| | | | Lab SD | Total SD | | |
| Derivatized - MS/MS non-kit | 872 | 0.56 | 0.07 | 0.11 | 0.06 | 1.0 |
| Non-derivatized - MS/MS non-kit | 235 | 0.55 | 0.05 | 0.10 | 0.04 | 1.0 |
| Derivatized - MS/MS PE NeoGram Kit | 109 | 0.50 | 0.09 | 0.10 | 0.05 | 0.9 |
| Non-derivatized - MS/MS PE NeoBase Kit | 688 | 0.48 | 0.04 | 0.06 | 0.03 | 0.9 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 125 | 0.47 | 0.05 | 0.08 | 0.07 | 0.8 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 107 | 0.44 | 0.03 | 0.04 | 0.03 | 0.8 |
| Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens | 39 | 0.54 | 0.03 | 0.04 | 0.04 | 1.0 |

Lot 1563 - Enriched 1.5 $\mu\text{mol/L blood}$

| METHOD | N | Mean | Average Within | | Y- Intercept* | Slope |
|--|-----|------|----------------|----------|---------------|-------|
| | | | Lab SD | Total SD | | |
| Derivatized - MS/MS non-kit | 868 | 1.52 | 0.18 | 0.26 | 0.06 | 1.0 |
| Non-derivatized - MS/MS non-kit | 230 | 1.57 | 0.14 | 0.30 | 0.04 | 1.0 |
| Derivatized - MS/MS PE NeoGram Kit | 108 | 1.33 | 0.16 | 0.21 | 0.05 | 0.9 |
| Non-derivatized - MS/MS PE NeoBase Kit | 674 | 1.38 | 0.09 | 0.13 | 0.03 | 0.9 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 129 | 1.18 | 0.12 | 0.24 | 0.07 | 0.8 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 107 | 1.27 | 0.08 | 0.12 | 0.03 | 0.8 |
| Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens | 40 | 1.56 | 0.11 | 0.15 | 0.04 | 1.0 |

Lot 1564 - Enriched 3.0 $\mu\text{mol/L blood}$

| METHOD | N | Mean | Average Within | | Y- Intercept* | Slope |
|--|-----|------|----------------|----------|---------------|-------|
| | | | Lab SD | Total SD | | |
| Derivatized - MS/MS non-kit | 866 | 3.00 | 0.31 | 0.50 | 0.06 | 1.0 |
| Non-derivatized - MS/MS non-kit | 233 | 3.10 | 0.26 | 0.51 | 0.04 | 1.0 |
| Derivatized - MS/MS PE NeoGram Kit | 107 | 2.76 | 0.27 | 0.37 | 0.05 | 0.9 |
| Non-derivatized - MS/MS PE NeoBase Kit | 685 | 2.76 | 0.17 | 0.25 | 0.03 | 0.9 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 118 | 2.34 | 0.21 | 0.31 | 0.07 | 0.8 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 106 | 2.52 | 0.17 | 0.25 | 0.03 | 0.8 |
| Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens | 40 | 3.06 | 0.19 | 0.32 | 0.04 | 1.0 |

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

**Table 17ee. 2015 Quality Control Data Summaries of Statistical Analyses
PALMITOYL Carnitine (μmol C16/L blood)**

Lot 1465 - Nonenriched 0 μmol/L blood

| METHOD | N | Mean | Average Within | | Y- Intercept* | Slope |
|--|-----|------|----------------|----------|---------------|-------|
| | | | Lab SD | Total SD | | |
| Derivatized - MS/MS non-kit | 845 | 0.79 | 0.10 | 0.15 | 0.86 | 0.9 |
| Non-derivatized - MS/MS non-kit | 196 | 0.81 | 0.07 | 0.13 | 0.87 | 0.9 |
| Derivatized - MS/MS PE NeoGram Kit | 130 | 0.74 | 0.10 | 0.13 | 0.73 | 0.8 |
| Non-derivatized - MS/MS PE NeoBase Kit | 654 | 0.72 | 0.06 | 0.08 | 0.76 | 0.8 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 106 | 0.81 | 0.11 | 0.15 | 0.87 | 0.8 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 89 | 0.70 | 0.06 | 0.09 | 0.74 | 0.8 |
| Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens | 50 | 0.86 | 0.06 | 0.11 | 0.92 | 0.9 |

Lot 1466 - Enriched 3.0 μmol/L blood

| METHOD | N | Mean | Average Within | | Y- Intercept* | Slope |
|--|-----|------|----------------|----------|---------------|-------|
| | | | Lab SD | Total SD | | |
| Derivatized - MS/MS non-kit | 858 | 3.44 | 0.33 | 0.45 | 0.86 | 0.9 |
| Non-derivatized - MS/MS non-kit | 199 | 3.64 | 0.30 | 0.56 | 0.87 | 0.9 |
| Derivatized - MS/MS PE NeoGram Kit | 124 | 3.07 | 0.29 | 0.41 | 0.73 | 0.8 |
| Non-derivatized - MS/MS PE NeoBase Kit | 656 | 3.27 | 0.23 | 0.34 | 0.76 | 0.8 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 106 | 3.44 | 0.33 | 0.42 | 0.87 | 0.8 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 88 | 3.28 | 0.26 | 0.40 | 0.74 | 0.8 |
| Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens | 49 | 3.66 | 0.25 | 0.35 | 0.92 | 0.9 |

Lot 1467 - Enriched 8.0 μmol/L blood

| METHOD | N | Mean | Average Within | | Y- Intercept* | Slope |
|--|-----|------|----------------|----------|---------------|-------|
| | | | Lab SD | Total SD | | |
| Derivatized - MS/MS non-kit | 864 | 7.81 | 0.77 | 1.13 | 0.86 | 0.9 |
| Non-derivatized - MS/MS non-kit | 197 | 8.25 | 0.76 | 1.19 | 0.87 | 0.9 |
| Derivatized - MS/MS PE NeoGram Kit | 126 | 7.27 | 0.69 | 0.96 | 0.73 | 0.8 |
| Non-derivatized - MS/MS PE NeoBase Kit | 650 | 7.55 | 0.55 | 0.77 | 0.76 | 0.8 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 109 | 7.68 | 0.74 | 1.04 | 0.87 | 0.8 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 85 | 7.41 | 0.53 | 0.62 | 0.74 | 0.8 |
| Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens | 49 | 8.34 | 0.55 | 0.70 | 0.92 | 0.9 |

Lot 1468 - Enriched 12.0 μmol/L blood

| METHOD | N | Mean | Average Within | | Y- Intercept* | Slope |
|--|-----|-------|----------------|----------|---------------|-------|
| | | | Lab SD | Total SD | | |
| Derivatized - MS/MS non-kit | 860 | 11.00 | 0.99 | 1.51 | 0.86 | 0.9 |
| Non-derivatized - MS/MS non-kit | 200 | 11.70 | 0.87 | 1.69 | 0.87 | 0.9 |
| Derivatized - MS/MS PE NeoGram Kit | 129 | 10.27 | 0.97 | 1.42 | 0.73 | 0.8 |
| Non-derivatized - MS/MS PE NeoBase Kit | 653 | 10.68 | 0.75 | 1.10 | 0.76 | 0.8 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 107 | 10.93 | 0.99 | 1.23 | 0.87 | 0.8 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 89 | 10.72 | 0.73 | 1.01 | 0.74 | 0.8 |
| Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens | 48 | 11.75 | 0.84 | 1.21 | 0.92 | 0.9 |

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

2015 Quality Control Data Summaries of Statistical Analyses
PALMITOYL Carnitine (μmol C16/L blood)

Lot 1561 - Nonenriched 0 μmol/L blood

| METHOD | N | Mean | Average Within | | Y- Intercept* | Slope |
|--|-----|------|----------------|----------|---------------|-------|
| | | | Lab SD | Total SD | | |
| Derivatized - MS/MS non-kit | 921 | 0.74 | 0.09 | 0.13 | 0.72 | 0.9 |
| Non-derivatized - MS/MS non-kit | 244 | 0.75 | 0.07 | 0.11 | 0.73 | 0.9 |
| Derivatized - MS/MS PE NeoGram Kit | 108 | 0.63 | 0.10 | 0.11 | 0.60 | 0.8 |
| Non-derivatized - MS/MS PE NeoBase Kit | 702 | 0.65 | 0.05 | 0.07 | 0.57 | 0.8 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 126 | 0.69 | 0.08 | 0.11 | 0.62 | 0.8 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 109 | 0.64 | 0.05 | 0.07 | 0.63 | 0.8 |
| Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens | 48 | 0.75 | 0.04 | 0.05 | 0.71 | 1.0 |

Lot 1562 - Enriched 4.0 μmol/L blood

| METHOD | N | Mean | Average Within | | Y- Intercept* | Slope |
|--|-----|------|----------------|----------|---------------|-------|
| | | | Lab SD | Total SD | | |
| Derivatized - MS/MS non-kit | 925 | 4.28 | 0.41 | 0.61 | 0.72 | 0.9 |
| Non-derivatized - MS/MS non-kit | 249 | 4.45 | 0.37 | 0.70 | 0.73 | 0.9 |
| Derivatized - MS/MS PE NeoGram Kit | 109 | 3.76 | 0.45 | 0.58 | 0.60 | 0.8 |
| Non-derivatized - MS/MS PE NeoBase Kit | 709 | 3.91 | 0.25 | 0.36 | 0.57 | 0.8 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 128 | 3.96 | 0.35 | 0.46 | 0.62 | 0.8 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 107 | 3.93 | 0.22 | 0.33 | 0.63 | 0.8 |
| Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens | 49 | 4.60 | 0.25 | 0.36 | 0.71 | 1.0 |

Lot 1563 - Enriched 8.0 μmol/L blood

| METHOD | N | Mean | Average Within | | Y- Intercept* | Slope |
|--|-----|------|----------------|----------|---------------|-------|
| | | | Lab SD | Total SD | | |
| Derivatized - MS/MS non-kit | 912 | 7.47 | 0.68 | 1.03 | 0.72 | 0.9 |
| Non-derivatized - MS/MS non-kit | 243 | 8.01 | 0.73 | 1.22 | 0.73 | 0.9 |
| Derivatized - MS/MS PE NeoGram Kit | 109 | 6.54 | 0.69 | 1.10 | 0.60 | 0.8 |
| Non-derivatized - MS/MS PE NeoBase Kit | 710 | 7.03 | 0.42 | 0.63 | 0.57 | 0.8 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 127 | 7.06 | 0.50 | 0.79 | 0.62 | 0.8 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 109 | 7.09 | 0.49 | 0.68 | 0.63 | 0.8 |
| Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens | 50 | 8.33 | 0.50 | 0.76 | 0.71 | 1.0 |

Lot 1564 - Enriched 12.0 μmol/L blood

| METHOD | N | Mean | Average Within | | Y- Intercept* | Slope |
|--|-----|-------|----------------|----------|---------------|-------|
| | | | Lab SD | Total SD | | |
| Derivatized - MS/MS non-kit | 925 | 11.30 | 1.01 | 1.57 | 0.72 | 0.9 |
| Non-derivatized - MS/MS non-kit | 249 | 11.89 | 0.89 | 1.72 | 0.73 | 0.9 |
| Derivatized - MS/MS PE NeoGram Kit | 107 | 10.00 | 1.06 | 1.65 | 0.60 | 0.8 |
| Non-derivatized - MS/MS PE NeoBase Kit | 705 | 10.78 | 0.64 | 0.96 | 0.57 | 0.8 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 127 | 10.77 | 0.78 | 1.21 | 0.62 | 0.8 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 107 | 10.49 | 0.64 | 0.87 | 0.63 | 0.8 |
| Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens | 50 | 12.44 | 0.74 | 1.14 | 0.71 | 1.0 |

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

**Table 17ff. 2015 Quality Control Data Summaries of Statistical Analyses
HYDROXYPALMITOYL CARNITINE ($\mu\text{mol C16OH/L blood}$)**

Lot 1465 - Nonenriched 0 $\mu\text{mol/L blood}$

| METHOD | N | Mean | Average Within | | Y- Intercept* | Slope |
|--|-----|------|----------------|----------|---------------|-------|
| | | | Lab SD | Total SD | | |
| Derivatized - MS/MS non-kit | 830 | 0.02 | 0.01 | 0.02 | 0.01 | 0.7 |
| Non-derivatized - MS/MS non-kit | 179 | 0.01 | 0.00 | 0.01 | 0.01 | 0.7 |
| Derivatized - MS/MS PE NeoGram Kit | 126 | 0.02 | 0.01 | 0.01 | 0.01 | 0.7 |
| Non-derivatized - MS/MS PE NeoBase Kit | 642 | 0.01 | 0.00 | 0.01 | 0.01 | 0.6 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 96 | 0.01 | 0.01 | 0.01 | 0.01 | 0.7 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 84 | 0.01 | 0.00 | 0.01 | 0.00 | 0.6 |
| Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens | 70 | 0.01 | 0.00 | 0.00 | 0.00 | 0.7 |

Lot 1466 - Enriched 0.25 $\mu\text{mol/L blood}$

| METHOD | N | Mean | Average Within | | Y- Intercept* | Slope |
|--|-----|------|----------------|----------|---------------|-------|
| | | | Lab SD | Total SD | | |
| Derivatized - MS/MS non-kit | 823 | 0.19 | 0.03 | 0.05 | 0.01 | 0.7 |
| Non-derivatized - MS/MS non-kit | 178 | 0.18 | 0.02 | 0.03 | 0.01 | 0.7 |
| Derivatized - MS/MS PE NeoGram Kit | 124 | 0.17 | 0.03 | 0.03 | 0.01 | 0.7 |
| Non-derivatized - MS/MS PE NeoBase Kit | 627 | 0.15 | 0.01 | 0.02 | 0.01 | 0.6 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 98 | 0.19 | 0.04 | 0.07 | 0.01 | 0.7 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 86 | 0.17 | 0.04 | 0.07 | 0.00 | 0.6 |
| Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens | 70 | 0.16 | 0.01 | 0.05 | 0.00 | 0.7 |

Lot 1467 - Enriched 0.5 $\mu\text{mol/L blood}$

| METHOD | N | Mean | Average Within | | Y- Intercept* | Slope |
|--|-----|------|----------------|----------|---------------|-------|
| | | | Lab SD | Total SD | | |
| Derivatized - MS/MS non-kit | 823 | 0.35 | 0.06 | 0.10 | 0.01 | 0.7 |
| Non-derivatized - MS/MS non-kit | 178 | 0.34 | 0.04 | 0.06 | 0.01 | 0.7 |
| Derivatized - MS/MS PE NeoGram Kit | 128 | 0.33 | 0.05 | 0.07 | 0.01 | 0.7 |
| Non-derivatized - MS/MS PE NeoBase Kit | 626 | 0.29 | 0.03 | 0.04 | 0.01 | 0.6 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 99 | 0.37 | 0.06 | 0.09 | 0.01 | 0.7 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 85 | 0.30 | 0.06 | 0.13 | 0.00 | 0.6 |
| Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens | 69 | 0.34 | 0.02 | 0.07 | 0.00 | 0.7 |

Lot 1468 - Enriched 1.0 $\mu\text{mol/L blood}$

| METHOD | N | Mean | Average Within | | Y- Intercept* | Slope |
|--|-----|------|----------------|----------|---------------|-------|
| | | | Lab SD | Total SD | | |
| Derivatized - MS/MS non-kit | 828 | 0.70 | 0.09 | 0.18 | 0.01 | 0.7 |
| Non-derivatized - MS/MS non-kit | 183 | 0.70 | 0.09 | 0.14 | 0.01 | 0.7 |
| Derivatized - MS/MS PE NeoGram Kit | 130 | 0.67 | 0.09 | 0.14 | 0.01 | 0.7 |
| Non-derivatized - MS/MS PE NeoBase Kit | 626 | 0.60 | 0.05 | 0.08 | 0.01 | 0.6 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 91 | 0.72 | 0.09 | 0.13 | 0.01 | 0.7 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 89 | 0.65 | 0.09 | 0.25 | 0.00 | 0.6 |
| Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens | 70 | 0.69 | 0.05 | 0.14 | 0.00 | 0.7 |

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

2015 Quality Control Data Summaries of Statistical Analyses
HYDROXYPALMITOYL CARNITINE ($\mu\text{mol C16OH/L blood}$)

Lot 1561 - Nonenriched 0 $\mu\text{mol/L blood}$

| METHOD | N | Mean | Average Within | | Y- Intercept* | Slope |
|--|-----|------|----------------|----------|---------------|-------|
| | | | Lab SD | Total SD | | |
| Derivatized - MS/MS non-kit | 879 | 0.01 | 0.01 | 0.01 | 0.01 | 0.7 |
| Non-derivatized - MS/MS non-kit | 233 | 0.01 | 0.00 | 0.01 | 0.00 | 0.8 |
| Derivatized - MS/MS PE NeoGram Kit | 94 | 0.01 | 0.01 | 0.01 | 0.02 | 0.7 |
| Non-derivatized - MS/MS PE NeoBase Kit | 718 | 0.01 | 0.00 | 0.01 | 0.01 | 0.6 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 123 | 0.01 | 0.01 | 0.01 | 0.01 | 0.7 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 93 | 0.00 | 0.00 | 0.00 | 0.00 | 0.6 |
| Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens | 50 | 0.00 | 0.00 | 0.00 | 0.00 | 0.8 |

Lot 1562 - Enriched 0.25 $\mu\text{mol/L blood}$

| METHOD | N | Mean | Average Within | | Y- Intercept* | Slope |
|--|-----|------|----------------|----------|---------------|-------|
| | | | Lab SD | Total SD | | |
| Derivatized - MS/MS non-kit | 878 | 0.20 | 0.03 | 0.05 | 0.01 | 0.7 |
| Non-derivatized - MS/MS non-kit | 242 | 0.20 | 0.03 | 0.06 | 0.00 | 0.8 |
| Derivatized - MS/MS PE NeoGram Kit | 99 | 0.19 | 0.04 | 0.04 | 0.02 | 0.7 |
| Non-derivatized - MS/MS PE NeoBase Kit | 696 | 0.16 | 0.02 | 0.03 | 0.01 | 0.6 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 121 | 0.19 | 0.03 | 0.05 | 0.01 | 0.7 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 99 | 0.15 | 0.01 | 0.05 | 0.00 | 0.6 |
| Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens | 50 | 0.21 | 0.02 | 0.06 | 0.00 | 0.8 |

Lot 1563 - Enriched 1.0 $\mu\text{mol/L blood}$

| METHOD | N | Mean | Average Within | | Y- Intercept* | Slope |
|--|-----|------|----------------|----------|---------------|-------|
| | | | Lab SD | Total SD | | |
| Derivatized - MS/MS non-kit | 876 | 0.74 | 0.08 | 0.15 | 0.01 | 0.7 |
| Non-derivatized - MS/MS non-kit | 239 | 0.78 | 0.09 | 0.23 | 0.00 | 0.8 |
| Derivatized - MS/MS PE NeoGram Kit | 100 | 0.68 | 0.09 | 0.12 | 0.02 | 0.7 |
| Non-derivatized - MS/MS PE NeoBase Kit | 710 | 0.62 | 0.04 | 0.08 | 0.01 | 0.6 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 118 | 0.71 | 0.07 | 0.12 | 0.01 | 0.7 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 93 | 0.56 | 0.04 | 0.14 | 0.00 | 0.6 |
| Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens | 50 | 0.80 | 0.05 | 0.26 | 0.00 | 0.8 |

Lot 1564 - Enriched 1.5 $\mu\text{mol/L blood}$

| METHOD | N | Mean | Average Within | | Y- Intercept* | Slope |
|--|-----|------|----------------|----------|---------------|-------|
| | | | Lab SD | Total SD | | |
| Derivatized - MS/MS non-kit | 884 | 1.13 | 0.12 | 0.24 | 0.01 | 0.7 |
| Non-derivatized - MS/MS non-kit | 237 | 1.18 | 0.13 | 0.33 | 0.00 | 0.8 |
| Derivatized - MS/MS PE NeoGram Kit | 98 | 1.04 | 0.16 | 0.23 | 0.02 | 0.7 |
| Non-derivatized - MS/MS PE NeoBase Kit | 704 | 0.94 | 0.07 | 0.12 | 0.01 | 0.6 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 116 | 1.06 | 0.13 | 0.20 | 0.01 | 0.7 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 94 | 0.88 | 0.07 | 0.25 | 0.00 | 0.6 |
| Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens | 50 | 1.21 | 0.08 | 0.39 | 0.00 | 0.8 |

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

**Table 17gg. 2015 Quality Control Data Summaries of Statistical Analyses
STEAROYL Carnitine ($\mu\text{mol C18/L blood}$)**

Lot 1465 - Nonenriched 0 $\mu\text{mol/L blood}$

| METHOD | N | Mean | Average Within | | Y- Intercept* | Slope |
|--|-----|------|----------------|----------|---------------|-------|
| | | | Lab SD | Total SD | | |
| Derivatized - MS/MS non-kit | 796 | 0.64 | 0.08 | 0.13 | 0.67 | 0.9 |
| Non-derivatized - MS/MS non-kit | 157 | 0.64 | 0.06 | 0.08 | 0.64 | 0.9 |
| Derivatized - MS/MS PE NeoGram Kit | 119 | 0.63 | 0.08 | 0.11 | 0.63 | 0.9 |
| Non-derivatized - MS/MS PE NeoBase Kit | 646 | 0.63 | 0.05 | 0.06 | 0.64 | 0.9 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 104 | 0.65 | 0.09 | 0.11 | 0.65 | 0.9 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 90 | 0.59 | 0.06 | 0.13 | 0.60 | 0.9 |

Lot 1466 - Enriched 1.0 $\mu\text{mol/L blood}$

| METHOD | N | Mean | Average Within | | Y- Intercept* | Slope |
|--|-----|------|----------------|----------|---------------|-------|
| | | | Lab SD | Total SD | | |
| Derivatized - MS/MS non-kit | 810 | 1.54 | 0.18 | 0.29 | 0.67 | 0.9 |
| Non-derivatized - MS/MS non-kit | 158 | 1.56 | 0.14 | 0.21 | 0.64 | 0.9 |
| Derivatized - MS/MS PE NeoGram Kit | 117 | 1.49 | 0.15 | 0.19 | 0.63 | 0.9 |
| Non-derivatized - MS/MS PE NeoBase Kit | 646 | 1.57 | 0.11 | 0.14 | 0.64 | 0.9 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 108 | 1.52 | 0.22 | 0.29 | 0.65 | 0.9 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 90 | 1.44 | 0.14 | 0.31 | 0.60 | 0.9 |

Lot 1467 - Enriched 2.0 $\mu\text{mol/L blood}$

| METHOD | N | Mean | Average Within | | Y- Intercept* | Slope |
|--|-----|------|----------------|----------|---------------|-------|
| | | | Lab SD | Total SD | | |
| Derivatized - MS/MS non-kit | 811 | 2.42 | 0.26 | 0.44 | 0.67 | 0.9 |
| Non-derivatized - MS/MS non-kit | 154 | 2.46 | 0.22 | 0.32 | 0.64 | 0.9 |
| Derivatized - MS/MS PE NeoGram Kit | 118 | 2.44 | 0.24 | 0.34 | 0.63 | 0.9 |
| Non-derivatized - MS/MS PE NeoBase Kit | 656 | 2.52 | 0.18 | 0.25 | 0.64 | 0.9 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 107 | 2.42 | 0.29 | 0.39 | 0.65 | 0.9 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 87 | 2.32 | 0.21 | 0.47 | 0.60 | 0.9 |

Lot 1468 - Enriched 5.0 $\mu\text{mol/L blood}$

| METHOD | N | Mean | Average Within | | Y- Intercept* | Slope |
|--|-----|------|----------------|----------|---------------|-------|
| | | | Lab SD | Total SD | | |
| Derivatized - MS/MS non-kit | 804 | 4.97 | 0.50 | 0.88 | 0.67 | 0.9 |
| Non-derivatized - MS/MS non-kit | 154 | 5.17 | 0.37 | 0.75 | 0.64 | 0.9 |
| Derivatized - MS/MS PE NeoGram Kit | 118 | 5.01 | 0.49 | 0.64 | 0.63 | 0.9 |
| Non-derivatized - MS/MS PE NeoBase Kit | 654 | 5.30 | 0.38 | 0.54 | 0.64 | 0.9 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 104 | 5.02 | 0.50 | 0.68 | 0.65 | 0.9 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 90 | 4.84 | 0.40 | 0.82 | 0.60 | 0.9 |

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

2015 Quality Control Data Summaries of Statistical Analyses STEAROYL Carnitine (µmol C18/L blood)

Lot 1561 - Nonenriched 0 µmol/L blood

| METHOD | N | Mean | Average Within | | Y- Intercept* | Slope |
|--|-----|------|----------------|----------|---------------|-------|
| | | | Lab SD | Total SD | | |
| Derivatized - MS/MS non-kit | 862 | 0.64 | 0.09 | 0.14 | 0.63 | 0.9 |
| Non-derivatized - MS/MS non-kit | 203 | 0.64 | 0.06 | 0.10 | 0.63 | 0.9 |
| Derivatized - MS/MS PE NeoGram Kit | 105 | 0.63 | 0.10 | 0.12 | 0.61 | 0.9 |
| Non-derivatized - MS/MS PE NeoBase Kit | 685 | 0.60 | 0.04 | 0.06 | 0.58 | 0.9 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 119 | 0.58 | 0.09 | 0.19 | 0.55 | 0.9 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 108 | 0.55 | 0.05 | 0.07 | 0.55 | 0.9 |
| Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens | 48 | 0.62 | 0.04 | 0.04 | 0.60 | 1.0 |

Lot 1562 - Enriched 1.0 µmol/L blood

| METHOD | N | Mean | Average Within | | Y- Intercept* | Slope |
|--|-----|------|----------------|----------|---------------|-------|
| | | | Lab SD | Total SD | | |
| Derivatized - MS/MS non-kit | 856 | 1.55 | 0.17 | 0.31 | 0.63 | 0.9 |
| Non-derivatized - MS/MS non-kit | 205 | 1.58 | 0.13 | 0.23 | 0.63 | 0.9 |
| Derivatized - MS/MS PE NeoGram Kit | 109 | 1.52 | 0.20 | 0.23 | 0.61 | 0.9 |
| Non-derivatized - MS/MS PE NeoBase Kit | 704 | 1.55 | 0.11 | 0.16 | 0.58 | 0.9 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 116 | 1.44 | 0.16 | 0.33 | 0.55 | 0.9 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 107 | 1.42 | 0.09 | 0.12 | 0.55 | 0.9 |
| Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens | 47 | 1.59 | 0.08 | 0.09 | 0.60 | 1.0 |

Lot 1563 - Enriched 3.0 µmol/L blood

| METHOD | N | Mean | Average Within | | Y- Intercept* | Slope |
|--|-----|------|----------------|----------|---------------|-------|
| | | | Lab SD | Total SD | | |
| Derivatized - MS/MS non-kit | 844 | 3.19 | 0.33 | 0.59 | 0.63 | 0.9 |
| Non-derivatized - MS/MS non-kit | 205 | 3.40 | 0.25 | 0.44 | 0.63 | 0.9 |
| Derivatized - MS/MS PE NeoGram Kit | 110 | 3.12 | 0.31 | 0.41 | 0.61 | 0.9 |
| Non-derivatized - MS/MS PE NeoBase Kit | 690 | 3.30 | 0.22 | 0.31 | 0.58 | 0.9 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 116 | 3.04 | 0.28 | 0.68 | 0.55 | 0.9 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 107 | 3.11 | 0.21 | 0.29 | 0.55 | 0.9 |
| Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens | 50 | 3.49 | 0.23 | 0.24 | 0.60 | 1.0 |

Lot 1564 - Enriched 5.0 µmol/L blood

| METHOD | N | Mean | Average Within | | Y- Intercept* | Slope |
|--|-----|------|----------------|----------|---------------|-------|
| | | | Lab SD | Total SD | | |
| Derivatized - MS/MS non-kit | 851 | 5.09 | 0.53 | 0.93 | 0.63 | 0.9 |
| Non-derivatized - MS/MS non-kit | 210 | 5.35 | 0.37 | 0.73 | 0.63 | 0.9 |
| Derivatized - MS/MS PE NeoGram Kit | 109 | 5.06 | 0.60 | 0.72 | 0.61 | 0.9 |
| Non-derivatized - MS/MS PE NeoBase Kit | 695 | 5.33 | 0.32 | 0.47 | 0.58 | 0.9 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 117 | 4.97 | 0.52 | 1.00 | 0.55 | 0.9 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 107 | 4.82 | 0.33 | 0.44 | 0.55 | 0.9 |
| Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens | 48 | 5.55 | 0.32 | 0.34 | 0.60 | 1.0 |

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

**Table 17hh. 2015 Quality Control Data Summaries of Statistical Analyses
HYDROXYSTEAROYL Carnitine ($\mu\text{mol C18OH/L blood}$)**

Lot 1465 - Nonenriched 0 $\mu\text{mol/L blood}$

| METHOD | N | Mean | Average Within | | Y- Intercept* | Slope |
|--|-----|------|----------------|----------|---------------|-------|
| | | | Lab SD | Total SD | | |
| Derivatized - MS/MS non-kit | 609 | 0.01 | 0.01 | 0.02 | 0.01 | 0.6 |
| Non-derivatized - MS/MS non-kit | 95 | 0.01 | 0.00 | 0.01 | 0.01 | 0.5 |
| Derivatized - MS/MS PE NeoGram Kit | 121 | 0.01 | 0.01 | 0.01 | 0.01 | 0.6 |
| Non-derivatized - MS/MS PE NeoBase Kit | 542 | 0.00 | 0.00 | 0.00 | 0.00 | 0.6 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 84 | 0.01 | 0.01 | 0.01 | 0.02 | 0.7 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 85 | 0.01 | 0.00 | 0.01 | 0.01 | 0.5 |

Lot 1466 - Enriched 0.5 $\mu\text{mol/L blood}$

| METHOD | N | Mean | Average Within | | Y- Intercept* | Slope |
|--|-----|------|----------------|----------|---------------|-------|
| | | | Lab SD | Total SD | | |
| Derivatized - MS/MS non-kit | 614 | 0.31 | 0.06 | 0.11 | 0.01 | 0.6 |
| Non-derivatized - MS/MS non-kit | 98 | 0.27 | 0.03 | 0.11 | 0.01 | 0.5 |
| Derivatized - MS/MS PE NeoGram Kit | 128 | 0.31 | 0.05 | 0.07 | 0.01 | 0.6 |
| Non-derivatized - MS/MS PE NeoBase Kit | 535 | 0.28 | 0.02 | 0.04 | 0.00 | 0.6 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 90 | 0.35 | 0.10 | 0.15 | 0.02 | 0.7 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 89 | 0.26 | 0.04 | 0.12 | 0.01 | 0.5 |

Lot 1467 - Enriched 1.0 $\mu\text{mol/L blood}$

| METHOD | N | Mean | Average Within | | Y- Intercept* | Slope |
|--|-----|------|----------------|----------|---------------|-------|
| | | | Lab SD | Total SD | | |
| Derivatized - MS/MS non-kit | 615 | 0.61 | 0.09 | 0.22 | 0.01 | 0.6 |
| Non-derivatized - MS/MS non-kit | 96 | 0.52 | 0.07 | 0.23 | 0.01 | 0.5 |
| Derivatized - MS/MS PE NeoGram Kit | 127 | 0.60 | 0.08 | 0.12 | 0.01 | 0.6 |
| Non-derivatized - MS/MS PE NeoBase Kit | 537 | 0.55 | 0.05 | 0.08 | 0.00 | 0.6 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 87 | 0.67 | 0.11 | 0.20 | 0.02 | 0.7 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 88 | 0.48 | 0.08 | 0.23 | 0.01 | 0.5 |

Lot 1468 - Enriched 1.5 $\mu\text{mol/L blood}$

| METHOD | N | Mean | Average Within | | Y- Intercept* | Slope |
|--|-----|------|----------------|----------|---------------|-------|
| | | | Lab SD | Total SD | | |
| Derivatized - MS/MS non-kit | 594 | 0.94 | 0.13 | 0.27 | 0.01 | 0.6 |
| Non-derivatized - MS/MS non-kit | 98 | 0.80 | 0.08 | 0.40 | 0.01 | 0.5 |
| Derivatized - MS/MS PE NeoGram Kit | 130 | 0.91 | 0.11 | 0.18 | 0.01 | 0.6 |
| Non-derivatized - MS/MS PE NeoBase Kit | 540 | 0.85 | 0.07 | 0.13 | 0.00 | 0.6 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 86 | 0.99 | 0.11 | 0.30 | 0.02 | 0.7 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 87 | 0.73 | 0.10 | 0.37 | 0.01 | 0.5 |

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

2015 Quality Control Data Summaries of Statistical Analyses
HYDROXYSTEAROYL CARNITINE ($\mu\text{mol C18OH/L blood}$)

Lot 1561 - Nonenriched 0 $\mu\text{mol/L blood}$

| METHOD | N | Mean | Average Within | | Y- Intercept* | Slope |
|--|-----|------|----------------|----------|---------------|-------|
| | | | Lab SD | Total SD | | |
| Derivatized - MS/MS non-kit | 627 | 0.01 | 0.01 | 0.01 | 0.01 | 0.7 |
| Non-derivatized - MS/MS non-kit | 136 | 0.01 | 0.00 | 0.01 | 0.01 | 0.7 |
| Derivatized - MS/MS PE NeoGram Kit | 96 | 0.01 | 0.01 | 0.01 | 0.02 | 0.6 |
| Non-derivatized - MS/MS PE NeoBase Kit | 586 | 0.00 | 0.00 | 0.01 | 0.00 | 0.6 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 99 | 0.01 | 0.00 | 0.01 | 0.03 | 0.6 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 93 | 0.00 | 0.00 | 0.00 | 0.00 | 0.5 |

Lot 1562 - Enriched 0.25 $\mu\text{mol/L blood}$

| METHOD | N | Mean | Average Within | | Y- Intercept* | Slope |
|--|-----|------|----------------|----------|---------------|-------|
| | | | Lab SD | Total SD | | |
| Derivatized - MS/MS non-kit | 631 | 0.18 | 0.03 | 0.06 | 0.01 | 0.7 |
| Non-derivatized - MS/MS non-kit | 135 | 0.17 | 0.03 | 0.12 | 0.01 | 0.7 |
| Derivatized - MS/MS PE NeoGram Kit | 99 | 0.18 | 0.04 | 0.04 | 0.02 | 0.6 |
| Non-derivatized - MS/MS PE NeoBase Kit | 566 | 0.15 | 0.02 | 0.02 | 0.00 | 0.6 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 107 | 0.19 | 0.03 | 0.07 | 0.03 | 0.6 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 96 | 0.12 | 0.02 | 0.04 | 0.00 | 0.5 |

Lot 1563 - Enriched 1.0 $\mu\text{mol/L blood}$

| METHOD | N | Mean | Average Within | | Y- Intercept* | Slope |
|--|-----|------|----------------|----------|---------------|-------|
| | | | Lab SD | Total SD | | |
| Derivatized - MS/MS non-kit | 648 | 0.68 | 0.09 | 0.20 | 0.01 | 0.7 |
| Non-derivatized - MS/MS non-kit | 135 | 0.70 | 0.11 | 0.45 | 0.01 | 0.7 |
| Derivatized - MS/MS PE NeoGram Kit | 98 | 0.66 | 0.09 | 0.12 | 0.02 | 0.6 |
| Non-derivatized - MS/MS PE NeoBase Kit | 568 | 0.60 | 0.04 | 0.07 | 0.00 | 0.6 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 110 | 0.69 | 0.10 | 0.19 | 0.03 | 0.6 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 100 | 0.52 | 0.05 | 0.15 | 0.00 | 0.5 |

Lot 1564 - Enriched 1.5 $\mu\text{mol/L blood}$

| METHOD | N | Mean | Average Within | | Y- Intercept* | Slope |
|--|-----|------|----------------|----------|---------------|-------|
| | | | Lab SD | Total SD | | |
| Derivatized - MS/MS non-kit | 628 | 1.00 | 0.12 | 0.26 | 0.01 | 0.7 |
| Non-derivatized - MS/MS non-kit | 135 | 1.02 | 0.10 | 0.70 | 0.01 | 0.7 |
| Derivatized - MS/MS PE NeoGram Kit | 99 | 0.97 | 0.14 | 0.20 | 0.02 | 0.6 |
| Non-derivatized - MS/MS PE NeoBase Kit | 592 | 0.89 | 0.06 | 0.12 | 0.00 | 0.6 |
| Derivatized - MS/MS Chromsystems MassChrom Kit | 107 | 0.96 | 0.12 | 0.29 | 0.03 | 0.6 |
| Non-derivatized - MS/MS Chromsystems MassChrom Kit | 97 | 0.76 | 0.09 | 0.19 | 0.00 | 0.5 |

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

Table 17ii. 2015 Quality Control Data Summaries of Statistical Analyses
24:0-LYSOPHOSPHATIDYLCHOLINE (μmol 24LPC/L blood)

Lot 14101 - Nonenriched 0 μmol /L blood

| METHOD | N | Mean | Average Within | | Y- Intercept* | Slope |
|-----------|----|------|----------------|----------|---------------|-------|
| | | | Lab SD | Total SD | | |
| LC-MS/MS | 50 | 0.09 | 0.02 | 0.08 | 0.12 | 1.0 |
| FIA-MS/MS | 30 | 0.30 | 0.09 | 0.12 | 0.28 | 1.4 |

Lot 14102 - Enriched 1.0 μmol /L blood

| METHOD | N | Mean | Average Within | | Y- Intercept* | Slope |
|-----------|----|------|----------------|----------|---------------|-------|
| | | | Lab SD | Total SD | | |
| LC-MS/MS | 49 | 1.10 | 0.20 | 0.46 | 0.12 | 1.0 |
| FIA-MS/MS | 30 | 1.65 | 0.29 | 0.29 | 0.28 | 1.4 |

Lot 14103 - Enriched 5.0 μmol /L blood

| METHOD | N | Mean | Average Within | | Y- Intercept* | Slope |
|-----------|----|------|----------------|----------|---------------|-------|
| | | | Lab SD | Total SD | | |
| LC-MS/MS | 50 | 4.87 | 1.05 | 2.00 | 0.12 | 1.0 |
| FIA-MS/MS | 30 | 7.25 | 1.23 | 1.23 | 0.28 | 1.4 |

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

**Table 17jj. 2015 Quality Control Data Summaries of Statistical Analyses
26:0 LYSOPHOSPHATIDYLCHOLINE (μmol 26LPC/L blood)**

Lot 14101 - Nonenriched 0 μmol/L blood

| METHOD | N | Mean | Average Within | | Y- Intercept* | Slope |
|-----------|----|------|----------------|----------|---------------|-------|
| | | | Lab SD | Total SD | | |
| LC-MS/MS | 50 | 0.06 | 0.01 | 0.08 | 0.08 | 0.9 |
| FIA-MS/MS | 40 | 0.26 | 0.11 | 0.12 | 0.27 | 1.1 |

Lot 14102 - Enriched 1.0 μmol/L blood

| METHOD | N | Mean | Average Within | | Y- Intercept* | Slope |
|-----------|----|------|----------------|----------|---------------|-------|
| | | | Lab SD | Total SD | | |
| LC-MS/MS | 50 | 1.00 | 0.14 | 0.24 | 0.08 | 0.9 |
| FIA-MS/MS | 40 | 1.34 | 0.32 | 0.40 | 0.27 | 1.1 |

Lot 14103 - Enriched 5.0 μmol/L blood

| METHOD | N | Mean | Average Within | | Y- Intercept* | Slope |
|-----------|----|------|----------------|----------|---------------|-------|
| | | | Lab SD | Total SD | | |
| LC-MS/MS | 50 | 4.51 | 0.46 | 0.84 | 0.08 | 0.9 |
| FIA-MS/MS | 39 | 5.61 | 0.99 | 1.55 | 0.27 | 1.1 |

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

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CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC) ATLANTA, GA 30341

Director

Thomas R. Frieden, M.D., M.P.H.

Director

National Center for Environmental Health
Patrick Breyse, Ph.D.

Director

Division of Laboratory Sciences
James L. Pirkle, M.D., Ph.D.

Chief

Newborn Screening and Molecular Biology Branch
Carla Cuthbert, Ph.D.

Contributors:

Carter Asef
Suzanne Cordovado, Ph.D.
Paul Dantonio
Victor R. De Jesus, Ph.D.
Zachery Detwiler
Katherine Duneman
Sharon Flores
Christopher Greene, Ph.D.
Elizabeth M. Hall

Laura Hancock
Christopher Haynes, Ph.D.
Miyono Hendrix
Thai Le
Kameron Khaksarfard
Deborah Koontz, Ph.D.
Francis Lee, Ph.D.
Lixia Li, Ph.D.
Timothy Lim, Ph.D.
Daniel Mandel, Ph.D.
Joanne Mei, Ph.D.

Stanimila Nikolova, Ph.D.
Gyliann Peña
Dino Romero
Kelsey Sheard
Robert Vogt, Ph.D.
Irene Williams
Golriz Yazdanpanah
Hui Zhou, Ph.D.
Sherri Zobel

Production:

Sarah Brown
Kimberly Coulter

Chinh Nguyen
LoNeka Shockley

ASSOCIATION OF PUBLIC HEALTH LABORATORIES SILVER SPRING, MD 20910

President

Judith C. Lovchik, Ph.D., D(ABMM)

Chairman, Newborn Screening and Genetics in Public Health Committee

Susan M. Tanksley, Ph.D.

Chairman, Newborn Screening Quality Assurance Quality Control Subcommittee

Patricia R. Hunt, B.A. and Joseph Orsini, Ph.D.

Chairman, Newborn Screening Molecular Subcommittee

Michele Caggana, Sc.D., FACMG



INQUIRIES TO:

Sherri Zobel, Editor • Centers for Disease Control and Prevention (CDC) • Newborn Screening Quality Assurance Program
Mailstop F-24 • 4770 Buford Highway, N.E. • Atlanta, GA 30341-3724
Phone (770) 488-4582 • FAX (770) 488-4255
E-mail: SZobel@cdc.gov

