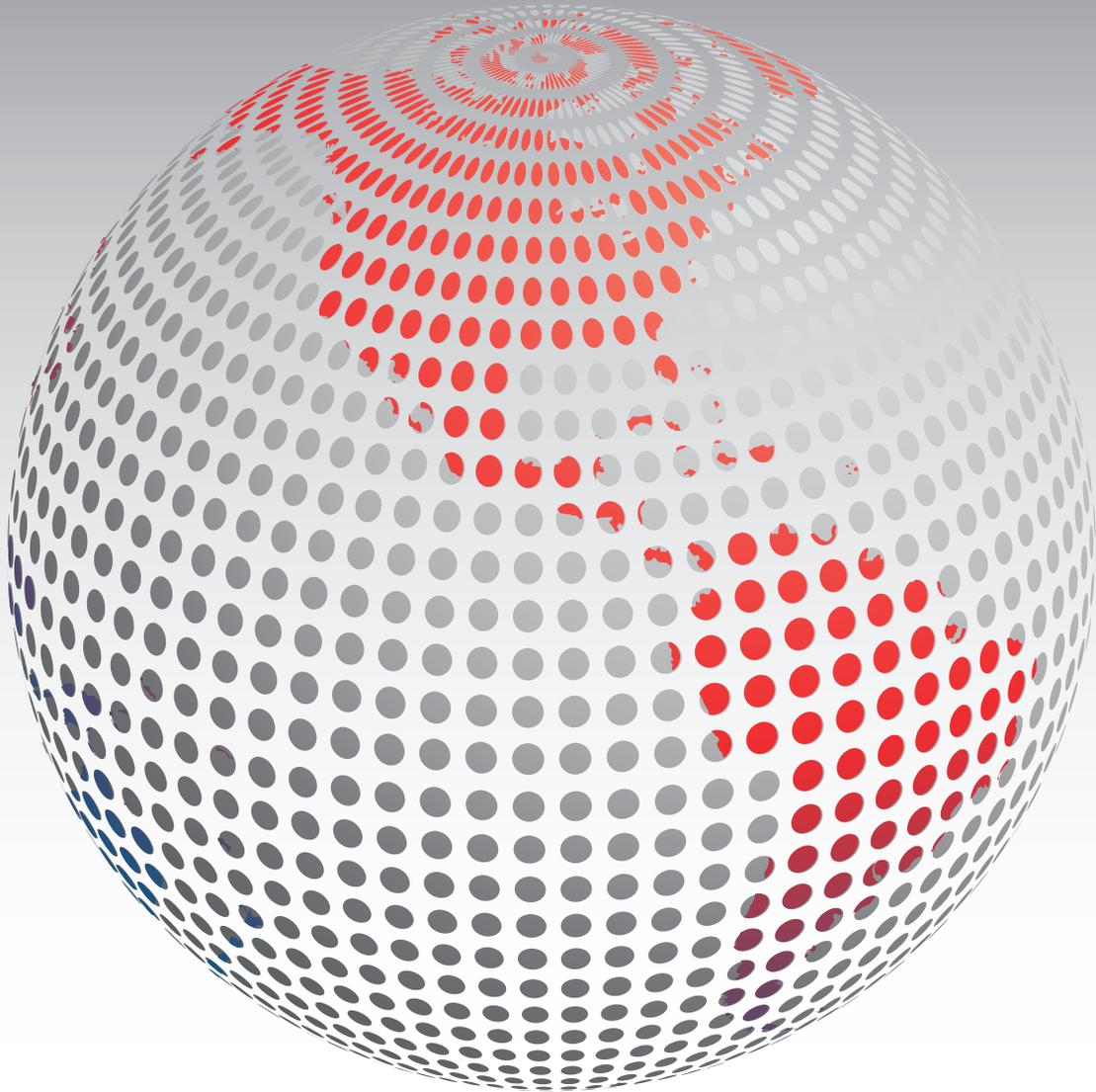


NEWBORN SCREENING

Annual Summary Report
volume 32

2014

Quality Assurance Program

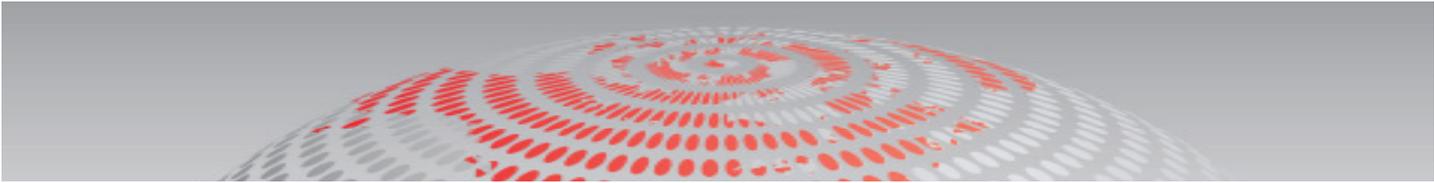


National Center for Environmental Health
Division of Laboratory Sciences



Centers for Disease Control and Prevention
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Newborn Screening Quality Assurance Program **Table of Contents**

4	In the News
5	Introduction
6	2014 Newborn Screening Program Highlights
8	2014 Biochemical Mass Spectrometry Laboratory Activities
9	2014 Newborn Screening Translation Research Initiative Activities
9	2014 Molecular Quality Improvement Program Activities
10	Additional 2014 NSQAP Activities
10	Filter Paper <i>Information about PerkinElmer and GE Healthcare Bio-Sciences papers; lots used for preparing CDC spots</i>
12	PT and QC Specimen Preparation and Data Handling <i>Specimen preparation; weighted linear regression</i>
12	Cutoffs <i>Means, medians, and modes for each analyte</i>
19	Proficiency Testing <i>Summary of analyte means and performance errors; bias plots</i>
23	Quality Control
24	References
26	Staff Peer-Reviewed Publications/Staff Posters and Presentations
28	Explanation of the Newborn Screening Quality Assurance Program's Grading Algorithm
30	Proficiency Testing Bias Plots
49	Index of Quality Control Tables
50	Quality Control Tables <i>By-method statistical analyses of QC data</i>
120	Credits <i>Listing of staff and partners</i>

Program Information Web site:
<http://www.cdc.gov/labstandards/nsqap.html>

Data-reporting Web site:
<https://wwwn.cdc.gov/nsqap/public/default.aspx>

In The News

Newborn Screening Quality Assurance Program says good-bye to Connie Singleton

For 15 years, Connie Singleton was the shipping coordinator for the Newborn Screening Quality Assurance Program (NSQAP). When Connie began work in 1999, there were only 200 participants in NSQAP. By the time she left, our program had grown to over 600 participants. Despite her title, Connie did so much more than shipping packages. She was responsible for new participant registration, domestic and international shipping, working with customs offices all over the world to ship dried blood spot (DBS) materials, encoding macros for data reporting spreadsheets used by proficiency testing and quality control participants, maintaining and programming internal databases, and providing excellent customer service to NSQAP participating laboratories.

Connie raised four wonderful sons, became a grandmother to a beautiful granddaughter in 2014, and completed her Master's degree in computer security. Connie recently joined and information technology security group within CDC and still keeps in touch with NSQAP.

She will be missed but we all wish her well in her new career.

Newborn Screening Quality Assurance Program

2014 NSQAP BY THE NUMBERS

100 percentage of states covered

77 countries participated

516,267 DBS produced

46 new enrollments

12 labs moved to inactive status

612 labs enrolled at end of year

609 labs reported data

512 labs participated in PT

461 labs participated in QC

31 reports provided to participants

2 filter paper lots evaluated

31 US labs participated when NSQAP was established in 1978

Source: Newborn Screening Quality Assurance Program, December 2014

INTRODUCTION

In the United States and much of the world, screening newborns for treatable, inherited metabolic diseases is a common practice. Detecting such diseases is a major public health responsibility [1]. Screening tests help identify newborns who, although asymptomatic, are likely to have a disease.

It is important to note that these screening tests alone are not intended to yield a diagnostic testing outcome. However, effective screening of newborns, combined with the use of DBS specimens collected at birth; follow up; diagnostic confirmation; and treatment, helps prevent mental retardation and premature death. State public health laboratories or their associated laboratories routinely screen DBS specimens for inborn errors of metabolism and other disorders that might require medical intervention. 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) NSQAP assists newborn screening laboratories with these testing processes. This report summarizes all phases of NSQAP's proficiency testing (PT) activities and summarizes all quality control (QC) data reported in 2014.

The NSQAP produces certified DBS materials for laboratory reference and 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. By working closely with participating laboratories, the 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. In that regard, we welcome comments and suggestions about how we can better serve participants' needs.

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). Although the NSQAP services support newborn screening testing by U.S. laboratories primarily, it also allows private and international laboratories to enroll in the program. All laboratories that test newborn DBS specimens participate voluntarily. The NSQAP provides QA services for the core (primary) and secondary conditions listed in the U.S. Recommended

5

New countries
joined NSQAP:
Bolivia, Ecuador,
Iraq, Macedonia,
Sri Lanka

Uniform Screening Panel (RUSP) [2]. 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

NSQAP produces and distributes two types of certified laboratory DBS materials: QC materials for periodic use, and PT materials three times a year. 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 program also helps laboratories maintain the requisite high-volume specimen throughput. The QC materials, which supplement the participants' method- or kit-control materials, allow participants to monitor long-term assay stability.

The PT program offers panels of blind-coded DBS specimens to laboratories; these specimens provide an independent, external assessment of each laboratory's performance. The NSQAP certifies DBS materials for QC and PT homogeneity, accuracy, stability, and suitability for newborn screening assays. However, the limited availability of appropriate blood sources means the program does not distribute QC materials for biotinidase deficiency, hemoglobins, CF Mutation Detection (CFDNA),



T-cell Receptor Excision Circle (TREC), or *Toxoplasma gondii* antibodies.

Over the years, the NSQAP has grown substantially. In 2014, active program participants included 612 newborn screening laboratories in 77 countries (at least one laboratory per country) (Figure 1). Of these laboratories, 512 participated in PT (Figure 2) and 461 in QC (Figure 3). The program distributed DBS materials for 45 analytes comprising primary markers for 48 disorders to participating laboratories (Figures 2–3).

Tandem mass spectrometry (MS/MS) has had a major impact on the data that laboratories report to the NSQAP. MS/MS-based methods that detect phenylalanine (Phe) in DBS have revolutionized the practice of newborn screening for amino acid, fatty acid oxidation, and organic acid metabolic disorders. Specifically, introducing MS/MS programs added more than 25 biomarkers into the NSQAP's PT and QC projects. These biomarkers comprise 42 disorders from the core (primary) and secondary RUSP panels.

2014 NEWBORN SCREENING PROGRAM HIGHLIGHTS

- NSQAP modified the amino acid PT panels to include succinylacetone (SUAC). Beginning July 2014, SUAC was included as part of the amino acid PT panels.
- NSQAP began shipping galactose-1-phosphate uridylyltransferase (GALT) QC materials. The materials include three levels of certified GALT QC, and participants in the program submitted quantitative data. Results of these data are included in the QC tables of this report.
- In cooperation with APHL, the Molecular Quality Improvement Program (MQIP) hosted the fourth annual Newborn Screening Molecular Training Workshop. This dynamic, annual, hands-on workshop comprised lectures and laboratory training activities that directly related to detecting newborn disorders using molecular methods.
- In May, the APHL-sponsored QA/QC Subcommittee of the Newborn Screening and Genetics in Public Health Committee met in Atlanta, GA. The subcommittee provides guidance to the NSQAP on procedures, policies, and activities for quality assessment of laboratory testing. Input from this subcommittee enhances our continuing efforts to serve our participants better.
- In May, the Biochemical Mass Spectrometry Laboratory (BMSL) hosted a 5-day workshop titled "Newborn Screening by Tandem Mass Spectrometry (MS/MS): A Hands-On Course in Understanding Laboratory Issues and Interpreting Test Results." APHL and CDC co-sponsored the workshop at CDC's laboratories in Atlanta, GA.
- In October, the APHL held the 2014 Newborn Screening and Genetic Testing Symposium titled

Figure 2. Number of Participants in Proficiency Testing Program, 2014
Total - 512

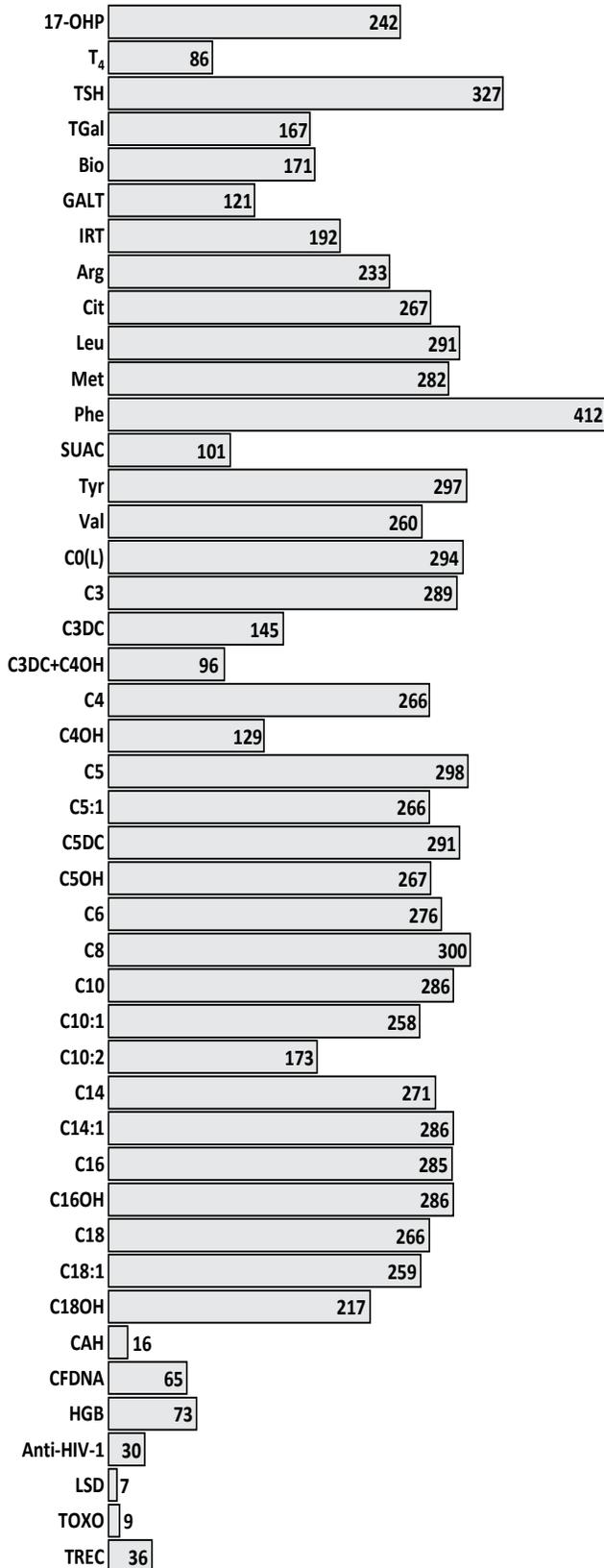
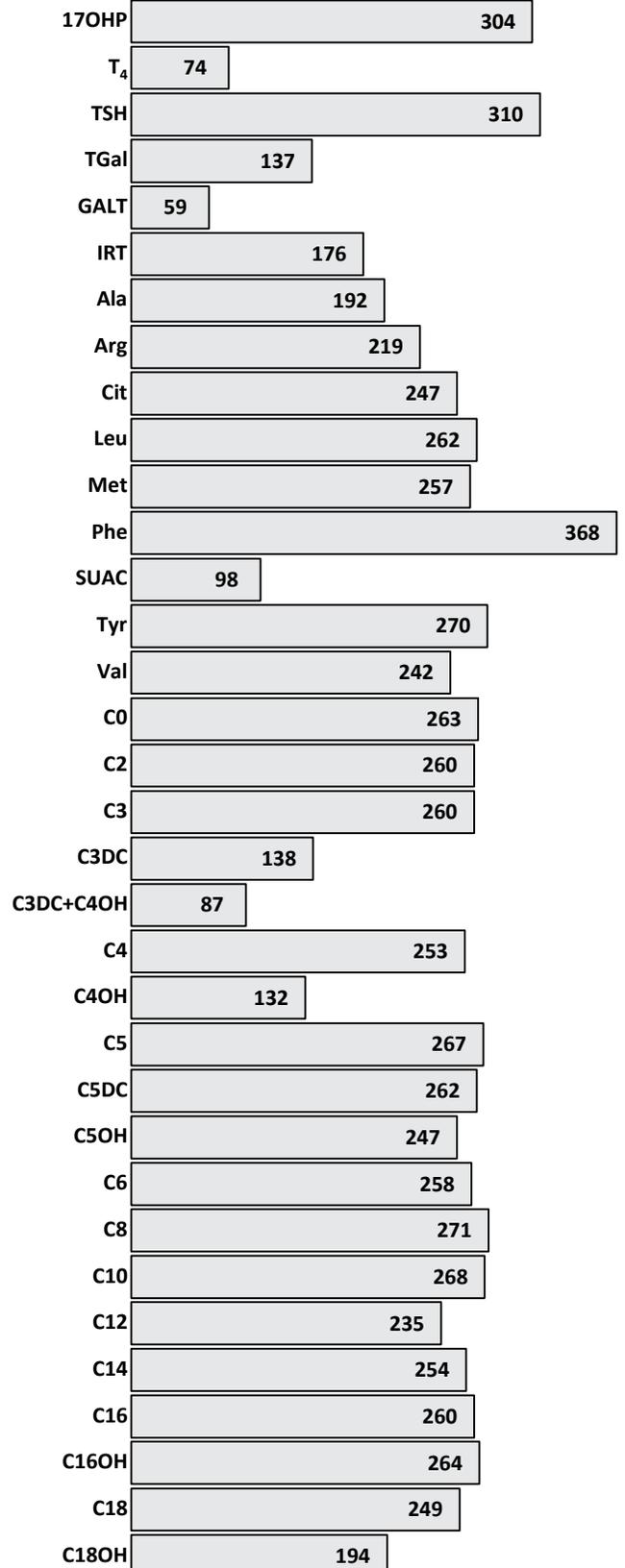


Figure 3. Number of Participants in Quality Control Program, 2014
Total - 461



“Newborn Screening: Re-assessing Business as Usual.” Newborn screening professionals from all over the world gathered in Anaheim, CA, for this 5-day symposium.

- With the help of MQIP, the Newborn Screening Molecular Resources expanded the APHL Web site to include information about adding robotic liquid-handling platforms to existing molecular analysis laboratories at <http://www.aphl.org/aphlprograms/newborn-screening-and-genetics/Pages/Molecular-Resources.aspx>. For more information, see the MQIP section of this report.
- The Newborn Screening Molecular Assessment Program (MAP) completed 13 site visits, and plans more visits in 2015. The MAP program offers onsite molecular laboratory visits to assist state newborn screening laboratories with quality assessments of their molecular programs. For more information, see the MQIP section of this report.
- NSQAP developed enhancements to the data-reporting Web site. Our goal is to make reporting easy and efficient for participants.
- Participants report the following program data by email: QC, hemoglobinopathies, TREC, lysosomal storage disorders, *Toxoplasma gondii*, CFDNA, and second-tier Congenital Adrenal Hyperplasia (CAH). Electronic reporting streamlines data processing, facilitates accumulation of statistical data, and allows better data sharing with our participants.

2014 BIOCHEMICAL MASS SPECTROMETRY LABORATORY ACTIVITIES

The Newborn Screening and Molecular Biology Branch’s (NSMBB) BMSL offers newborn screening MS/MS services, education, and research opportunities. In addition to amino acids and acylcarnitines, BMSL also oversees the biotinidase, Total Galactose (TGal), GALT, and filter-paper evaluation programs.

In May, BMSL hosted a highly successful laboratory workshop on newborn screening using MS/MS instrumentation. The 5-day intensive workshop was titled “Newborn Screening by Tandem Mass Spectrometry (MS/MS): A Hands-On Course in Understanding Laboratory Issues and Interpreting Test Results.” APHL and CDC co-sponsored the workshop at CDC’s NSMBB laboratories in Atlanta, GA. Ten attendees participated in four MS/MS hands-on exercises. The exercises

included both routine MS/MS newborn screening tests and second-tier testing using MS/MS methods applicable to the modern newborn screening system. The course is offered yearly.

The Clinical and Laboratory Standards Institute’s (CLSI) Document Development Committee on Newborn Screening by Tandem Mass Spectrometry (NBS04-A2) is currently revising the document. The revision committee (chaired by Dr. Víctor R. De Jesús) includes representatives from public health laboratories, industry, government, and other international stakeholders. BMSL scientists will provide extensive input. The standard will address:

- guidance on specimen and reagent preparation.
- instrument and analyte calibration.
- method validation.
- QA and QC, run-acceptance criteria with multi-analyte platforms.
- external treatment effects on test results (e.g., transfusions and total parenteral nutrition [TPN]).
- result interpretation and reporting.
- follow-up recommendations.
- use of MS/MS for second-tier testing.

BMSL led an investigation into NBS laboratories using SUAC as a primary marker to detect tyrosinemia type 1 (TYR 1). A review of the inconsistent implementation of effective screening for TYR 1, a condition included in the RUSP, prompted discussions with the Laboratory Standards and Procedures Subcommittee of the U.S. Health and Human Services Secretary’s (Discretionary) Advisory Committee on Heritable Disorders in Newborns and Children. Results were published in the journal *Molecular Genetics and Metabolism* [3].

BMSL continues to expand its QC and PT offerings for Galactosemia. The laboratory successfully prepared high-quality GALT QC materials distributed in July [4]. BMSL staff offered the GALT QC program to all participants. Fifty-nine NSQAP participants reported GALT QC data.

BMSL staff also successfully developed QC materials for X-linked adrenoleukodystrophy (X-ALD); these materials contain the marker 26:0-lysophosphatidylcholine (26-LPC), measured by MS/MS in DBS. BMSL distributed the materials to selected laboratories for evaluation, and the results indicated they are suitable for QC purposes. BMSL will launch the X-ALD QC program in January 2015. A companion X-ALD PT program is under development.

BMSL welcomes the opportunity to investigate new analytes and new mass spectrometry-based methods to serve our participants' needs. For more information about the laboratory or any of its current projects, please contact Dr. Víctor R. De Jesús at vdejesus@cdc.gov.

2014 NEWBORN SCREENING TRANSLATION RESEARCH INITIATIVE ACTIVITIES

CDC's Newborn Screening Translation Research Initiative ("the Initiative") is an ongoing collaboration between the CDC Foundation and CDC's NSMBB. In 2014, the Initiative completed its ninth year of operation. The Initiative's vision is the methodical expansion of newborn screening to detect more conditions in more infants throughout the world. The goal is for all infants with identified congenital disorders to have a better chance for a healthy childhood. The Initiative assembles public, academic, foundation, and corporate partnerships to support, both scientifically and financially, translational research efforts in newborn screening.

In 2014, representatives from six state public health programs participated in laboratory training workshops at CDC, where they produced and analyzed DBS reference materials for the TREC assay used to detect Severe Combined Immunodeficiency (SCID). The NSQAP expanded the TREC PT program to include international laboratories that screen newborns for SCID. The Initiative created a new cellular calibrator by inserting a TREC sequence into an immortalized B-cell line. The program participants evaluated the new TREC reference materials. Working with NSQAP, the Initiative continued to support PT challenges for Pompe and Krabbe disorders using condition-specific DBS reference materials made from immortalized cell lines. The Initiative optimized additional condition-specific materials for Fabry and MPS I and prepared them for inter-laboratory evaluation; they will be added to the NSQAP PT program in 2015. The Initiative developed and published a method to detect SCID and spinal muscular atrophy simultaneously in the same real-time PCR reaction on DBS [5]. More than a dozen partnerships were involved in these projects, and many of those partners contributed both scientific and financial support.

For more information about the Newborn Screening Translation Research Initiative, please contact Dr. Robert Vogt at rvogt@cdc.gov. We welcome ideas for new projects and partnerships.

2014 MOLECULAR QUALITY IMPROVEMENT PROGRAM ACTIVITIES

CDC MQIP provides comprehensive molecular testing assistance to newborn screening laboratories. Most of the state programs offer at least one molecular test, therefore MQIP provides molecular-specific technical assistance on QA issues, troubleshooting, and educational resources for newborn screening laboratories that conduct molecular testing. In addition, MQIP works closely with APHL's Molecular Subcommittee to facilitate the exchange of molecular best practices and to anticipate future newborn screening molecular needs.

MQIP's Newborn Screening MAP has performed 13 invited site visits in the United States, and plans additional program visits in 2015. MQIP staff, state public health molecular biologists, and APHL perform the on-site visits and tailor them to the unique needs of each newborn screening laboratory. Each MAP visit encompasses all components of the molecular testing procedure(s), including program-tailored guidance for laboratory-specified needs and assistance in evaluating ongoing and future molecular testing procedures. To request a MAP visit, visit the Newborn Screening Molecular Resources Web site at <http://www.aphl.org/aphlprograms/newborn-screening-and-genetics/molecular/pages/default.aspx>.

MQIP developed and launched the Newborn Screening Molecular Resources Web site in early 2014. The Web site provides detailed summaries and information about ongoing molecular assays, allows access the Newborn Screening MAP site visit portal and checklists, and allows viewing of archived presentations from newborn screening molecular workshops and webinars. In October 2014, MQIP expanded the Web site to include information to assist newborn screening laboratories that were considering adding robotic liquid-handling platforms for molecular analysis. Within the automation section of the Web site, information about both semi-automated and highly automated instruments is available, including pros and cons for each type of system. The Web site also has descriptions detailing three types of molecular automation methods used in newborn screening (NBS) laboratories:

- 1) DNA extraction into a 96-well plate to be used for downstream applications,
- 2) PCR set-up description for DNA extract and amplification reagent transfer to either a 96- or 384-well PCR plate, and
- 3) On-card Assay method in which the DBS punch is washed in a 96-well plate and the PCR reagents are added directly to the well containing the punch.

In addition, a list of questions laboratories can use in their decision-making process to evaluate instrument hardware, software, maintenance, and manufacturer support is provided.

In March, MQIP hosted its fourth annual Newborn Screening Molecular Training Course and Laboratory Workshop. This dynamic course consisted of both lecture and laboratory segments directly related to detecting newborn disorders using molecular methods. Lecture topics included molecular assays in newborn screening, laboratory design and unidirectional workflow, comparison of instrument platforms for DBS genotyping, assay requirements for multiplex assay development, Next Generation sequencing and newborn screening, and data reporting and clinical interpretation. Newborn screening scientists from 14 states participated in this workshop.

In June, the March of Dimes awarded a grant to the University of Minnesota, the Minnesota Department of Health Newborn Screening Laboratory, and the MQIP program to develop and pilot test a second-tier molecular assay to detect mutations in the CYP21A2 gene, which causes congenital adrenal hyperplasia. Over the course of the three-year award period, MQIP will work together to develop and validate a molecular assay and to determine if a second-tier molecular approach could be used to increase the specificity of the primary 17-OHP assay.

MQIP has worked also with a manufacturer to develop a Next Generation sequencing assay for DNA extracted from DBS using the Ion Torrent to detect cystic fibrosis mutations in the CFTR gene. MQIP scientists enjoy working with participants to assist with any molecular laboratory needs and explore future needs. For more information, please contact Dr. Suzanne Cordovado at scordovado@cdc.gov.

ADDITIONAL 2014 NSQAP ACTIVITIES

FILTER PAPER

As a vital service to the newborn screening community, NSQAP evaluates the filter paper's absorption characteristics and other parameters of filter paper lots from manufacturers that have received FDA clearance (approval) for their blood-collection filter paper [6]. According to a mutually voluntary agreement, the filter paper manufacturers (GE Healthcare Bio-sciences Corporation and PerkinElmer Health Sciences) provide NSQAP with statistically valid sample sets from different reels of the unprinted filter paper production lot for evaluation using NSQAP's standardized procedures. The manufacturers are responsible for establishing their own parallel evalu-

ation laboratory. NSQAP provides evaluation results for comparison with those from the primary evaluator. NSQAP's independent 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. Description of the method is in the latest version of the CLSI Standard NBS01-A6, Blood Collection on Filter Paper for Newborn Screening Programs [6]. Mean counts per minute of added radioisotope-labeled thyroxine (T_4) contained within a 3.2-mm disk are equated with the serum volume of the disks made from whole-blood specimens. In comparing production lots, we use statistical analyses of the counting data to determine values for homogeneity, absorption time, and disk serum absorption. We also measure spot diameters to ensure they are within acceptable CLSI limits [6]. Initially, we used lysed-cell whole blood to avoid variability contributed by uncontrolled red blood cell (RBC) lysis during the 4-day QC production span. Results of later studies confirmed that the RBC lysis that occurred while processing intact-cell blood pools was not sufficient to contribute substantially to the variance. Therefore, we no longer evaluate lysed-cell whole blood on new filter paper lots.

The published and standardized acceptable serum volumes per 3.2-mm disk are (mean value and 95% confidence interval [CI]) $1.54 \pm 0.17 \mu\text{L}$ for intact-cell blood [6]. The mean values and CIs are the filter paper evaluation parameters published in the CLSI standard. The CDC mean value for intact-cell evaluations for all lots is within the 95% CI defined by CLSI but below the mean value indicated by the CLSI standard [6].

Tables 1 and 2 indicate serum absorption volumes of the last 10 lots from two FDA-approved sources determined using intact RBCs. For W141, the most recent production lot tested of Whatman 903 filter paper, we found the mean serum absorption volume was $1.53 \mu\text{L}$ per 3.2-mm disk for intact-cell blood. Lot W141 was homogeneous (i.e., the measured within-spot, within-sheet, and among-sheets variances were within acceptable limits). We found the mean serum absorption volume for the most recent production lot of PerkinElmer 226 filter paper tested, lot 103649, was $1.53 \mu\text{L}$ per 3.2-mm disk for intact-cell blood; lot 103649 was homogeneous as well. Each mean value was within the acceptable range for the matrix used. The NSQAP's data for a production lot depended on the filter paper sample provided by

PerkinElmer

**TABLE 1. PerkinElmer 226 Specimen Collection Paper
Filter Paper Characteristics by Lot Number - Intact Red Blood Cells**

Filter Paper Lot	Date of Evaluation (month-year)	Serum Volume Per 1/8" Punch (µL)		Absorption Time (sec)		Spot Diameter (mm)	
		Avg	StDev	Avg	StDev	Avg	StDev
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	0.6
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
7231001	Nov-07	1.42	0.10	15.5	2.6	16.0	0.5
7181001	Nov-07	1.44	0.10	14.5	2.3	16	0.5

GE Healthcare Bio-Sciences

**TABLE 2. Whatman 903 Specimen Collection Paper
Filter Paper Characteristics by Lot Number - Intact Red Blood Cells**

Filter Paper Lot	Date of Evaluation (month-year)	Serum Volume Per 1/8" Punch (µL)		Absorption Time (sec)		Spot Diameter (mm)	
		Avg	StDev	Avg	StDev	Avg	StDev
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
W102	Oct-10	1.54	0.08	9.6	1.7	15.7	0.6
W101	May-10	1.44	0.08	9.5	1.3	16.1	0.5
W092	Feb-10	1.48	0.09	11.9	2.1	16.0	0.7

the manufacturer as representative of the entire production batch (i.e., statistically valid sampling). The testing results provided in Tables 1 and 2 are for information purposes only.

Filter paper lots used in the CDC production of QC and PT specimens distributed in 2014 were W111, W112, and W113 of Whatman 903.

PT AND QC SPECIMEN PREPARATION AND DATA HANDLING

Tables and figures in this report show the expected or assayed values of PT specimens and QC lots, as well as the summarized quantitative data. The expected value of each specimen or lot equals the sum of the enriched value and the endogenous (non-enriched) value. Because of differences in the blood sources used for DBS production of GALT and immunoreactive trypsinogen (IRT) PT specimens, we reported the CDC-assayed values.

We prepared all PT and QC specimens from whole blood of 50% hematocrit. Purified analytes or unaltered donor blood were used for PT and QC material enrichments, with the exception of thyroid stimulating hormone (TSH), for which the Third International Reference Preparation (81/565) was used. We enriched some congenital hypothyroid specimens above the endogenous T_4 concentration, and enriched some with T_4 after T_4 depletion of the base serum. We enriched TGal with galactose and galactose-1-phosphate, allowing measurement of both free galactose (galactose alone) and total galactose (free galactose plus galactose present as TGal). We made biotinidase pools using heat-treated serum combined with compatible donor red cells. Deficient GALT PT and QC materials were made using a 50/50 saline/heat treated serum solution combined with compatible red cells and then heat-treating the pool. Low free carnitine (C0(L)) PT pools are produced by washing fresh red blood cells at least six times and then combining with charcoal-stripped serum. We made CFDNA PT materials with blood from individual donors and expressed CF mutations, without hematocrit

adjustment. We excluded all reported analytic values outside the 99% CI from the quantitative result summaries.

To obtain data on the QC materials, we estimated the method response to endogenous materials by performing weighted linear regression analyses for mean-reported concentrations versus enriched concentrations. We then extrapolated the regression lines to the Y-axis (intercept) to obtain an estimate for each method category of the observed, endogenous analyte concentration. When enrichments are accurate, these estimates are reliable. The analytical method gives a linear response across the range of the measurements. The slopes for regression lines are approximately equal to one.

For PT reporting, we apply the laboratory-reported specific cutoff values, when available, to our grading algorithm for evaluation. If no cutoff value was reported for a particular specimen, the grading algorithm defaulted to the NSQAP-assigned working cutoff values, which were based on the domestic mean value.

CUTOFFS

The NSQAP requested that participants, when reporting cutoff values, report the decision level for sorting test results as presumptive positive (outside normal limits) from results reported as negative (within normal limits). Tables 3–5 summarize the reported cutoff values for

TABLE 3. 2014 Summary of Non-MS/MS Cutoff Values of Domestic and Foreign Laboratories

Domestic						
Analyte	N	Mean	Median	Mode	Min	Max
17-OHP (ng/mL serum)	44	34.7	33.0	33.0	19.0	65.0
GALT (U/g Hb)	17	3.0	3.1	3.5	1.7	4.0
IRT (ng/mL blood)	45	67.0	65.0	67.0	37.0	132.0
TSH (μ IU/mL serum)	44	32.6	26.5	20.0	19.0	58.0
T_4 (μ g/dL serum)	22	6.2	6.1	8.0	4.0	8.0
TGal (mg/dL blood)	20	10.7	10.0	10.0	6.0	20.0
Phe (μ mol/L blood)	3	145.3	151.5	151.5	133.0	151.5
Foreign						
Analyte	N	Mean	Median	Mode	Min	Max
17OHP (ng/mL serum)	162	29.8	21.9	19.8	6.6	250.0
GALT (U/g Hb)	38	3.0	3.1	3.5	1.4	5.0
IRT (ng/mL blood)	123	70.7	65.0	60.0	40.0	325.0
TSH (μ IU/mL serum)	230	22.9	20.0	20.0	5.5	50.0
T_4 (μ g/dL serum)	37	6.9	6.0	6.0	4.0	22.2
TGal (mg/dL blood)	111	12.1	10.0	10.0	6.0	30.0
Leu (μ mol/L blood)	5	283.9	305.0	NA	180.0	381.5
Phe (μ mol/L blood)	83	170.0	151.5	121.2	60.6	723.1
Tyr (μ mol/L blood)	3	335.0	397.0	NA	200.0	408.0
Val (μ mol/L blood)	3	287.3	282.0	NA	180.0	400.0

**TABLE 4. 2014 Summary of MS/MS Cutoff Values
of Domestic Laboratories ($\mu\text{mol/L}$)**

Analyte	N	Mean	Median	Mode	Min	Max
Arginine	37	66.2	50.0	50.0	20.0	125.0
Citrulline	47	55.7	56.0	60.0	18.0	148.5
Leucine	47	281.5	275.0	250.0	175.0	400.0
Methionine	47	74.0	70.0	100.0	30.0	100.0
Phenylalanine	51	142.0	150.0	155.0	99.0	182.0
SUAC	30	2.8	2.8	4.5	0.5	5.4
Tyrosine	50	414.0	347.5	400.0	88.0	850.0
Valine	32	294.7	280.0	250.0	200.0	530.0
C0(L)	51	8.89	8.00	7.00	5.00	33.00
C3	51	5.68	6.00	6.30	1.10	8.00
C3DC	25	0.22	0.20	0.20	0.02	0.45
C3DC+C4OH	18	0.41	0.38	0.38	0.25	0.60
C4	47	1.29	1.30	1.70	0.49	1.90
C4OH	23	0.64	0.69	0.70	0.27	1.00
C5	52	0.70	0.66	1.00	0.38	1.20
C5:1	51	0.25	0.18	0.60	0.05	0.60
C5DC	51	0.36	0.32	0.60	0.05	0.80
C5OH	51	0.79	0.80	0.90	0.19	1.18
C6	49	0.41	0.30	0.95	0.16	0.95
C8	52	0.45	0.41	0.60	0.25	0.79
C10	48	0.46	0.43	0.65	0.22	0.80
C10:1	46	0.30	0.30	0.45	0.14	0.48
C10:2	25	0.16	0.14	0.10	0.06	0.46
C14	48	0.77	0.73	0.70	0.17	1.20
C14:1	52	0.61	0.65	0.80	0.07	0.80
C16	49	7.60	7.50	10.00	0.41	10.00
C16OH	52	0.13	0.13	0.10	0.07	0.25
C18	44	2.46	2.30	4.00	0.22	4.00
C18:1	45	3.57	3.00	3.00	0.36	7.00
C18OH	39	0.13	0.10	0.10	0.04	0.88

**TABLE 5. 2014 Summary of MS/MS Cutoff Values
of Foreign Laboratories ($\mu\text{mol/L}$)**

Analyte	N	Mean	Median	Mode	Min	Max
Arginine	167	58.9	52.0	50.0	10.0	195.0
Citrulline	192	54.1	50.0	40.0	19.5	200.0
Leucine	207	306.3	300.0	300.0	147.0	600.0
Methionine	204	58.6	56.8	50.0	20.0	140.0
Phenylalanine	219	136.0	129.0	120.0	48.0	300.0
SUAC	64	2.4	1.7	2.0	0.4	10.0
Tyrosine	208	298.8	260.0	400.0	79.9	1000.0
Valine	196	271.4	257.7	250.0	149.9	576.9
C0(L)	209	13.6	8.6	10.0	4.0	220.0
C10	205	5.3	5.2	6.0	1.7	11.0
C3	97	0.3	0.3	0.3	0.0	2.6
C3DC	65	0.6	0.5	0.5	0.1	4.4
C3DC + C4OH	187	1.0	1.0	1.3	0.1	2.5
C4	91	0.6	0.6	0.5	0.1	1.4
C4OH	215	0.7	0.6	1.0	0.3	2.0
C5	181	0.2	0.2	0.3	0.0	0.9
C5:1	211	0.3	0.3	0.3	0.1	1.5
C5DC	189	0.8	0.8	1.0	0.2	3.6
C5OH	193	0.3	0.3	0.2	0.1	1.3
C6	220	0.4	0.3	0.5	0.1	1.4
C8	204	0.4	0.4	0.5	0.1	1.5
C10:1	174	0.3	0.3	0.3	0.1	1.0
C10:2	123	0.2	0.1	0.2	0.0	1.0
C14	190	0.6	0.6	0.8	0.1	1.5
C14:1	194	0.5	0.4	0.4	0.1	1.3
C16	203	6.6	6.9	7.5	0.3	14.0
C16OH	204	0.1	0.1	0.1	0.0	0.8
C18	189	2.2	2.0	2.5	0.3	7.0
C18:1	182	3.0	3.0	3.0	0.4	7.0
C18OH	147	0.1	0.1	0.1	0.0	2.0

Table 6. 2014 Domestic Cutoff Summary by Analyte and Method - Hormones and Total Galactose

Analyte	Method	N	CUTOFF VALUE				
			Mean	Median	Mode	Min	Max
17-OHP ng/mL serum	ALL METHODS	44	34.7	33.0	33.0	19.0	65.0
	AutoDelfia	7	45.7	40.0	65.0	25.0	65.0
	AutoDelfia Neonatal 17-OHP (B024)	23	31.9	33.0	33.0	19.0	50.0
	PerkinElmer GSP Neonatal	14	33.8	31.5	25.0	25.0	60.0
TSH µIU/mL serum	ALL METHODS	44	32.6	26.5	20.0	19.0	58.0
	AutoDelfia	29	36.5	33.0	20.0	20.0	58.0
	PerkinElmer GSP Neonatal	15	24.9	25.0	25.0	19.0	35.0
Thyroxine µg/dL serum	ALL METHODS	22	6.2	6.1	8.0	4.0	8.0
	AutoDelfia	9	6.3	6.5	8.0	4.0	8.0
	PerkinElmer GSP Neonatal	13	6.2	6.0	5.0	5.0	8.0
Total Galactose mg/dL blood	ALL METHODS	20	10.7	10.0	10.0	6.0	20.0
	Astoria-Pacific 50 Hour Reagent Kit	9	10.8	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 Neonatal Kit	6	8.7	8.8	9.5	6.0	11.0

Table 7. 2014 Domestic Cutoff Summary by Analyte and Method - IRT and GALT

Analyte	Method	N	CUTOFF VALUE				
			Mean	Median	Mode	Min	Max
GALT U/g Hb	ALL METHODS	17	3.0	3.1	3.5	1.7	4.0
	Astoria-Pacific Neonatal Microplate Reagent Kit	4	2.2	2.1	N/A*	1.7	2.9
	PerkinElmer Neonatal Kit	13	3.3	3.2	3.5	2.4	4.0
IRT ng/mL blood	ALL METHODS	45	67.0	65.0	67.0	37.0	132.0
	Auto Delfia	30	68.2	66.0	67.0	37.0	132.0
	PerkinElmer GSP Neonatal	15	64.6	55.0	60.0	42.0	100.0

*Not Applicable

Table 8. 2014 Domestic Cutoff Summary by Analyte and Method - Amino Acids

Analyte	Method	N	CUTOFF VALUE				
			Mean	Median	Mode	Min	Max
Arginine µmol/L	ALL MS/MS METHODS	37	66.2	50.0	50.0	20.0	125.0
	Derivatized - MS/MS non-kit	13	48.3	35.0	30.0	20.0	125.0
	Derivatized - MS/MS PerkinElmer NeoGram Kit	8	79.4	80.0	100.0	50.0	100.0
	Non-derivatized - MS/MS PerkinElmer NeoBase Kit	16	74.2	50.0	50.0	50.0	120.0
Citrulline µmol/L	ALL MS/MS METHODS	47	55.7	56.0	60.0	18.0	148.5
	Derivatized - MS/MS non-kit	15	45.8	40.0	40.0	18.0	75.0
	Derivatized - MS/MS PerkinElmer NeoGram Kit	10	65.4	55.0	55.0	40.0	148.5
	Non-derivatized - MS/MS PerkinElmer NeoBase Kit	22	58.0	60.0	60.0	42.0	75.0
Leucine µmol/L	ALL MS/MS METHODS	47	281.5	275.0	250.0	175.0	400.0
	Derivatized - MS/MS non-kit	15	265.1	256.0	300.0	200.0	330.0
	Derivatized - MS/MS PerkinElmer NeoGram Kit	10	285.7	283.5	300.0	250.0	325.0
	Non-derivatized - MS/MS PerkinElmer NeoBase Kit	22	290.9	272.5	250.0	175.0	400.0
Methionine µmol/L	ALL MS/MS METHODS	47	74.0	70.0	100.0	30.0	100.0
	Derivatized - MS/MS non-kit	15	60.1	60.0	70.0	30.0	100.0
	Derivatized - MS/MS PerkinElmer NeoGram Kit	10	78.0	73.5	100.0	60.0	100.0
	Non-derivatized - MS/MS PerkinElmer NeoBase Kit	22	81.7	85.5	100.0	54.5	100.0
Phenylalanine µmol/L	ALL MS/MS METHODS	51	142.0	150.0	155.0	99.0	182.0
	Derivatized - MS/MS non-kit	19	135.6	135.0	150.0	99.0	182.0
	Derivatized - MS/MS PerkinElmer NeoGram Kit	10	137.9	130.0	130.0	120.0	181.8
	Non-derivatized - MS/MS PerkinElmer NeoBase Kit	22	149.4	155.0	155.0	120.0	180.0
	ALL NON-MS/MS METHODS	3	145.3	151.5	151.5	133.0	151.5
	High-performance liquid chromatography (HPLC)	3	145.3	151.5	151.5	133.0	151.5
SUAC µmol/L	ALL MS/MS METHODS	30	2.8	2.8	4.5	0.5	5.4
	Derivatized - MS/MS non-kit	11	2.5	2.5	3.0	0.5	5.4
	Non-derivatized - MS/MS PerkinElmer NeoBase Kit	19	3.0	3.0	4.5	1.0	4.5
Tyrosine µmol/L	ALL MS/MS METHODS	50	414.0	347.5	400.0	88.0	850.0
	Derivatized - MS/MS non-kit	18	299.5	300.0	400.0	88.0	442.0
	Derivatized - MS/MS PerkinElmer NeoGram Kit	10	308.8	288.0	300.0	200.0	552.0
	Non-derivatized - MS/MS PerkinElmer NeoBase Kit	22	555.4	455.0	850.0	300.0	850.0
Valine µmol/L	ALL MS/MS METHODS	32	294.7	280.0	250.0	200.0	530.0
	Derivatized - MS/MS non-kit	11	267.5	250.0	300.0	200.0	420.0
	Derivatized - MS/MS PerkinElmer NeoGram Kit	9	299.2	280.0	280.0	250.0	400.0
	Non-derivatized - MS/MS PerkinElmer NeoBase Kit	12	316.2	291.0	250.0	250.0	530.0

Table 9. 2014 Domestic Cutoff Summary by Analyte and Method - Acylcarnitines

Analyte	Method	N	CUTOFF VALUE				
			Mean	Median	Mode	Min	Max
C0(L) µmol/L blood	ALL METHODS	51	8.89	8.00	7.00	5.00	33.00
	Derivatized - MS/MS non-kit	19	10.08	9.00	9.00	5.00	33.00
	Derivatized - MS/MS PerkinElmer NeoGram Kit	10	10.25	10.23	10.00	6.00	13.00
	Non-derivatized - MS/MS PerkinElmer NeoBase Kit	22	7.25	7.00	7.00	6.00	10.00
C3 µmol/L blood	ALL METHODS	51	5.68	6.00	6.30	1.10	8.00
	Derivatized - MS/MS non-kit	20	5.09	5.25	6.00	1.10	7.30
	Derivatized - MS/MS PerkinElmer NeoGram Kit	10	5.72	5.72	6.00	4.50	7.21
	Non-derivatized - MS/MS PerkinElmer NeoBase Kit	22	6.20	6.30	6.30	4.00	8.00
C3DC µmol/L blood	ALL METHODS	25	0.22	0.20	0.20	0.02	0.45
	Derivatized - MS/MS non-kit	17	0.19	0.18	0.20	0.02	0.45
	Derivatized - MS/MS PerkinElmer NeoGram Kit	8	0.26	0.23	0.20	0.19	0.42
C3DC+C4OH µmol/L blood	ALL METHODS	18	0.41	0.38	0.38	0.25	0.60
	Non-derivatized - MS/MS PerkinElmer NeoBase Kit	18	0.41	0.38	0.38	0.25	0.60
C4 µmol/L blood	ALL METHODS	47	1.29	1.30	1.70	0.49	1.90
	Derivatized - MS/MS non-kit	18	1.17	1.23	1.40	0.49	1.90
	Derivatized - MS/MS PerkinElmer NeoGram Kit	8	1.11	1.17	N/A*	0.80	1.40
	Non-derivatized - MS/MS PerkinElmer NeoBase Kit	21	1.45	1.40	1.70	1.10	1.70
C4OH µmol/L blood	ALL METHODS	23	0.64	0.69	0.70	0.27	1.00
	Derivatized - MS/MS non-kit	16	0.59	0.65	0.70	0.27	1.00
	Derivatized - MS/MS PerkinElmer NeoGram Kit	7	0.77	0.70	1.00	0.52	1.00
C5 µmol/L blood	ALL METHODS	52	0.70	0.66	1.00	0.38	1.20
	Derivatized - MS/MS non-kit	20	0.66	0.63	0.50	0.38	1.20
	Derivatized - MS/MS PerkinElmer NeoGram Kit	10	0.63	0.60	0.60	0.45	0.87
	Non-derivatized - MS/MS PerkinElmer NeoBase Kit	22	0.78	0.71	1.00	0.50	1.00
C5:1 µmol/L blood	ALL METHODS	51	0.25	0.18	0.60	0.05	0.60
	Derivatized - MS/MS non-kit	20	0.21	0.15	0.08	0.05	0.60
	Derivatized - MS/MS PerkinElmer NeoGram Kit	10	0.20	0.19	0.25	0.15	0.25
	Non-derivatized - MS/MS PerkinElmer NeoBase Kit	21	0.32	0.20	0.60	0.05	0.60
C5DC µmol/L blood	ALL METHODS	51	0.36	0.32	0.60	0.05	0.80
	Derivatized - MS/MS non-kit	20	0.19	0.19	0.21	0.05	0.35
	Derivatized - MS/MS PerkinElmer NeoGram Kit	10	0.30	0.31	0.30	0.23	0.33
	Non-derivatized - MS/MS PerkinElmer NeoBase Kit	21	0.55	0.60	0.60	0.35	0.80
C5OH µmol/L blood	ALL METHODS	51	0.79	0.80	0.90	0.19	1.18
	Derivatized - MS/MS non-kit	20	0.75	0.78	1.00	0.19	1.18
	Derivatized - MS/MS PerkinElmer NeoGram Kit	10	0.76	0.75	0.65	0.60	1.03
	Non-derivatized - MS/MS PerkinElmer NeoBase Kit	21	0.84	0.90	0.90	0.50	1.05
C6 µmol/L blood	ALL METHODS	49	0.41	0.30	0.95	0.16	0.95
	Derivatized - MS/MS non-kit	19	0.35	0.30	0.35	0.16	0.86
	Derivatized - MS/MS PerkinElmer NeoGram Kit	9	0.26	0.25	0.25	0.20	0.33
	Non-derivatized - MS/MS PerkinElmer NeoBase Kit	21	0.54	0.40	0.95	0.17	0.95
C8 µmol/L blood	ALL METHODS	52	0.45	0.41	0.60	0.25	0.79
	Derivatized - MS/MS non-kit	20	0.39	0.35	0.50	0.25	0.72
	Derivatized - MS/MS PerkinElmer NeoGram Kit	10	0.40	0.38	0.38	0.30	0.60
	Non-derivatized - MS/MS PerkinElmer NeoBase Kit	22	0.54	0.60	0.60	0.35	0.79

*Not Applicable.

Table 9. 2014 Domestic Cutoff Summary by Analyte and Method - Acylcarnitines (continued)

Analyte	Method	N	CUTOFF VALUE				
			Mean	Median	Mode	Min	Max
C10 µmol/L blood	ALL METHODS	48	0.46	0.43	0.65	0.22	0.80
	Derivatized - MS/MS non-kit	18	0.43	0.42	0.40	0.22	0.80
	Derivatized - MS/MS PerkinElmer NeoGram Kit	9	0.40	0.40	0.40	0.27	0.54
	Non-derivatized - MS/MS PerkinElmer NeoBase Kit	21	0.50	0.50	0.65	0.22	0.70
C10:1 µmol/L blood	ALL METHODS	46	0.30	0.30	0.45	0.14	0.48
	Derivatized - MS/MS non-kit	17	0.26	0.23	0.35	0.17	0.44
	Derivatized - MS/MS PerkinElmer NeoGram Kit	10	0.32	0.30	0.30	0.25	0.48
	Non-derivatized - MS/MS PerkinElmer NeoBase Kit	19	0.33	0.35	0.45	0.14	0.45
C10:2 µmol/L blood	ALL METHODS	25	0.16	0.14	0.10	0.06	0.46
	Derivatized - MS/MS non-kit	14	0.18	0.13	0.10	0.06	0.46
	Derivatized - MS/MS PerkinElmer NeoGram Kit	7	0.15	0.15	0.15	0.10	0.20
	Non-derivatized - MS/MS PerkinElmer NeoBase Kit	4	0.11	0.11	N/A*	0.07	0.15
C14 µmol/L blood	ALL METHODS	48	0.77	0.73	0.70	0.17	1.20
	Derivatized - MS/MS non-kit	18	0.66	0.72	0.80	0.17	0.85
	Derivatized - MS/MS PerkinElmer NeoGram Kit	9	0.69	0.70	0.70	0.52	0.78
	Non-derivatized - MS/MS PerkinElmer NeoBase Kit	21	0.89	0.79	1.20	0.58	1.20
C14:1 µmol/L blood	ALL METHODS	52	0.61	0.65	0.80	0.07	0.80
	Derivatized - MS/MS non-kit	20	0.52	0.60	0.60	0.07	0.75
	Derivatized - MS/MS PerkinElmer NeoGram Kit	9	0.61	0.65	0.70	0.40	0.80
	Non-derivatized - MS/MS PerkinElmer NeoBase Kit	22	0.68	0.68	0.80	0.50	0.80
C16 µmol/L blood	ALL METHODS	49	7.60	7.50	10.00	0.41	10.00
	Derivatized - MS/MS non-kit	19	6.55	7.00	8.00	0.41	9.00
	Derivatized - MS/MS PerkinElmer NeoGram Kit	8	7.16	7.33	N/A*	6.00	7.80
	Non-derivatized - MS/MS PerkinElmer NeoBase Kit	22	8.66	8.53	10.00	6.71	10.00
C16OH µmol/L blood	ALL METHODS	52	0.13	0.13	0.10	0.07	0.25
	Derivatized - MS/MS non-kit	20	0.13	0.14	0.10	0.08	0.25
	Derivatized - MS/MS PerkinElmer NeoGram Kit	10	0.17	0.17	0.18	0.12	0.25
	Non-derivatized - MS/MS PerkinElmer NeoBase Kit	22	0.11	0.10	0.10	0.07	0.20
C18 µmol/L blood	ALL METHODS	44	2.46	2.30	4.00	0.22	4.00
	Derivatized - MS/MS non-kit	15	1.82	1.85	1.80	0.22	2.50
	Derivatized - MS/MS PerkinElmer NeoGram Kit	8	2.30	2.25	N/A*	1.80	3.00
	Non-derivatized - MS/MS PerkinElmer NeoBase Kit	21	2.97	2.63	4.00	1.55	4.00
C18:1 µmol/L blood	ALL METHODS	45	3.57	3.00	3.00	0.36	7.00
	Derivatized - MS/MS non-kit	16	2.54	2.50	3.00	0.36	3.50
	Derivatized - MS/MS PerkinElmer NeoGram Kit	8	2.95	2.80	N/A*	2.43	3.50
	Non-derivatized - MS/MS PerkinElmer NeoBase Kit	21	4.59	3.70	7.00	2.27	7.00
C18OH µmol/L blood	ALL METHODS	39	0.13	0.10	0.10	0.04	0.88
	Derivatized - MS/MS non-kit	13	0.16	0.10	0.10	0.04	0.88
	Derivatized - MS/MS PerkinElmer NeoGram Kit	9	0.14	0.14	0.10	0.10	0.20
	Non-derivatized - MS/MS PerkinElmer NeoBase Kit	17	0.09	0.10	0.10	0.04	0.16

*Not Applicable.

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 for select analytes and methods. To assess differences in reported cutoffs by method, we used data from domestic laboratories only. Table 3 shows the mean cutoff values for non-MS/MS domestic and foreign laboratories are similar. For both domestic and foreign laboratories, the range (min/max) of cutoff values is large for most analytes. As shown in Tables 4 and 5, among all laboratories, the mean and median cutoff summary values for the MS/MS amino acids are similar except for Tyrosine (Tyr) from the domestic laboratories. Among domestic methods used for Arginine (Arg) and Tyr, the mode value for domestic MS/

MS methods differed widely. This result indicates that a group of laboratories is using a cutoff value different from the mean of the other laboratories.

Tables 6 and 7 show cutoff distributions of non-MS/MS methods for TSH, IRT, 17-OHP, and TGal. The results show similar median cutoffs but also show variability within methods. Table 8 shows that the non-derivatized kit methods for Arg, Leucine (Leu), Methionine (Met), and Tyr have a broad range of cutoffs compared with other MS/MS-based methods. Cutoffs varied by more than 65% for some methods used to measure Leu, Phe, C5DC, C14, C16, and C18:1.

TABLE 10. 2014 Summary of Proficiency Testing Errors by Domestic Laboratories

	Positive Specimens Assayed (N)	False-Negative Errors (%)	Negative Specimens Assayed (N)	False-Positive Errors (%)
Congenital Adrenal Hyperplasia	132	0.0	528	0.6
Biotinidase Deficiency	174	0.0	481	0.0
GALT Deficiency	132	0.8	528	0.0
Immunoreactive Trypsinogen	268	1.9	402	0.5
Congenital Hypothyroidism	207	0.0	828	0.0
Galactosemia	118	0.0	237	0.0
Arginine Screen	109	0.0	436	0.0
Citrulline Screen	94	0.0	611	0.2
Leucine Screen	141	0.0	564	0.7
Methionine Screen	141	0.0	564	0.0
Phenylalanine Screen	174	0.0	696	0.0
Succinylacetone Screen	88	0.0	352	0.0
Tyrosine Screen	162	0.0	648	0.2
Valine Screen	98	0.0	392	0.0
C0(L) Screen	204	4.4	561	0.7
C3 Screen	156	1.3	624	0.0
C3DC Screen	76	2.6	304	0.0
C3DC+C4OH Screen	69	1.5	175	0.0
C4 Screen	140	1.4	560	0.0
C4OH Screen	68	5.9	272	0.0
C5 Screen	156	1.9	624	0.0
C5:1 Screen	152	4.0	608	0.0
C5DC Screen	153	1.3	612	0.0
C5OH Screen	153	1.3	560	0.4
C6 Screen	146	1.4	584	0.0
C8 Screen	156	1.3	624	0.0
C10 Screen	144	1.4	576	0.0
C10:1 Screen	182	0.6	503	0.2
C10:2 Screen	77	0.0	308	0.0
C14 Screen	144	1.4	576	0.2
C14:1 Screen	155	1.3	620	0.2
C16 Screen	147	1.4	539	0.2
C16OH Screen	155	0.7	620	0.0
C18 Screen	180	1.1	495	0.0
C18:1 Screen	180	0.0	495	0.0
C18OH Screen	113	1.8	452	0.0

PROFICIENCY TESTING

Tables 10 and 11 show the PT errors reported in 2014 by domestic and foreign laboratories for qualitative assessments by disorder/analyte. We applied the laboratory reported cutoff values to our grading algorithm for clinical assessments (Figure 4). Because of specific clinical assessment practices, presumptive clinical classifications (qualitative assessments) of some specimens might differ by participant. If participants provided their cutoff values, we applied those cutoffs in our final evaluation of the error judgment. We based the rates for false-positive misclassifications on the number of negative specimens tested, and the rates for false-negative misclassifications on the number of positive specimens tested. Laboratories should monitor false-positive misclassifications and keep

as low as possible. Many of the misclassifications were in the false-positive category, with false-positive rates ranging from 0% to 2.6%. For domestic laboratories, the rate was 0.5% or lower for 33 of 36 biomarkers or disorders, with the highest rate of false-positive errors for both Leu and C0(L). The foreign laboratories had an error rate of 1.8% or lower for 33 of 36 biomarkers or disorders, with the highest rate of false-positive errors for biotinidase.

Screening programs are designed to minimize false negative reports, but this precautionary approach could result in false-positive misclassifications. The false-negative rate, expected to be zero, ranged from 0% to 9.2%. For domestic laboratories, we found no false-negative errors

TABLE 11. 2014 Summary of Proficiency Testing Errors by Foreign Laboratories

	Positive Specimens Assayed (N)	False-Negative Errors (%)	Negative Specimens Assayed (N)	False-Positive Errors (%)
Congenital Adrenal Hyperplasia	512	0.6	2048	0.7
Biotinidase Deficiency	436	3.0	1184	2.6
GALT Deficiency	202	1.5	808	0.5
Immunoreactive Trypsinogen	756	1.1	1134	0.3
Congenital Hypothyroidism	853	1.1	3412	1.4
Galactosemia	591	1.4	1174	0.4
Arginine Screen	520	2.3	2080	0.4
Citrulline Screen	399	0.5	2541	1.2
Leucine Screen	652	0.9	2608	0.5
Methionine Screen	634	1.6	2536	0.6
Phenylalanine Screen	927	1.0	3708	1.4
Succinylacetone Screen	190	0.5	760	2.0
Tyrosine Screen	648	0.3	2592	0.2
Valine Screen	606	1.3	2424	0.6
C0(L) Screen	863	8.7	2397	1.3
C3 Screen	635	1.1	2540	1.2
C3DC Screen	308	1.3	1232	1.0
C3DC+C4OH Screen	272	9.2	672	1.8
C4 Screen	584	2.2	2336	0.4
C4OH Screen	275	2.2	1100	0.6
C5 Screen	663	2.1	2652	0.8
C5:1 Screen	564	1.1	2256	0.9
C5DC Screen	648	1.4	2592	0.9
C5OH Screen	579	1.4	2121	2.3
C6 Screen	605	2.2	2420	1.0
C8 Screen	672	1.2	2688	0.5
C10 Screen	638	2.4	2552	0.6
C10:1 Screen	743	2.6	2067	1.0
C10:2 Screen	386	1.8	1544	0.8
C14 Screen	595	1.9	2380	1.0
C14:1 Screen	627	1.6	2508	0.9
C16 Screen	631	2.4	2320	1.0
C16OH Screen	627	2.2	2508	1.3
C18 Screen	780	1.5	2170	0.7
C18:1 Screen	750	2.9	2080	0.9
C18OH Screen	468	2.6	1872	1.5

for 15 of the 36 biomarkers or disorders. Foreign laboratories had at least one false-negative error for each of the 36 disorders. A few of our PT specimens fell close to the decision level for classification, 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 were

and clinical assessment errors. Overall, 14 phenotype errors occurred for data reported by 73 laboratories in 2014. The classification errors were essentially the same for phenotype and clinical assessments within the domestic and foreign laboratory groups. Table 13 shows the phenotype challenges distributed in 2014 for hemoglobinopathies. In Panel 1, some participants were concerned about the appearance of Specimen 3; under those circumstances, we provided consensus data to establish specimen integrity. This specimen (Sample 114H3) demonstrated greater than 80% consensus among reported phenotype and clinical assessment classifications. Panel 2 included an educational specimen, EDU1, prepared by mixing umbilical cord blood with normal hemoglobin (HbA) and blood from an anonymous adult EE donor to mimic an FAE newborn specimen. Table 14 shows that participants used multi-level testing schemes to enhance the specificity of screening for hemoglobinopathies. Most screening laboratories use Isoelectric Focusing and High Performance Liquid Chromatography methods in their primary testing. Many laboratories use secondary testing with these same methods in repetitive or different combinations; only a few used tertiary or quaternary tests. Table 15 shows the performance errors for CF-DNA. The percentage of errors for qualitative assessments for genotype analysis ranged from 2.2% to 5.5%. Table 16 shows the CF mutation (CFTR gene) challenges distributed in 2014 for CFDNA.

TABLE 12. Summary of Proficiency Testing Errors for Hemoglobinopathies by Domestic and Foreign Laboratories in 2014

Hemoglobinopathies	Domestic	Foreign
Specimens assayed	720	335
Phenotype errors	1.5%	0.9%
Clinical assessment errors	1.5%	1.2%

Overall, there were 14 phenotype errors.

not included in Tables 10 and 11. For these specimens, we used participants' data to examine the relative analytical performance of the assays.

Table 12 shows the performance errors for hemoglobinopathies. The percentage of errors for qualitative assessments for sickle cell disease and other hemoglobinopathies ranged from 0.9% to 1.5% for both the phenotype

TABLE 13. 2014 Hemoglobinopathy Expected Presumptive Phenotype Distribution

	Specimen 1	Specimen 2	Specimen 3	Specimen 4	Specimen 5	EDU 1
Panel 1	FA	FAC	FA Bart's	FA	FA	—
Panel 2	FA	FAS	FA	FAS	FA	FAE
Panel 3	FAS	FAC	FA	FAS	FAC	—
EDU 1 Reported Phenotypes			2014 Phenotype Distribution Totals			
Phenotypes	# Participants					
FAE	51		FA	7		
FAE/O	2		FAS	4		
FAC	3		FAC	3		
FAV	2		FA Bart's	1		
FAS	1		FAE (EDU1)	1		
FAU	1					
FAE/A2	1					

TABLE 14. 2014 Hemoglobinopathy Methods Used for Proficiency Testing

Method	Isoelectric Focusing	BioRad HPLC	Extended Gradient HPLC	Trinity Biotech Ultra 2 HPLC	Electrophoresis Citrate Agar	Electrophoresis Cellulose Acetate	Monoclonal Antibody Methods	PCR Amplification of DNA
Level 1	33	41	2	0	0	0	1	0
Level 2	19	13	5	5	1	1	0	1
Level 3	2	2	1	0	2	0	0	0
Level 4	1	0	0	0	0	0	0	0

TABLE 15. Genotype Analysis of Cystic Fibrosis Mutation Detection Specimens in 2014

	Specimens Assayed (N)	Correct Results	Incorrect Genotypes & Misclassifications Results	Not Evaluated*	Sample Failure
Q1, 2014	300	97.6%	2.4%	0.4%	0.3%
Q2, 2014	295	95.3%	4.6%	18.6%	0.7%
Q3, 2014	305	94.4%	5.5%	28.5%	0.0%
Q4, 2014	315	97.8%	2.2%	25.7%	0.3%
Total	1215	96.2%	3.7%	19.2%	0.3%

*If one or both mutations were not on a laboratory's panel, the specimen is not evaluated.

TABLE 16. Cystic Fibrosis Mutation (CFTR gene) Challenges Distributed in 2014

Mutation (Legacy Name)	Mutation (HGVS* Nomenclature)	Number Sent
F508del	c.1521_1523delCTT	12
Wild type/no mutation	Wild type/no mutation	9
R553X	c.1657C>T	1
621+1G>T	c.489+1G>T	1
2183AA>G	c.2051_2052delAAinsG	1
E60X	c.178G>T	1
3272-26A>G	c.3140-26A->G	1
3905insT	c.3773_3774insT	1
A559T	c.1675G>A	1
A455E	c.1364C>A	1
2789+5G>A	c.2657+5G>A	1
2055del9>A	c.1923_1931del9insA	1

*Human Genome Variation Society

All PT panels consisted of five blind-coded, 75- μ L DBS specimens. We packaged specimen sets in a zip-closed, metalized plastic bag with desiccant, instructions for analysis, and instructions for reporting data. For all results received by the deadline dates, we prepared and distributed quarterly reports. In this annual report, we illustrate the comparisons of results by different methods (Figures 5–40) with the participants' reported PT data during the year for one selected challenge for each analyte. For these PT analytes, we compared results by using bias plots that show the difference (positive or negative) by laboratory and method of the reported value subtracted from the expected value. For T_4 , IRT, C0(L), and GALT, we subtracted the differences of the participant's reported values from the CDC-assayed value. For each plot, note the scale-changes of the Y-axis relative to the expected value. A reported value matching the expected value will show the illustrated value as falling on the plot's "0" line. For each figure, we tabulated in the left margin a summary of the specimen data for the selected quarter PT challenges in 2014. Ideally, a reasonable bias is less than 20% of the expected value (EV). The bias for twenty-nine of the 36 analytes is less than 20% of the EV.

For the bias plots, we selected a wide range of PT challenge specimens (Figures 5–40). When comparing data scatter among figures, the scale (Y-axis) might differ. We included the 95% CI for the mean participant bias. A tight scatter within this interval indicates good performance for a method or a group of methods. In general, the quantitative comparisons (Figures 5–40) for PT challenges are reasonable within a method but vary among methods. To illustrate any method-related differences in analyte recoveries, we group the PT quantitative results by kit or method. Because some of the pools in a routine PT survey represent a unique donor specimen, differences in endogenous materials in the donor specimens might influence method-related differences.

We show representative bias plots for all those analytes distributed in PT challenges that required a quantitative measurement to determine the presumptive clinical assessments. Figures 6 and 8 show that T_4 and TGal participant bias is slightly above the EV, with good agreement among participants. Figure 7 indicates TSH shows a positive bias compared to the CDC-expected value. Figure 5 indicates all methods show a tight scatter for 17-OHP. Figure 9 shows that the GALT participant bias is small, and the scatter of values is distinctly lower for one method. Figure 10 indicates that the bias plot for IRT shows distinctive bias for one method when compared to the CDC-assayed value. The bias plot in Figure 11 shows a strong negative bias due to reduced recovery

of Arg by all methods. The plot also shows that the MS/MS kit methods exhibit a higher recovery than the MS/MS non-kit methods. The Citrulline (Cit) plot shows some methods with a tight cluster of values but with distinct differences between methods (Figure 12). The plots for Leu, Met, Tyr, and Valine (Val) show a consistent negative bias, with the expected values and reasonably consistent scatter among users and methods (Figures 13, 14, 17, and 18, respectively). The bias plot for Phe shows good agreement between laboratories and among methods (Figure 15); compared with the EV, the Phe plot has a small participant bias. Most SUAC methods show a negative bias due to a reduced recovery of SUAC (Figure 16).

Bias plots for derivatized and non-derivatized MS/MS methods are shown for all acylcarnitines as selected representative PT challenges in 2014. 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. Figure 19 shows that C0(L) has a slight positive bias with good agreement among all users. The bias data for C3 shows tight cluster of values within each method (Figure 20). Figure 23 shows that the C4 enrichment is less than it was in the 2013 specimen, yet the recovery is higher for all methods.

A growing number of NSQAP participants use a non-derivatized MS/MS method for amino acids and acylcarnitine analysis. But, non-derivatized MS/MS methods cannot distinguish 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. C3DC shows a small negative bias for all methods except one (Figure 21). C3DC+C4OH shows a negative bias among most participants across all methods (Figure 22). C4OH bias plot shows a tight scatter among each method (Figure 24).

In Figure 25, the C5 values are minimally scattered, with good agreement with the expected value. The data for C5:1 show good agreement among most kit methods (Figure 26), and the participant mean value is only slightly lower than the expected value. For C5DC, a tight scatter appears within each method (Figure 27), with non-kit methods showing a negative bias and most kit methods showing a positive bias. The bias plot for C5OH illustrates good scatter for most methods (Figure 28), with one kit method showing a cluster below the mean bias. C6 data show a slight negative participant bias with tight scatter (Figure 29). C8 data demonstrate a tight scatter

around the slightly negative participant bias (Figure 30). C10 and C10:1 bias values show reasonable scatter among all laboratories and methods (Figures 31 and 32, respectively), with good agreement for the expected value. That said, we noted a negative method bias between the MS/MS kit and the non-kit methods.

C10:2 data show a negative bias due to low recovery by all methods (Figure 33). The C14 plot shows a much smaller participant bias and more even scatter than did the 2013 C14 data (Figure 34). Figure 35 indicates that all C14:1 methods show reasonable scatter, but the kit methods show a negatively clustered bias. C16 data show a low recovery by all participants, with one method showing a cluster below the mean bias (Figure 36). C16OH data demonstrate consistent scatter among all methods, with most laboratories showing a negative bias (Figure 37). C18 data illustrate a reasonable scatter of values within and among methods while showing a negative participant bias (Figure 38). C18:1 data show a positive participant bias with good scatter among all methods (Figure 39). C18OH's bias plot shows good scatter among most laboratories and methods (Figure 40).

QUALITY CONTROL

Each lot within a set of QC shipments of T₄, TSH, 17-OHP, IRT, TGal, GALT, amino acids (Phe, Leu, Met, Tyr, Val, Cit, Arg, Alanine, SUAC), and acylcarnitines (C0, C2, C3, C3DC, C4, C4OH, C5, C5DC, C5OH, C6, C8, C10, C12, C14, C16, C16OH, C18, C18OH) contained a different analyte concentration. To ensure that a laboratory received representative sheets of the production batch, we used randomizing systems from across the production batch to select blood spot cards. We distributed the QC materials, including the DBS cards, instructions for storage and analysis, and data report forms, semiannually. Midyear, we compiled data from five analytic runs of each lot and shipment, and distributed annual summary reports to each participant. Because each participant's reported data covered a different time span, intervals between runs were not the same for all laboratories.

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

Tables 17a–17hh show data about method-related differ-

ences in analytic recoveries and method biases. Because we prepared each QC lot series from one batch of hematocrit-adjusted, non-enriched blood, the endogenous concentration was the same for all specimens in a lot series. 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 1325, 1326, 1327, and 1328). Because only three or four concentrations of QC materials are available for each analyte, a bias error 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 measured 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; most slopes fell within a range from 0.8 to 1.0. Some analytes and methods continue to produce data with slopes as high as 2.1 and as low as 0.2. 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 was 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.

For the first time, NSQAP offered GALT QC beginning with 2014 Set 2. We received data from 55 laboratories, with most of the results reported in U/g hemoglobin, correlating with the assayed value. These methods demonstrated slope values near or within the optimal range of 0.8–1.2. Several laboratories reported their results in either $\mu\text{mol/L}$ blood or U/dL blood according to their analytic method; we accept quantitative results in units other than U/g hemoglobin, but we are unable to provide linear regression parameters for those laboratories due to the lack of a conversion factor. We provided basic peer-group statistics to assist in self-assessment under those circumstances.

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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 IU/mL

NSQAP Cutoff = 30 μ IU/mL

Participant cutoff = 35 μ IU/mL

Participant's Reported Clinical Assessment = "outside normal limits" for this sample.

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

NSQAP Certified Expected Value = 13 μ IU/mL

NSQAP Cutoff = 30 μ IU/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 IU/mL

Participant Cutoff = 35 μ IU/mL

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

3 – Participant Reported Clinical Assessment

Participant Reported Clinical Assessment = "2-Outside Normal Limits"

In this example, the NSQAP Expected Clinical Assessment and the Participant Expected Clinical Assessment were both "within normal limits" but the Participant Reported Clinical Assessment is "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”

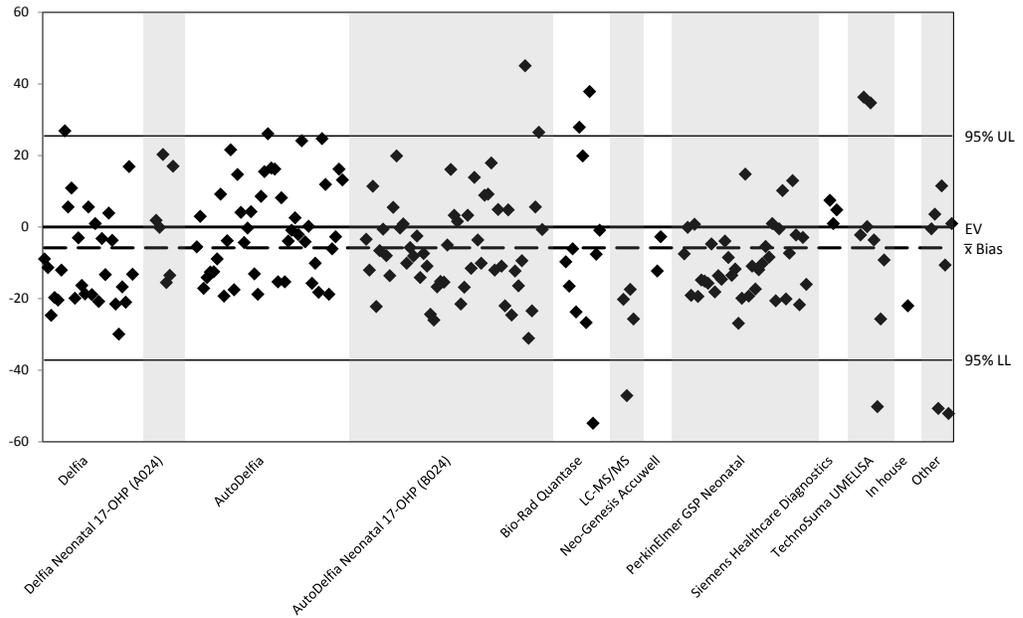
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Note that the grade is based on the Participant Reported Clinical Assessment, not on the reported value. Overall Statistics, which are generated from all participant data, and Mean Reported Concentrations by method are provided on the Web site for analytical reference only.

FIGURES 5-6. Reproducibility of Results by Method 17 α -Hydroxyprogesterone (17-OHP) and Thyroxine (T_4)

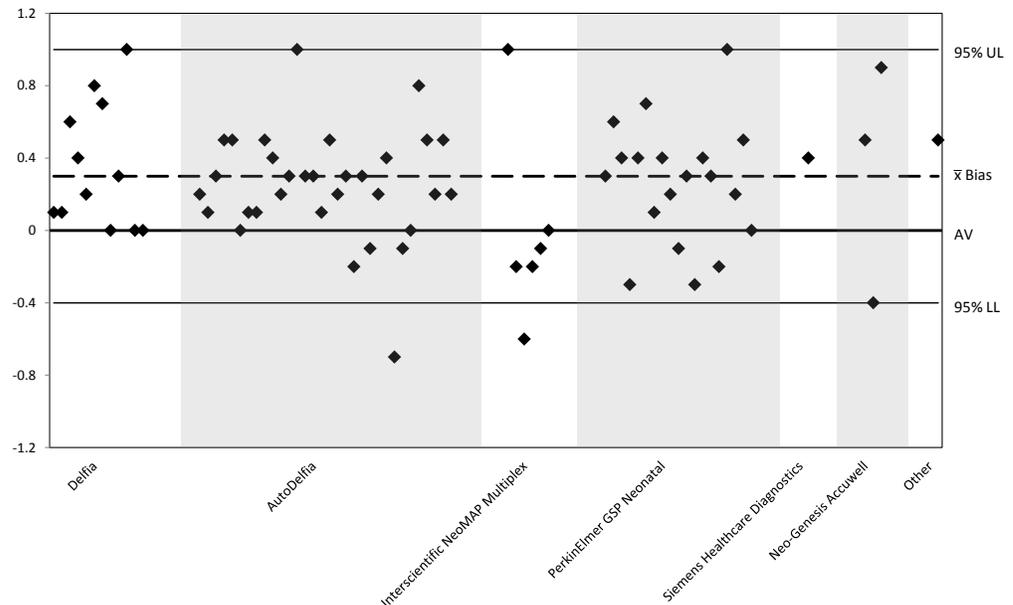
Bias Plot 17 of α -Hydroxyprogesterone (17-OHP) Values by Method
Quarter 3, Specimen 31412
Expected Value (EV)¹ = 90.1 ng/mL serum

Quarter 3	
Specimen 2	
Enriched	90.0
CDC Assayed	93.4
Participant Mean	84.3
Participant Bias ²	-5.8



Bias Plot of Thyroxine (T_4) Values by Method
Quarter 1, Specimen 11415
Assayed Value (AV)³ = 1.2 μ g/dL serum

Quarter 1	
Specimen 5	
CDC Assayed	1.2
Participant Mean	1.5
Participant Bias ²	0.3

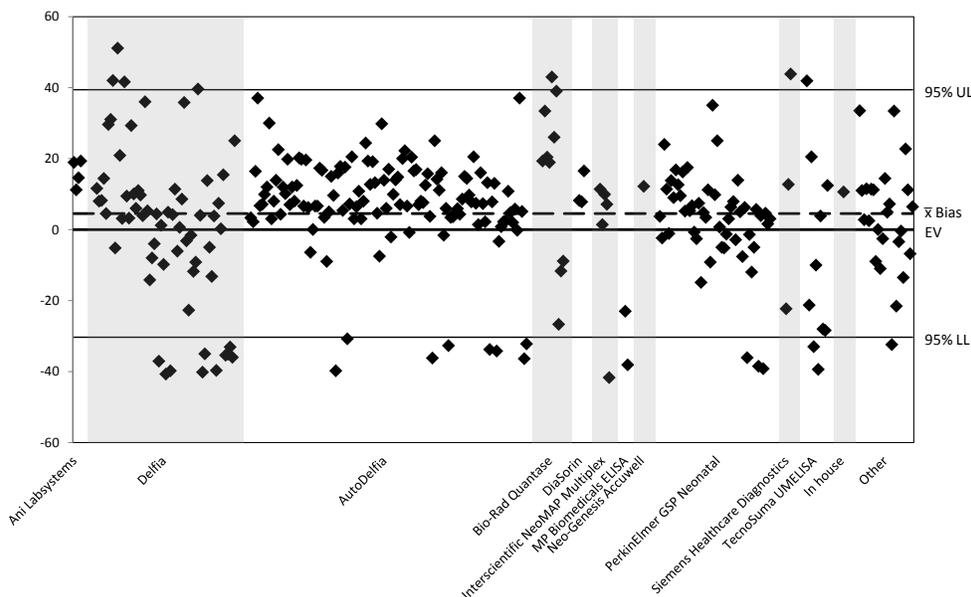


¹EV is the sum of the endogenous and enrichment values. The solid line represents perfect agreement with the EV or zero bias.
²Participant bias (\bar{X}) is the mean value of all participants' assayed values minus EV; represented by the broken line. Participant bias (\bar{X}) excludes outlier values. 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)

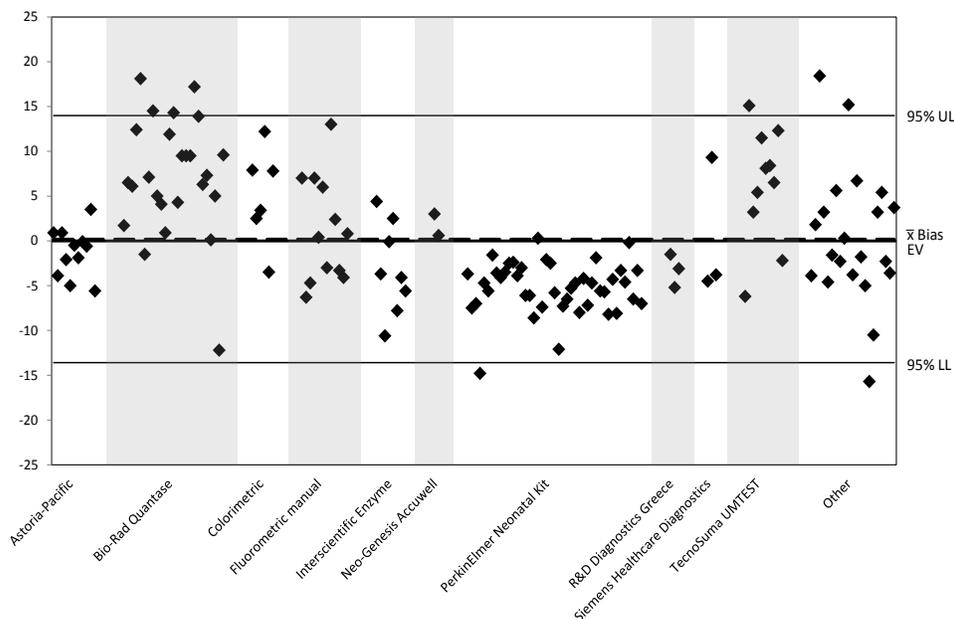
Bias Plot of Thyroid-Stimulating Hormone (TSH) Values by Method
Quarter 3, Specimen 31415
Expected Value (EV)¹ = 75.0 μ U/mL serum

Quarter 3	
<i>Specimen 5</i>	
Enriched	75.0
CDC Assayed	70.8
Participant Mean	79.5
Participant Bias ²	4.5



Bias Plot of Total Galactose (TGal) Values by Method
Quarter 3, Specimen 31413
Expected Value (EV)¹ = 23.0 mg/dL whole blood

Quarter 3	
<i>Specimen 3</i>	
Enriched	22.5
CDC Assayed	22.1
Participant Mean	23.2
Participant Bias ²	0.2



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

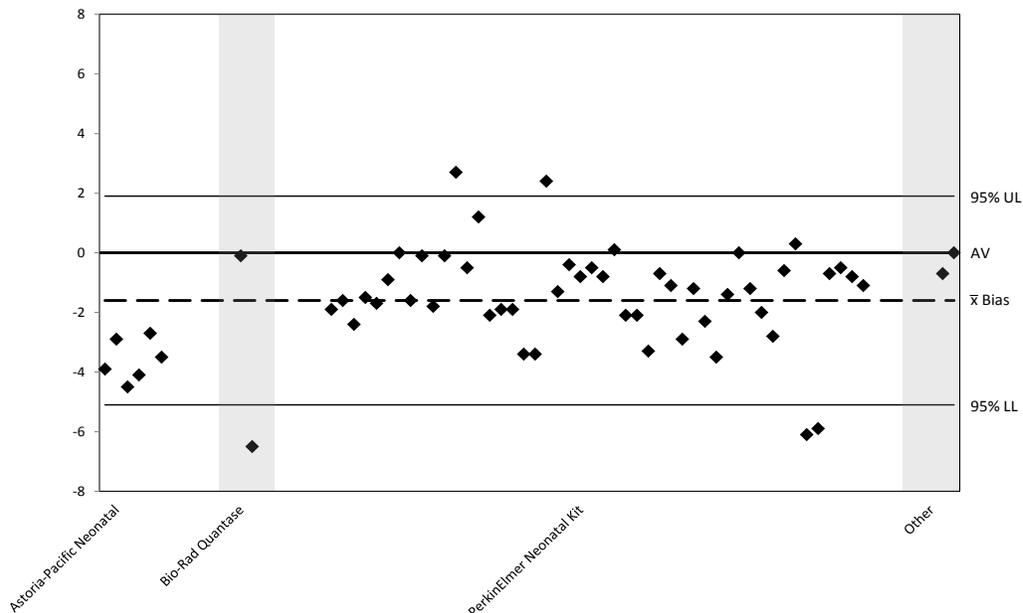
²Participant bias (\bar{X}) is the mean value of all participants' assayed values minus EV; represented by the broken line. Participant bias (\bar{X}) excludes outlier values. The 95% confidence interval is shown.

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)

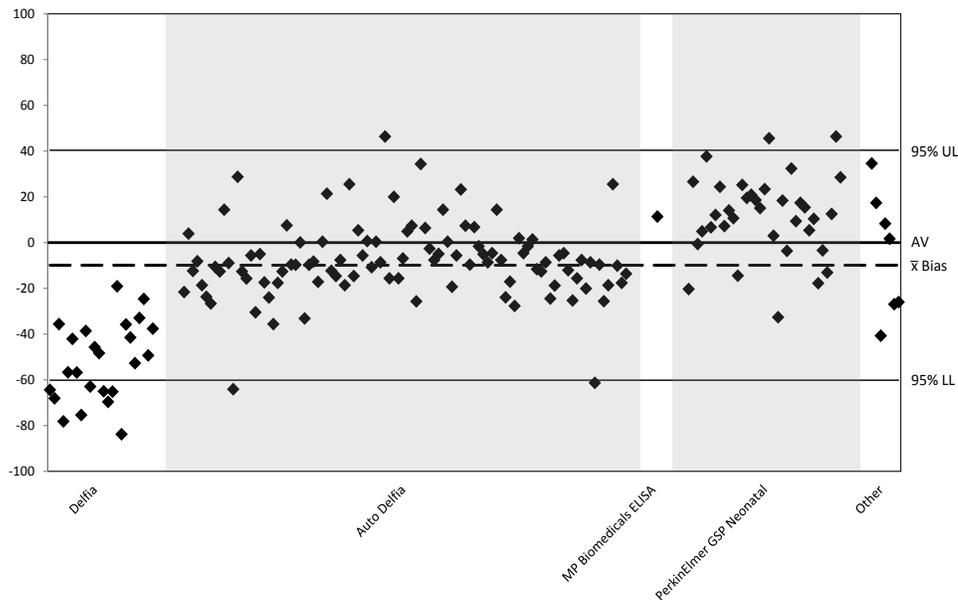
Bias Plot of Galactose-1-Phosphate Uridyltransferase (GALT) Values by Method
Quarter 3, Specimen 31493
Assayed Value (AV)³ = 10.5 U/g Hb

<u>Quarter 3</u>	
<i>Specimen 3</i>	
CDC Assayed	10.5
Participant Mean	8.9
Participant Bias ²	-1.6



Bias Plot of Immunoreactive Trypsinogen (IRT) Values by Method
Quarter 3, Specimen 31481
Assayed Value (AV)³ = 169.6 ng/mL whole blood

<u>Quarter 3</u>	
<i>Specimen 1</i>	
CDC Assayed	169.6
Participant Mean	159.7
Participant Bias ²	-9.9



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

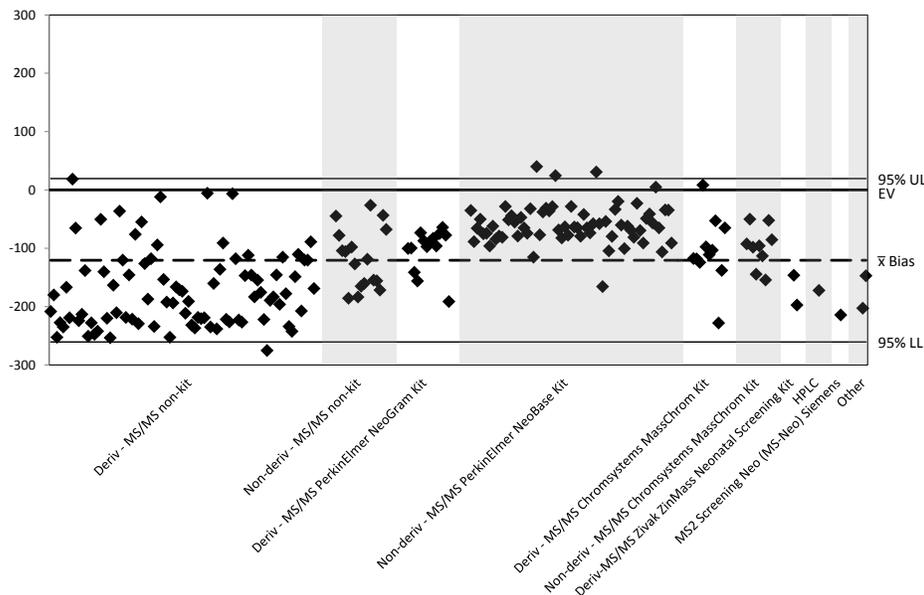
²Participant bias (\bar{X}) is the mean value of all participants' assayed values minus EV; represented by the broken line. Participant bias (\bar{X}) excludes outlier values. The 95% confidence interval is shown.

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)

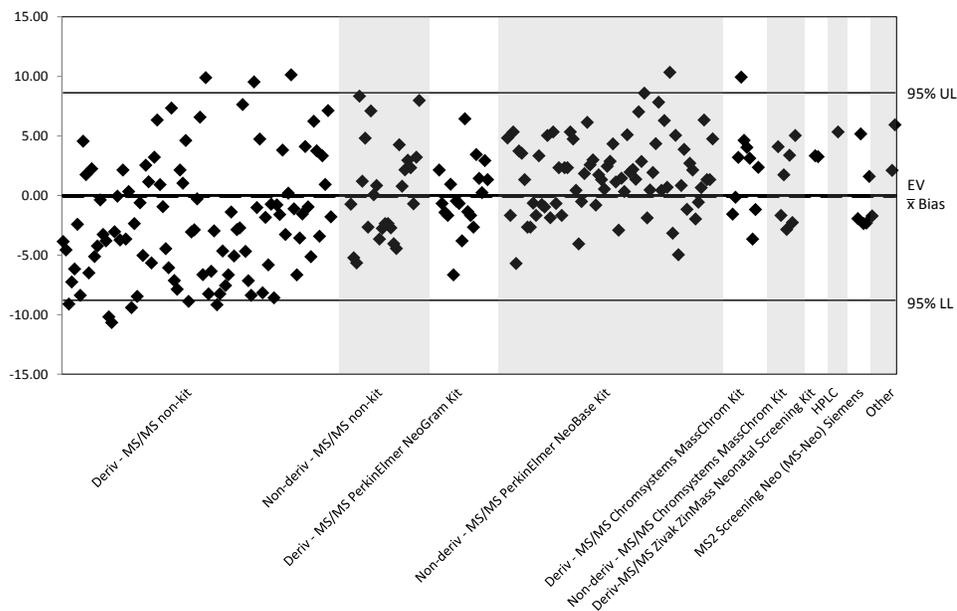
Bias Plot of Arginine (Arg) Values by Method
Quarter 1, Specimen 11454
Expected Value (EV)³ = 286.4 μmol/L whole blood

Quarter 1	
<i>Specimen 4</i>	
Enriched	275.0
CDC Assayed	213.4
Participant Mean	165.8
Participant Bias ²	-120.6



Bias Plot of Citrulline (Cit) Values by Method
Quarter 1, Specimen 11455
Expected Value (EV)³ = 22.7 μmol/L whole blood

Quarter 1	
<i>Specimen 5</i>	
Enriched	0.0
CDC Assayed	23.5
Participant Mean	22.6
Participant Bias ²	-0.1

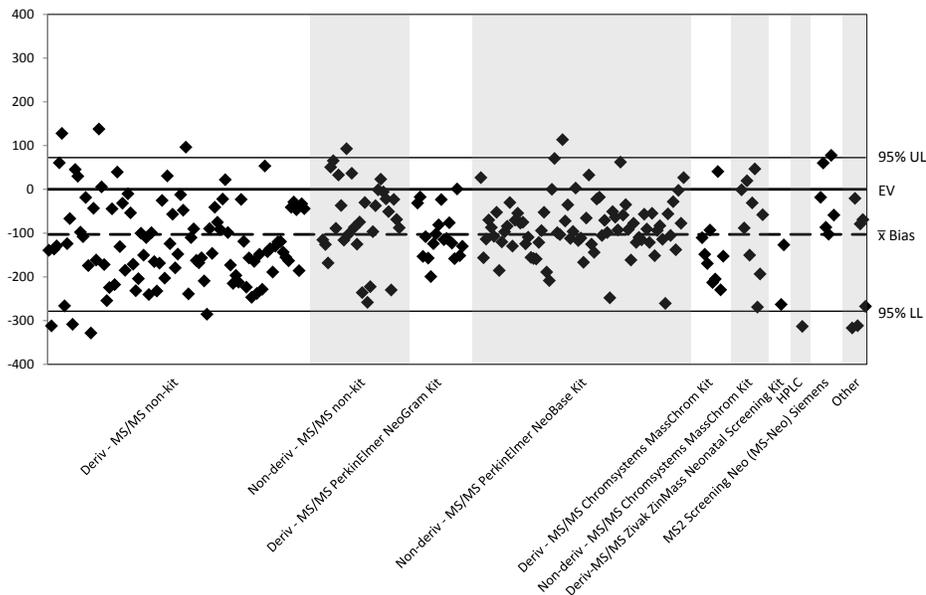


¹EV is the sum of the endogenous and enrichment values. The solid line represents perfect agreement with the EV or zero bias.
²Participant bias (\bar{X}) is the mean value of all participants' assayed values minus EV; represented by the broken line. Participant bias (\bar{X}) excludes outlier values. 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)

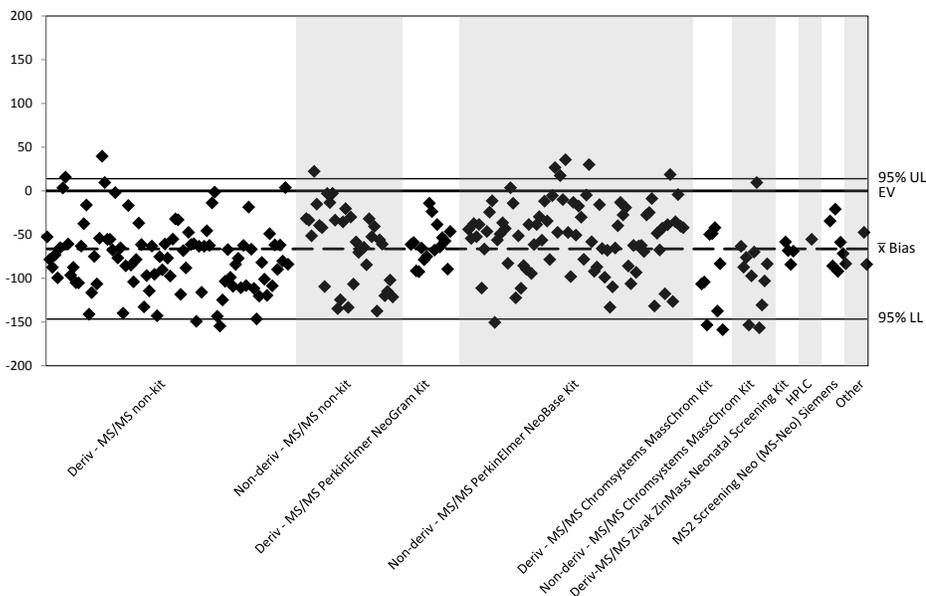
Bias Plot of Leucine (Leu) Values by Method
Quarter 1, Specimen 11451
Expected Value (EV)³ = 708.5 μmol/L whole blood

Quarter 1	
<i>Specimen 1</i>	
Enriched	600.0
CDC Assayed	602.1
Participant Mean	605.5
Participant Bias ²	-102.9



Bias Plot of Methionine (Met) Values by Method
Quarter 3, Specimen 31452
Expected Value (EV)¹ = 313.5 μmol/L whole blood

Quarter 3	
<i>Specimen 2</i>	
Enriched	300.0
CDC Assayed	244.2
Participant Mean	247.1
Participant Bias ²	-66.4

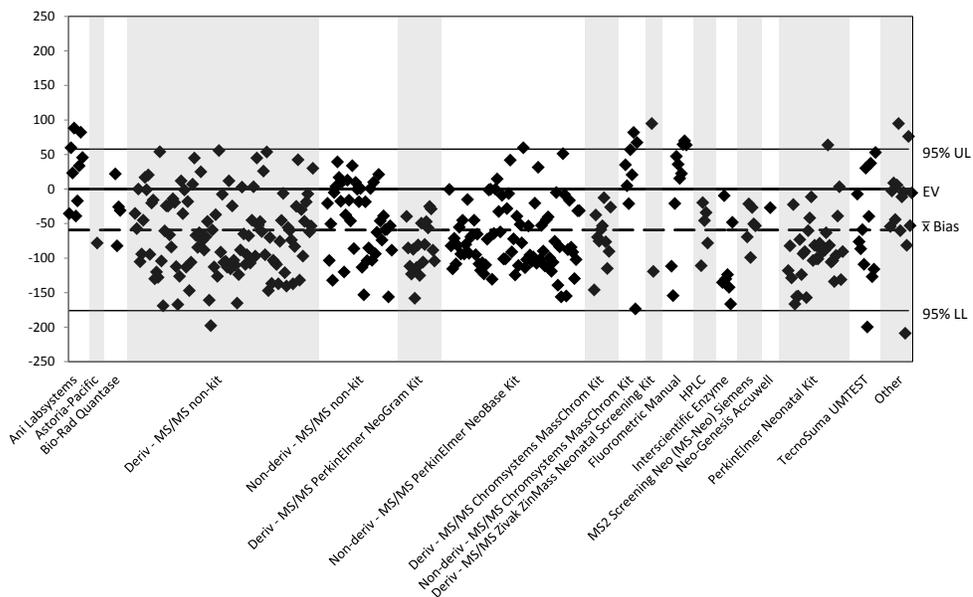


¹EV is the sum of the endogenous and enrichment values. The solid line represents perfect agreement with the EV or zero bias.
²Participant bias (\bar{X}) is the mean value of all participants' assayed values minus EV; represented by the broken line. Participant bias (\bar{X}) excludes outlier values. 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)

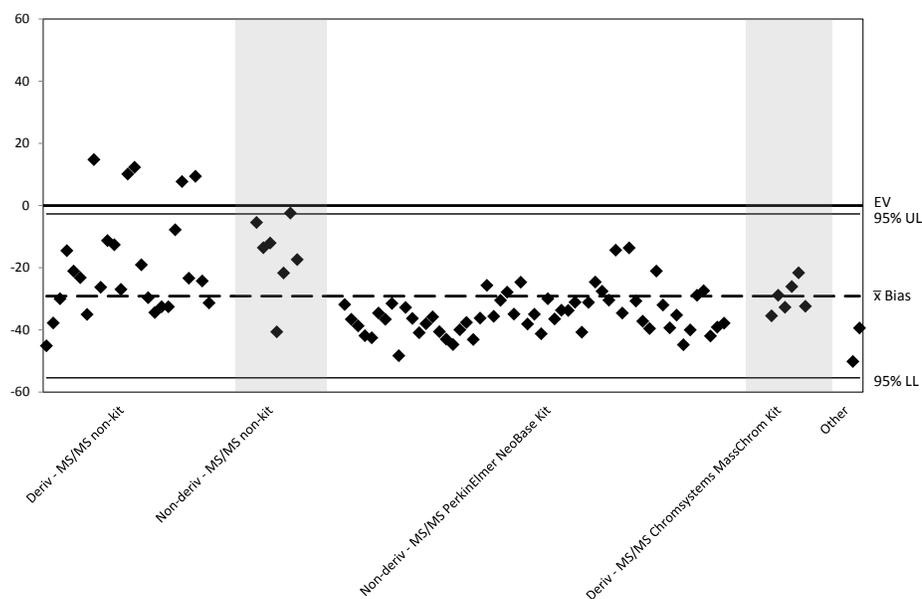
Bias Plot of Phenylalanine (Phe) Values by Method
Quarter 1, Specimen 11452
Expected Value (EV)³ = 445.3 μmol/L whole blood

Quarter 1	
<i>Specimen 2</i>	
Enriched	400.0
CDC Assayed	387.7
Participant Mean	386.1
Participant Bias ²	-59.1



Bias Plot of Succinylacetone (SUAC) Values by Method
Quarter 3, Specimen 31455
Expected Value (EV)¹ = 55.4 μmol/L whole blood

Quarter 3	
<i>Specimen 5</i>	
Enriched	55.0
CDC Assayed	34.8
Participant Mean	26.3
Participant Bias ²	-29.1



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

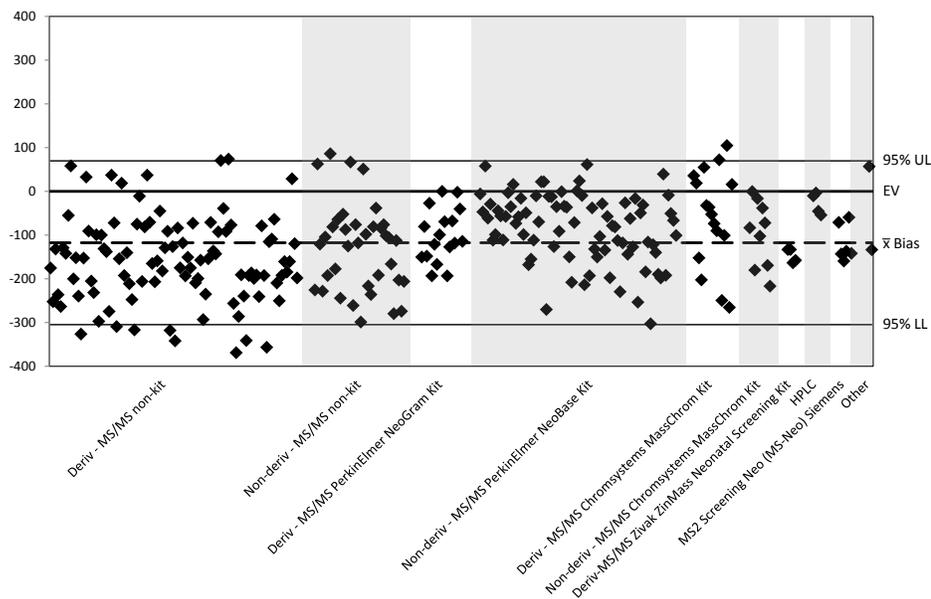
²Participant bias (\bar{X}) is the mean value of all participants' assayed values minus EV; represented by the broken line. Participant bias (\bar{X}) excludes outlier values. The 95% confidence interval is shown.

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)

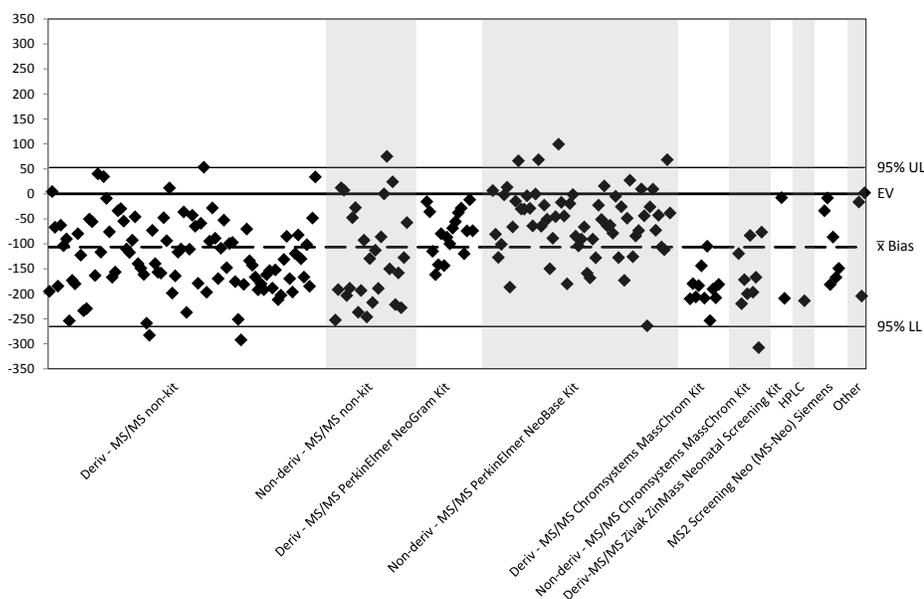
Bias Plot of Tyrosine (Tyr) Values by Method
Quarter 3, Specimen 31452
Expected Value (EV)¹ = 838.4 $\mu\text{mol/L}$ whole blood

Quarter 3	
Specimen 2	
Enriched	750.0
CDC Assayed	725.7
Participant Mean	720.8
Participant Bias ²	-117.5



Bias Plot of Valine (Val) Value by Method
Quarter 1, Specimen 11452
Expected Value (EV)³ = 547.8 $\mu\text{mol/L}$ whole blood

Quarter 1	
Specimen 2	
Enriched	450.0
CDC Assayed	371.0
Participant Mean	441.4
Participant Bias ²	-106.4



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

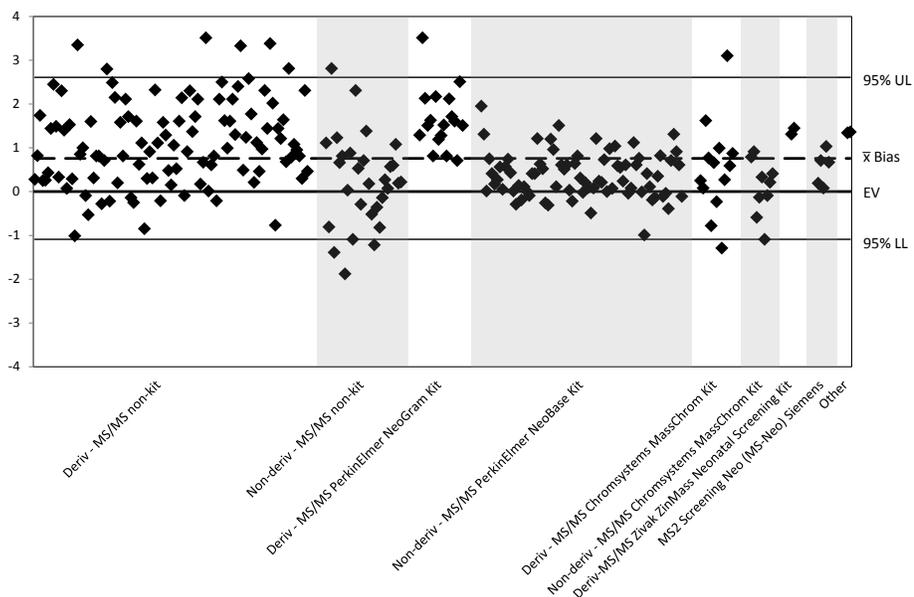
²Participant bias (\bar{X}) is the mean value of all participants' assayed values minus EV; represented by the broken line. Participant bias (\bar{X}) excludes outlier values. The 95% confidence interval is shown.

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 Free Carnitine (C0(L)) and Propionylcarnitine (C3)

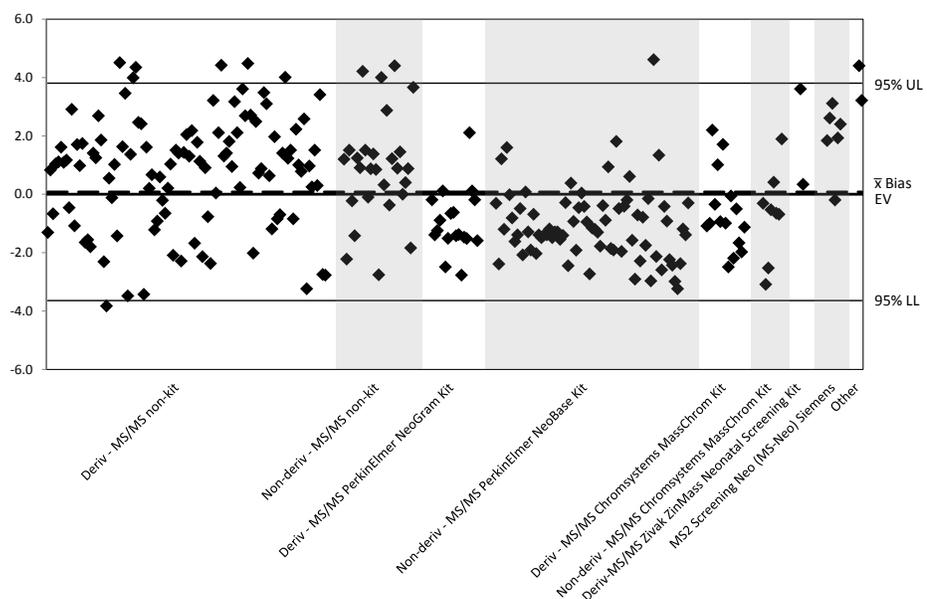
Bias Plot of Free Carnitine (C0(L)) Values by Method
Quarter 1, Specimen 11463
Expected Value (EV)³ = 3.19 μmol/L whole blood

Quarter 1	
Specimen 3	
Enriched	0.00
CDC Assayed	3.14
Participant Mean	3.95
Participant Bias ²	0.76



Bias Plot of Propionylcarnitine (C3) Values by Method
Quarter 1, Specimen 11465
Expected Value (EV)³ = 11.49 μmol/L whole blood

Quarter 1	
Specimen 5	
Enriched	10.00
CDC Assayed	11.61
Participant Mean	11.57
Participant Bias ²	0.08



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

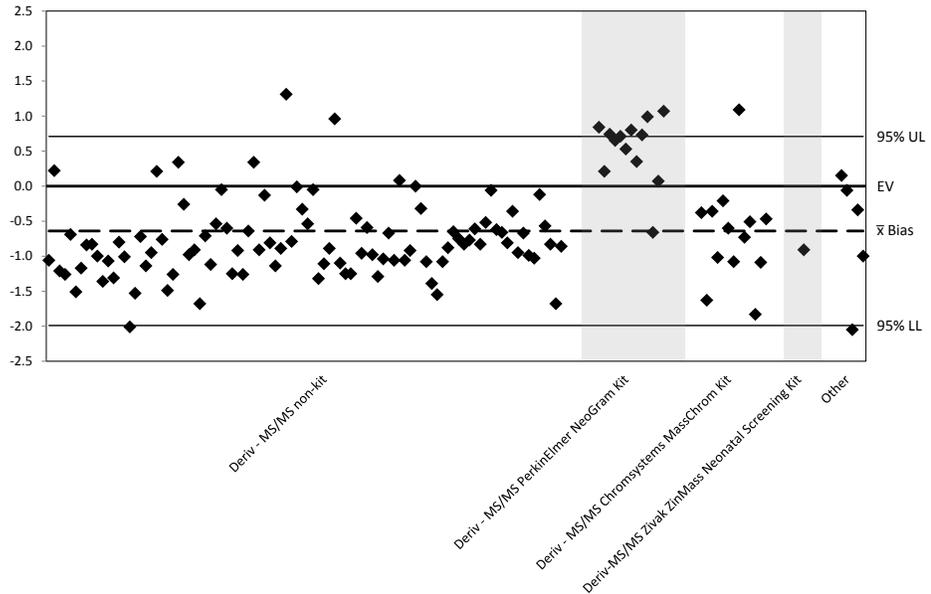
²Participant bias (\bar{X}) is the mean value of all participants' assayed values minus EV; represented by the broken line. Participant bias (\bar{X}) excludes outlier values. The 95% confidence interval is shown.

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+C4OH Non-derivatized

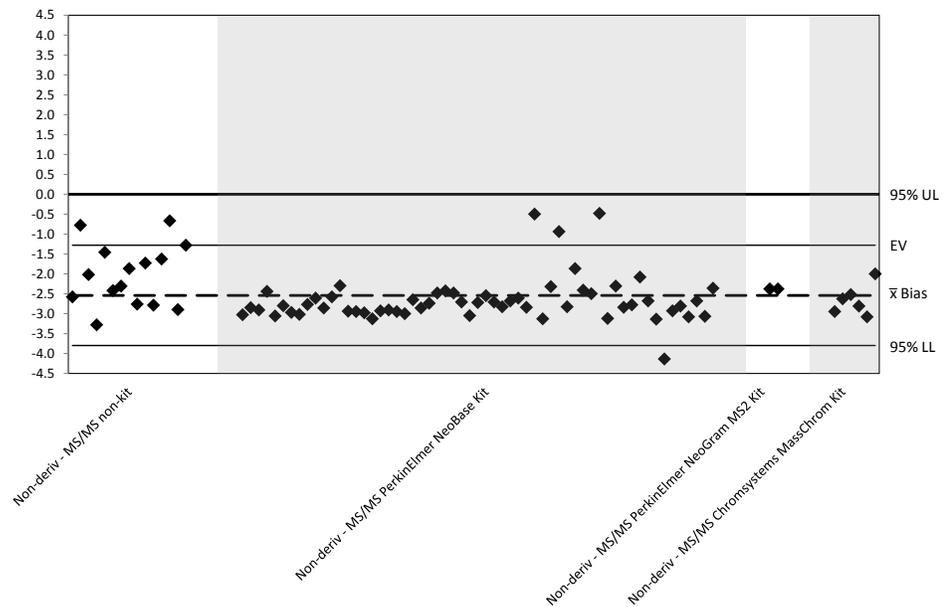
Bias Plot of Malonylcarnitine (C3DC) Derivatized Values by Method
Quarter 3, Specimen 31465
Expected Value (EV)¹ = 2.16 $\mu\text{mol/L}$ whole blood

Quarter 3	
Specimen 5	
Enriched	2.00
CDC Assayed	1.42
Participant Mean	1.52
Participant Bias ²	-0.64



Bias Plot of C3DC+C4OH Non-derivatized Value by Method
Quarter 3, Specimen 31465
Expected Value (EV)¹ = 4.18 $\mu\text{mol/L}$ whole blood

Quarter 3	
Specimen 5	
Enriched	4.00
CDC Assayed	3.75
Participant Mean	1.64
Participant Bias ²	-2.54



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

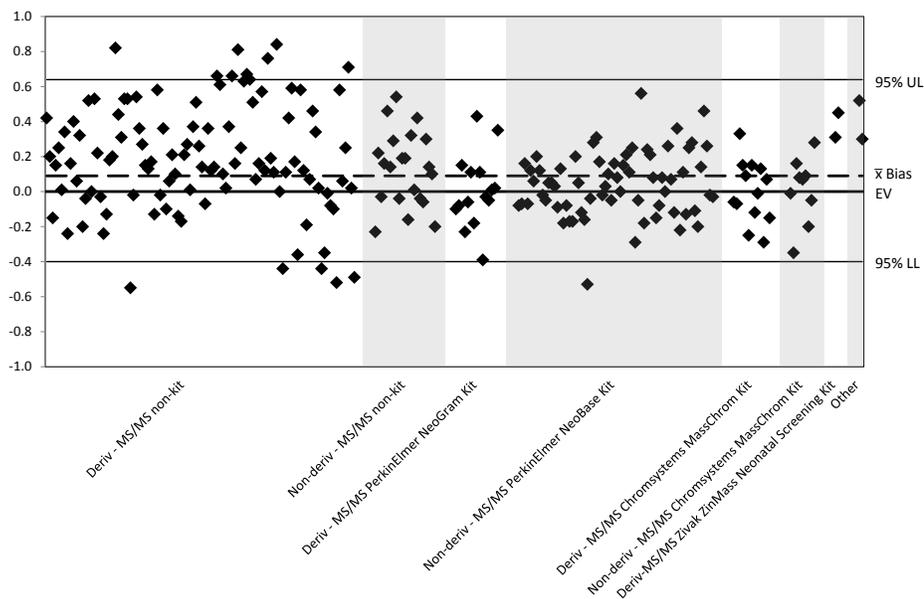
²Participant bias (\bar{X}) is the mean value of all participants' assayed values minus EV; represented by the broken line. Participant bias (\bar{X}) excludes outlier values. The 95% confidence interval is shown.

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

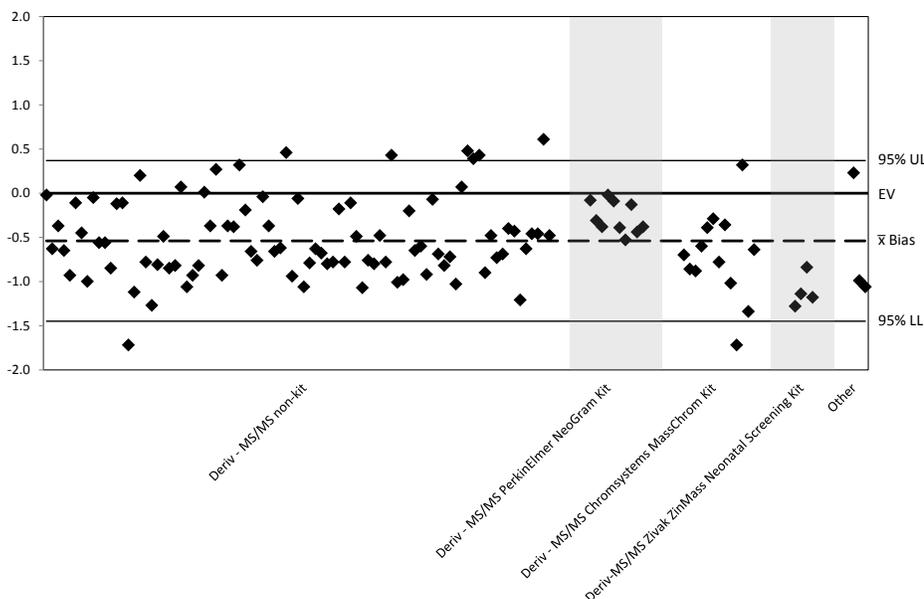
Bias Plot of Butyrylcarnitine (C4) Values by Method
Quarter 1, Specimen 11461
Expected Value (EV)³ = 1.64 μmol/L whole blood

<u>Quarter 1</u>	
Specimen 1	
Enriched	1.50
CDC Assayed	1.77
Participant Mean	1.76
Participant Bias ²	0.12



Bias Plot of Hydroxybutyrylcarnitine (C4OH) derivatized Values by Method
Quarter 3, Specimen 31465
Expected Value (EV)¹ = 2.08 μmol/L whole blood

<u>Quarter 3</u>	
Specimen 5	
Enriched	2.00
CDC Assayed	1.36
Participant Mean	1.54
Participant Bias ²	-0.54

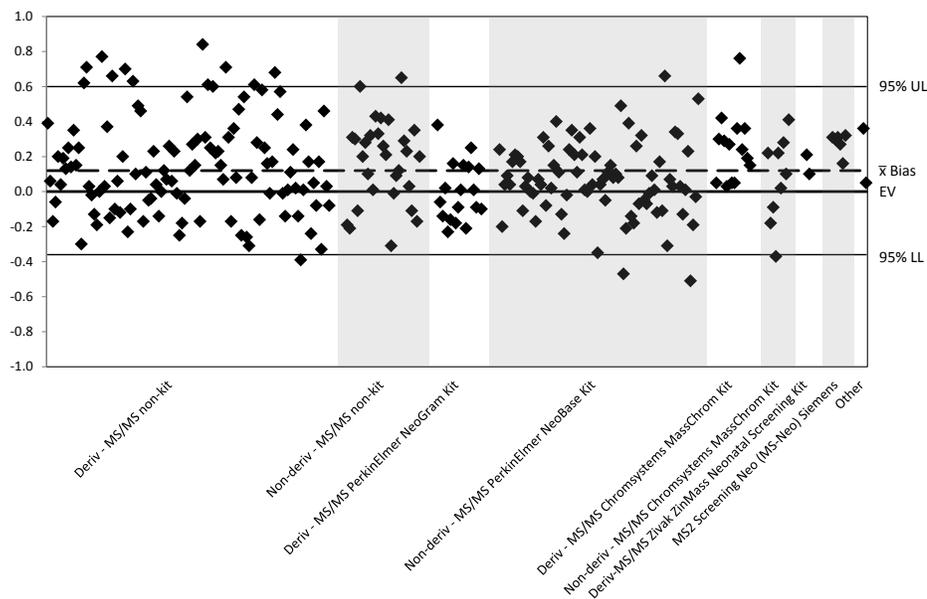


¹EV is the sum of the endogenous and enrichment values. The solid line represents perfect agreement with the EV or zero bias.
²Participant bias (\bar{X}) is the mean value of all participants' assayed values minus EV; represented by the broken line. Participant bias (\bar{X}) excludes outlier values. 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)

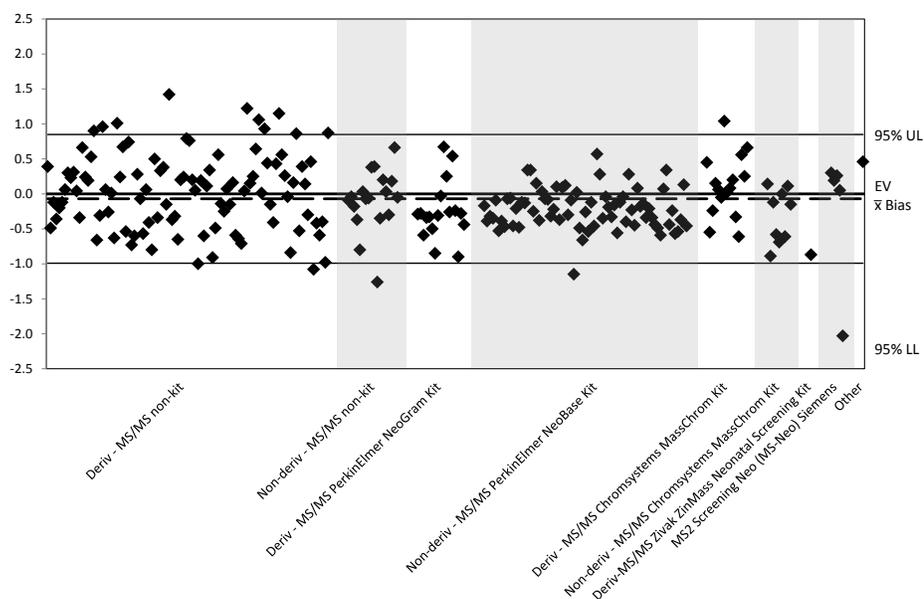
Bias Plot of Isovalerylcarnitine (C5) Values by Method
Quarter 1, Specimen 11461
Expected Value (EV)³ = 1.59 $\mu\text{mol/L}$ whole blood

Quarter 1	
Specimen 1	
Enriched	1.50
CDC Assayed	1.89
Participant Mean	1.71
Participant Bias ²	0.12



Bias Plot of Tiglylcarnitine (C5:1) Values by Method
Quarter 3, Specimen 31465
Expected Value (EV)¹ = 2.04 $\mu\text{mol/L}$ whole blood

Quarter 3	
Specimen 5	
Enriched	2.00
CDC Assayed	2.16
Participant Mean	1.97
Participant Bias ²	-0.07



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

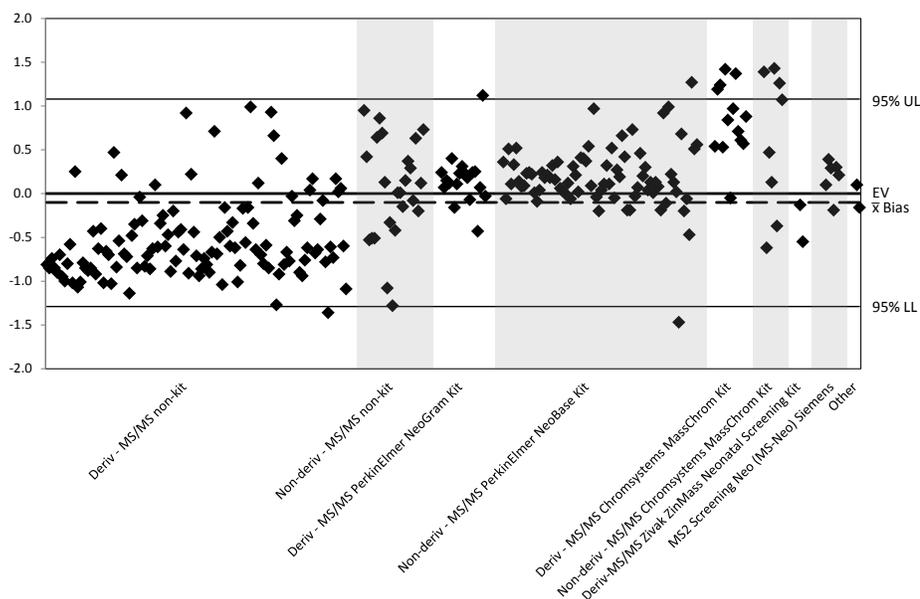
²Participant bias (\bar{X}) is the mean value of all participants' assayed values minus EV; represented by the broken line. Participant bias (\bar{X}) excludes outlier values. The 95% confidence interval is shown.

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)

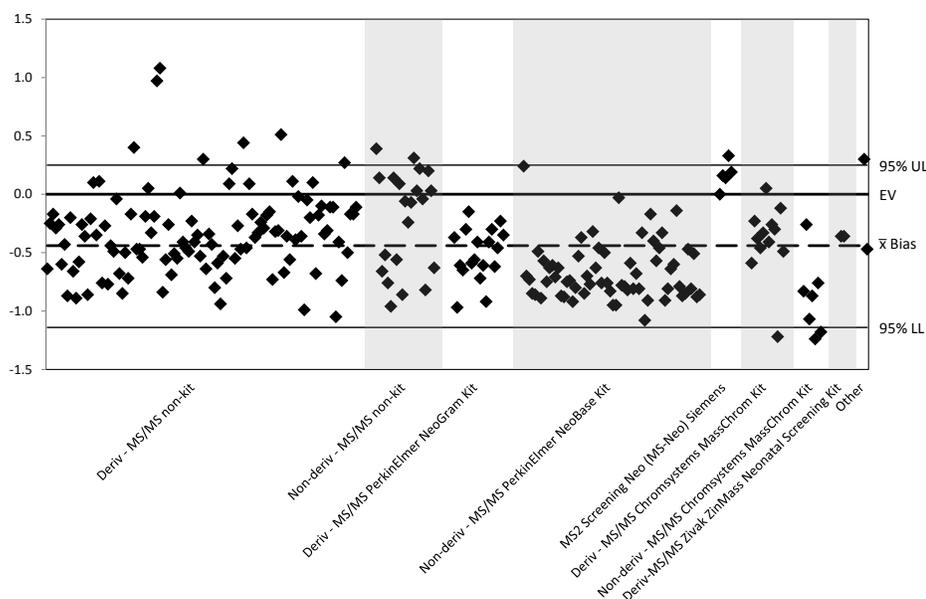
Bias Plot of Glutarylcarnitine (C5DC) Values by Method
Quarter 1, Specimen 11465
Expected Value (EV)³ = 1.53 μmol/L whole blood

Quarter 1	
<i>Specimen 5</i>	
Enriched	1.50
CDC Assayed	1.64
Participant Mean	1.43
Participant Bias ²	-0.10



Bias Plot of Hydroxyisovalerylcarnitine (C5OH) Values by Method
Quarter 1, Specimen 11462
Expected Value (EV)³ = 1.96 μmol/L whole blood

Quarter 1	
<i>Specimen 2</i>	
Enriched	1.50
CDC Assayed	1.62
Participant Mean	1.52
Participant Bias ²	-0.44

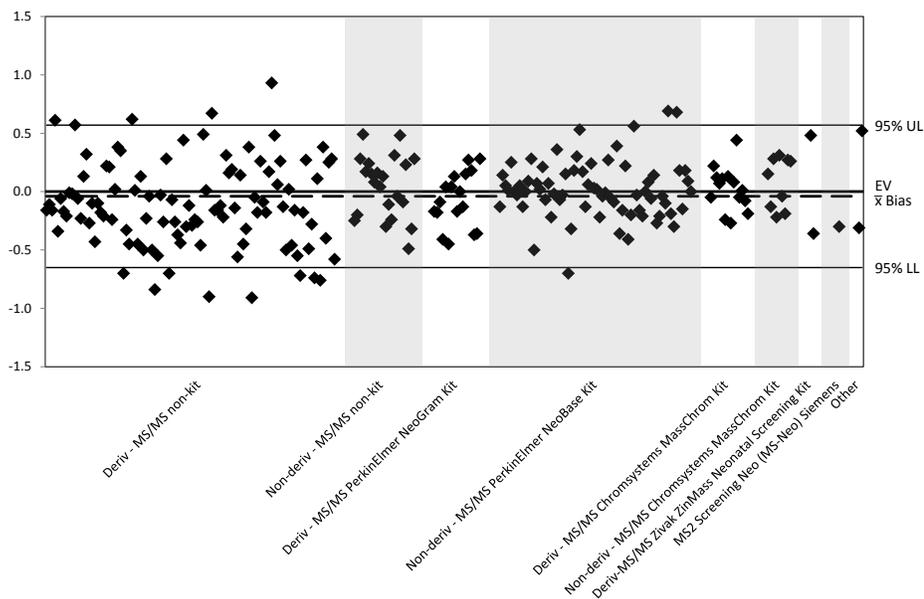


¹EV is the sum of the endogenous and enrichment values. The solid line represents perfect agreement with the EV or zero bias.
²Participant bias (\bar{X}) is the mean value of all participants' assayed values minus EV; represented by the broken line. Participant bias (\bar{X}) excludes outlier values. 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)

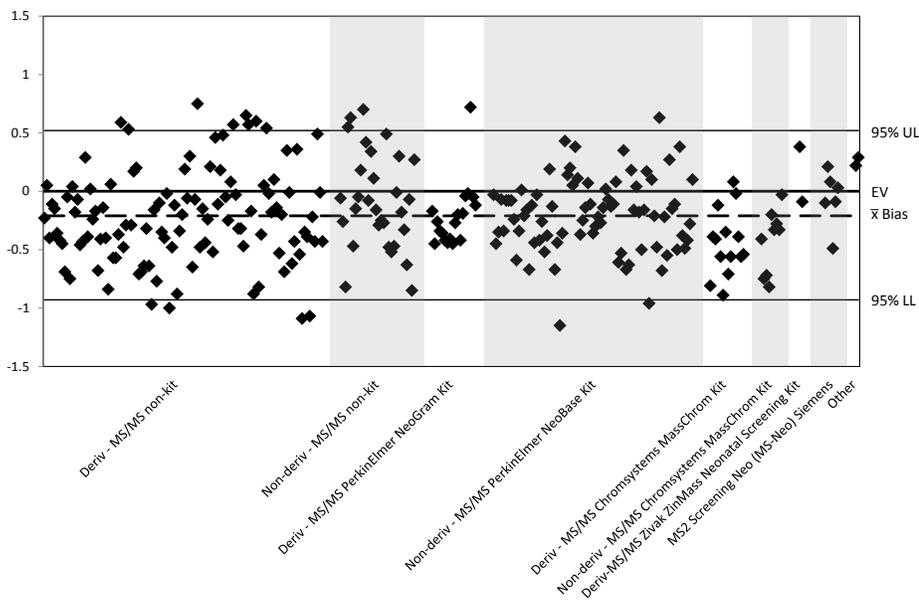
Bias Plot of Hexanoylcarnitine (C6) Values by Method
Quarter 1, Specimen 11461
Expected Value (EV)³ = 2.02 μ mol/L whole blood

Quarter 1	
Specimen 1	
Enriched	2.00
CDC Assayed	1.94
Participant Mean	1.98
Participant Bias ²	-0.04



Bias Plot of Octanoylcarnitine (C8) Values by Method
Quarter 1, Specimen 11461
Expected Value (EV)³ = 2.52 μ mol/L whole blood

Quarter 1	
Specimen 1	
Enriched	2.50
CDC Assayed	2.43
Participant Mean	2.31
Participant Bias ²	-0.21



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

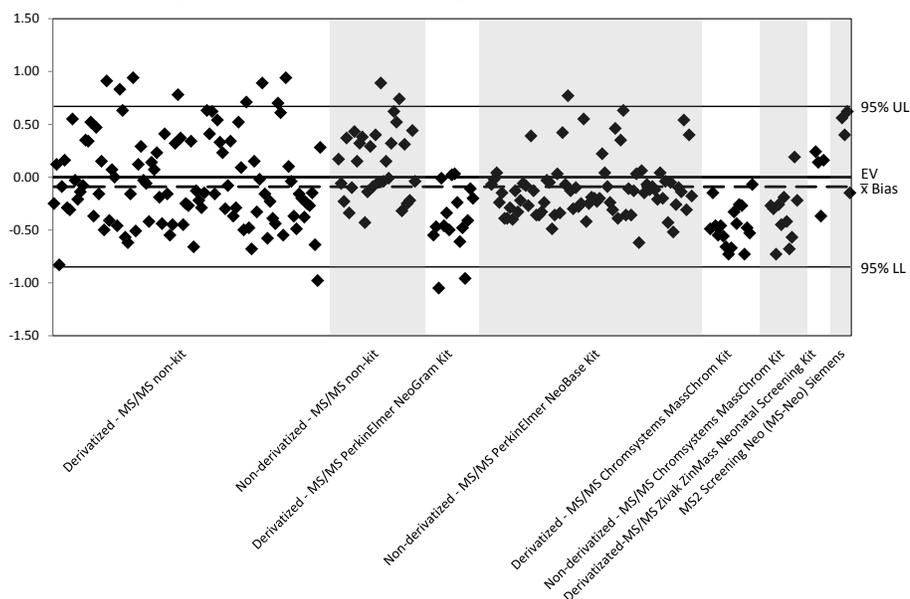
²Participant bias (\bar{X}) is the mean value of all participants' assayed values minus EV; represented by the broken line. Participant bias (\bar{X}) excludes outlier values. The 95% confidence interval is shown.

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

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

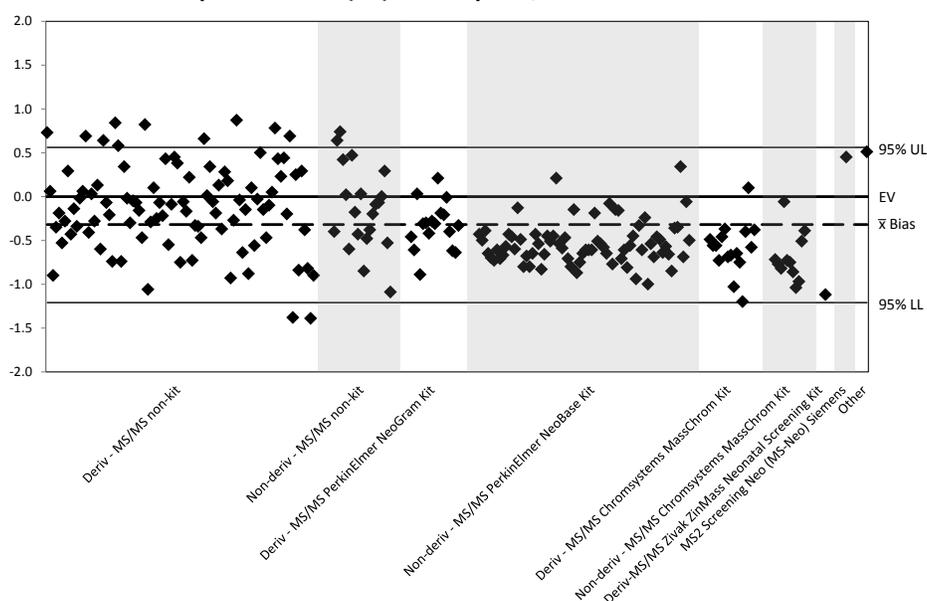
Bias Plot of Decanoylcarnitine (C10) Values by Method
Quarter 3, Specimen 31461
Expected Value (EV)¹ = 2.06 μmol/L whole blood

<u>Quarter 3</u>	
<i>Specimen 1</i>	
Enriched	2.00
CDC Assayed	2.06
Participant Mean	1.97
Participant Bias ²	-0.09



Bias Plot of Decenoylcarnitine (C10:1) Values by Method
Quarter 3, Specimen 31461
Expected Value (EV)¹ = 2.06 μmol/L whole blood

<u>Quarter 3</u>	
<i>Specimen 1</i>	
Enriched	2.00
CDC Assayed	1.93
Participant Mean	1.74
Participant Bias ²	-0.32

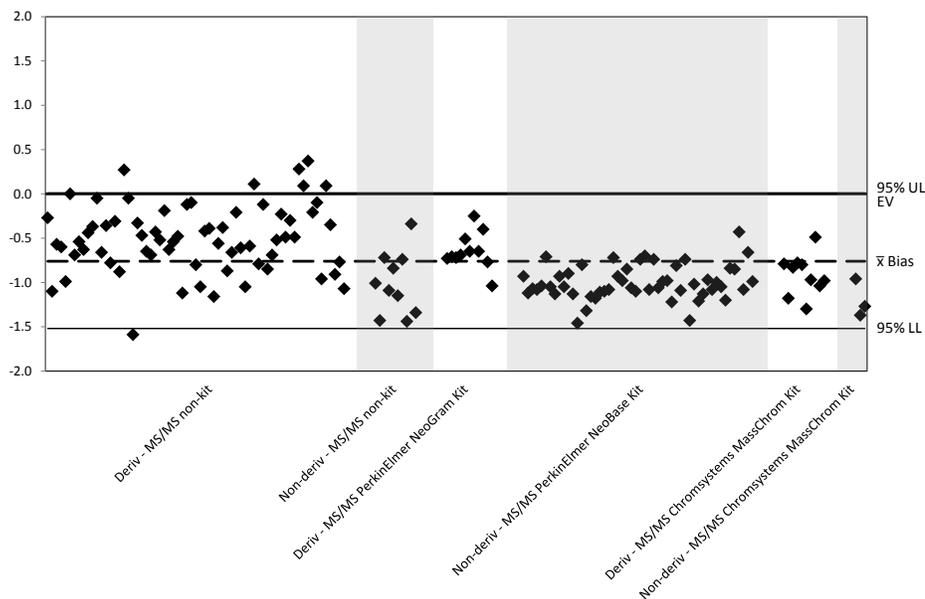


¹EV is the sum of the endogenous and enrichment values. The solid line represents perfect agreement with the EV or zero bias.
²Participant bias (\bar{X}) is the mean value of all participants' assayed values minus EV; represented by the broken line. Participant bias (\bar{X}) excludes outlier values. 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)

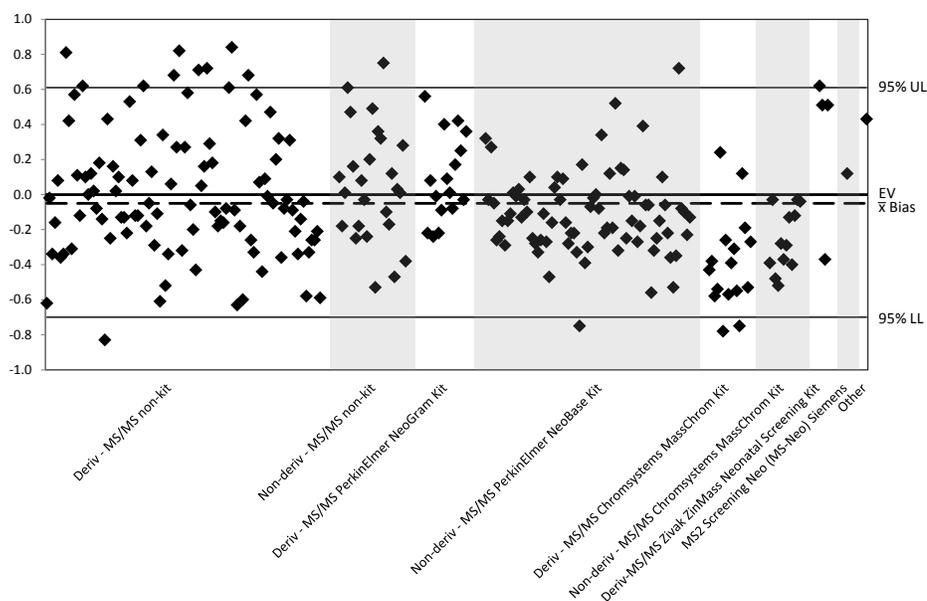
Bias Plot of Decadienoylcarnitine (C10:2) Values by Method
Quarter 3, Specimen 31461
Expected Value (EV)¹ = 2.03 $\mu\text{mol/L}$ whole blood

Quarter 3	
Specimen 1	
Enriched	2.00
CDC Assayed	1.57
Participant Mean	1.27
Participant Bias ²	-0.76



Bias Plot of Myristoylcarnitine (C14) Values by Method
Quarter 3, Specimen 31462
Expected Value (EV)¹ = 2.08 $\mu\text{mol/L}$ whole blood

Quarter 3	
Specimen 2	
Enriched	2.00
CDC Assayed	2.05
Participant Mean	2.03
Participant Bias ²	-0.05



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

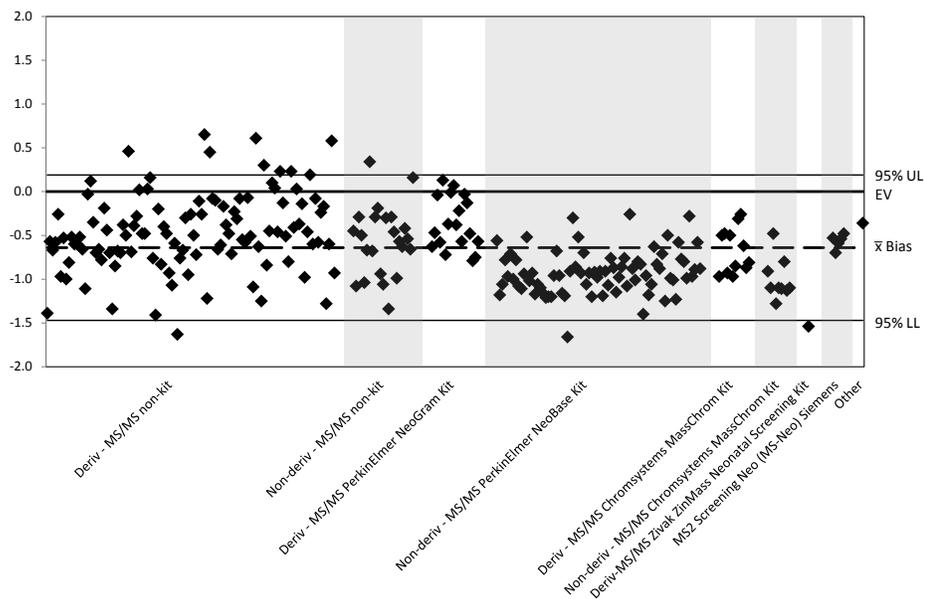
²Participant bias (\bar{X}) is the mean value of all participants' assayed values minus EV; represented by the broken line. Participant bias (\bar{X}) excludes outlier values. The 95% confidence interval is shown.

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)

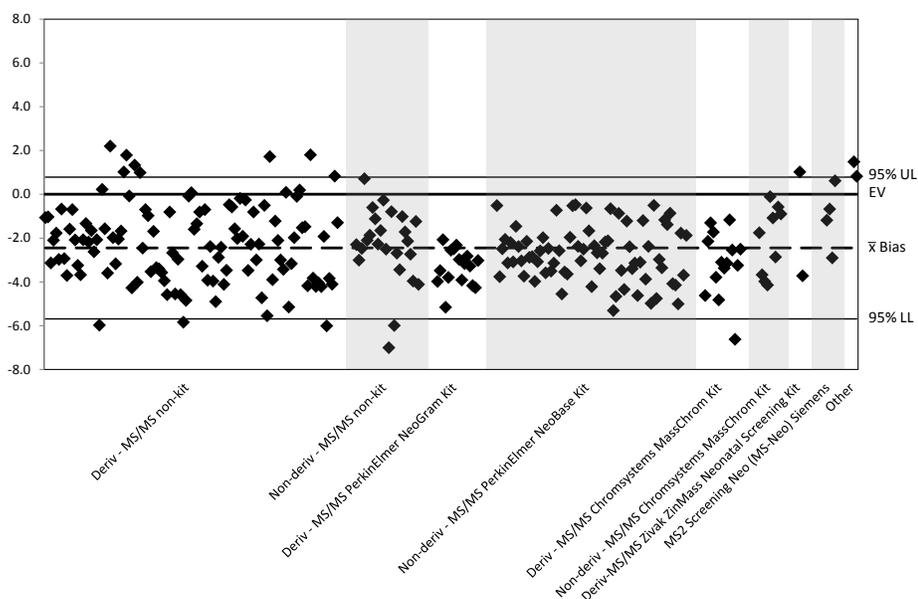
Bias Plot of Tetradecenoylcarnitine (C14:1) Values by Method
Quarter 1, Specimen 11462
Expected Value (EV)³ = 2.58 μmol/L whole blood

Quarter 1	
<i>Specimen 2</i>	
Enriched	2.50
CDC Assayed	2.20
Participant Mean	1.94
Participant Bias ²	-0.64



Bias Plot of Palmitoylcarnitine (C16) Values by Method
Quarter 1, Specimen 11461
Expected Value (EV)³ = 14.48 μmol/L whole blood

Quarter 1	
<i>Specimen 1</i>	
Enriched	14.00
CDC Assayed	12.36
Participant Mean	12.03
Participant Bias ²	-2.45

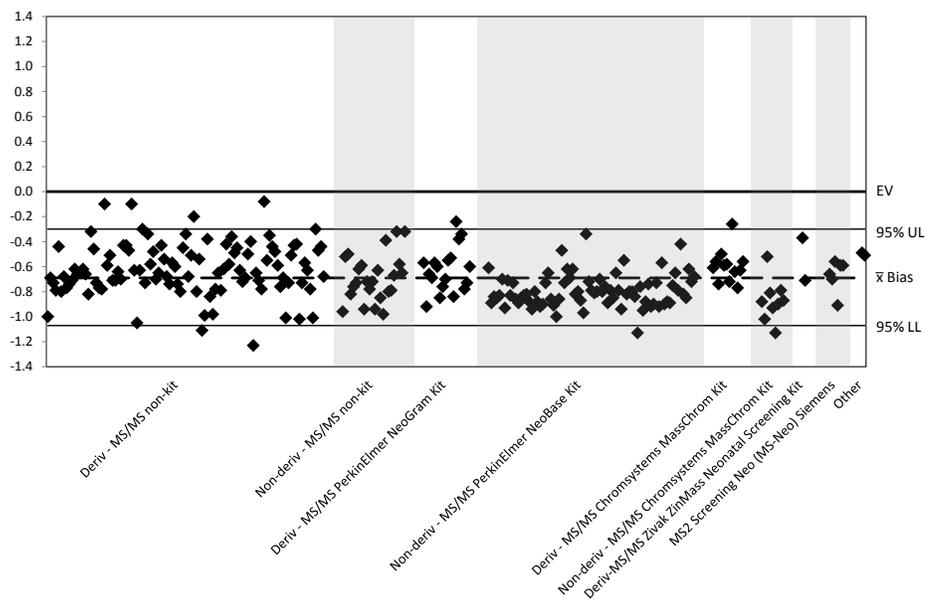


¹EV is the sum of the endogenous and enrichment values. The solid line represents perfect agreement with the EV or zero bias.
²Participant bias (\bar{X}) is the mean value of all participants' assayed values minus EV; represented by the broken line. Participant bias (\bar{X}) excludes outlier values. 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)

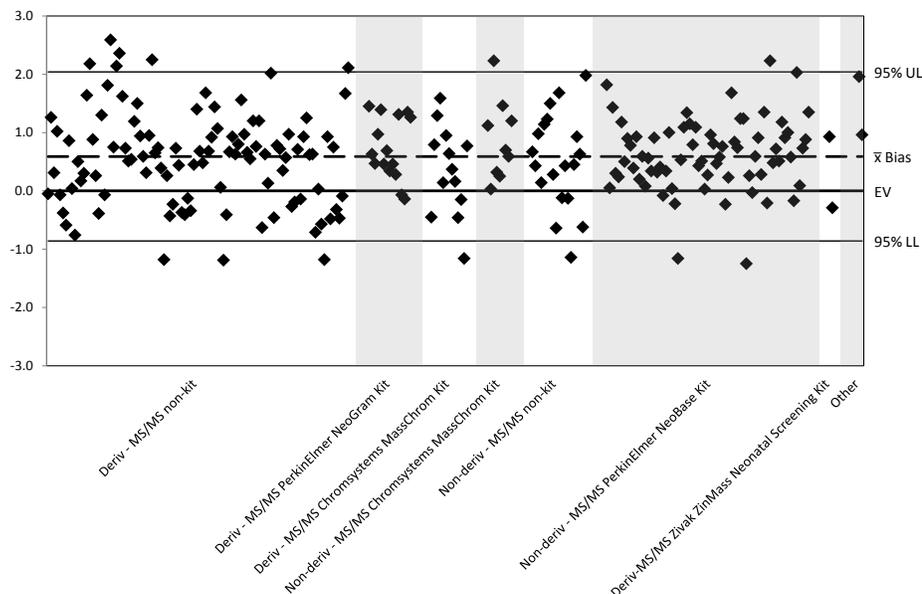
Bias Plot of Hydroxypalmitoylcarnitine (C16OH) Values by Method
Quarter 1, Specimen 11462
Expected Value (EV)³ = 1.52 $\mu\text{mol/L}$ whole blood

Quarter 1	
Specimen 2	
Enriched	1.50
CDC Assayed	1.07
Participant Mean	0.83
Participant Bias ²	-0.69



Bias Plot of Stearoylcarnitine (C18) Values by Method
Quarter 1, Specimen 11464
Expected Value (EV)³ = 4.17 $\mu\text{mol/L}$ whole blood

Quarter 1	
Specimen 4	
Enriched	4.00
CDC Assayed	4.61
Participant Mean	4.76
Participant Bias ²	0.59



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

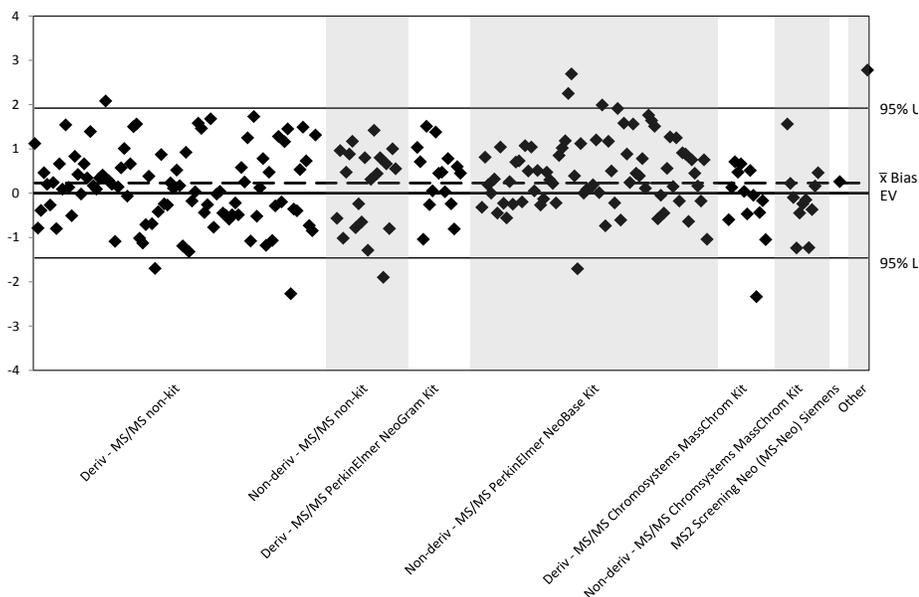
²Participant bias (\bar{X}) is the mean value of all participants' assayed values minus EV; represented by the broken line. Participant bias (\bar{X}) excludes outlier values. The 95% confidence interval is shown.

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)

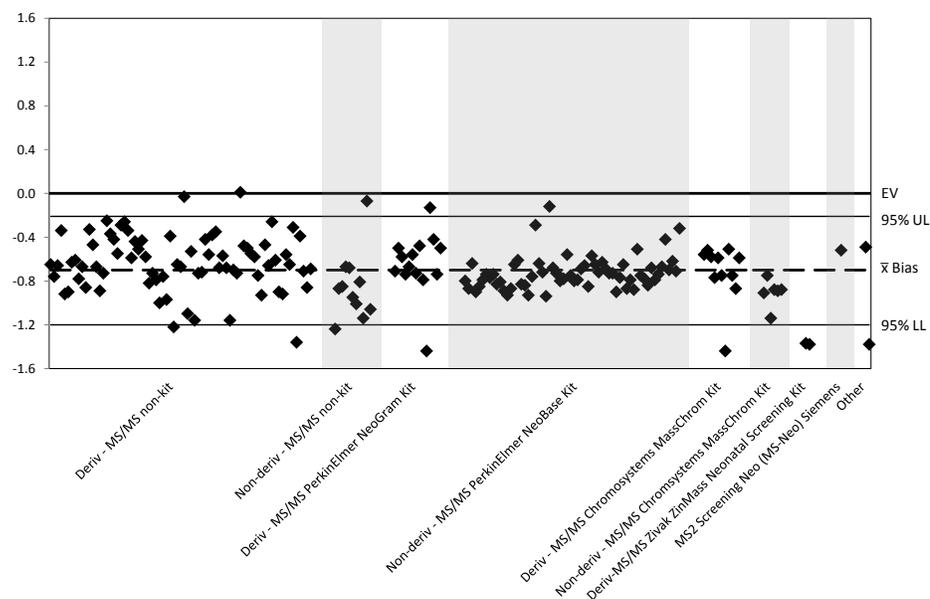
Bias Plot of Oleoylcarnitine (C18:1) Values by Method
Quarter 3, Specimen 31463
Expected Value (EV)¹ = 5.04 μmol/L whole blood

Quarter 3	
Specimen 3	
Enriched	4.00
CDC Assayed	5.33
Participant Mean	5.27
Participant Bias ²	0.23



Bias Plot of Hydroxystearoylcarnitine (C18OH) Values by Method
Quarter 1, Specimen 11462
Expected Value (EV)³ = 1.52 μmol/L whole blood

Quarter 1	
Specimen 2	
Enriched	1.50
CDC Assayed	1.00
Participant Mean	0.82
Participant Bias ²	-0.70



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

²Participant bias (\bar{X}) is the mean value of all participants' assayed values minus EV; represented by the broken line. Participant bias (\bar{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.

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Index of Quality Control Tables

Analyte	Page
17 α -Hydroxyprogesterone (17-OHP)	50
Thyroxine (T ₄)	51
Thyroid-Stimulating Hormone (TSH)	52
Total Galactose (TGal)	54
Galactose-1-Phosphate Uridyltransferase (GALT)	58
Immunoreactive Trypsinogen (IRT)	60
Alanine (Ala)	62
Arginine (Arg)	64
Citrulline (Cit)	66
Leucine (Leu)	68
Methionine (Met)	70
Phenylalanine (Phe)	72
Succinylacetone (SUAC)	76
Tyrosine (Tyr)	78
Valine (Val)	80
Free Carnitine (C0)	82
Acetylcarnitine (C2)	84
Propionylcarnitine (C3)	86
Malonylcarnitine (C3DC)	88
Malonylcarnitine + Hydroxybutyrylcarnitine (C3DC + C4OH)	90
Butyrylcarnitine (C4)	92
Hydroxybutyrylcarnitine (C4OH)	94
Isovalerylcarnitine (C5)	96
Glutarylcarnitine (C5DC)	98
Hydroxyisovalerylcarnitine (C5OH)	100
Hexanoylcarnitine (C6)	102
Octanoylcarnitine (C8)	104
Decanoylcarnitine (C10)	106
Dodecanoylcarnitine (C12)	108
Myristoylcarnitine (C14)	110
Palmitoylcarnitine (C16)	112
Hydroxypalmitoylcarnitine (C16OH)	114
Stearoylcarnitine (C18)	116
Hydroxystearoylcarnitine (C18OH)	118

Table 17a. 2014 Quality Control Data
Summaries of Statistical Analyses

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

METHOD	N	Average		Y- Intercept*	Slope
		Mean	Within Lab SD		
Lot 1351 - Enriched 25.0 ng/mL serum					
Siemens Healthcare Diagnostics	57	23.3	2.4	3.1	3.7 0.8
Neo-Genesis Accuwell	40	23.9	2.7	3.4	1.9 0.9
Delfia	338	18.9	2.0	3.3	-0.8 0.8
Delfia Neonatal 17-OHP (A024)	127	20.3	3.1	4.9	-2.4 0.9
AutoDelfia	479	20.7	2.1	3.1	-0.5 0.9
AutoDelfia Neonatal 17-OHP (B024)	743	19.9	2.2	2.9	0.2 0.8
Bio-Rad Quantase	180	21.8	4.7	7.6	1.3 0.8
TecnoSuma UMELISA	29	27.3	1.8	6.1	-2.2 1.2
LC-MS/MS	60	23.5	3.4	4.8	0.1 0.9
MP Biomedicals RIA	50	25.7	3.7	4.1	2.0 0.9
PerkinElmer GSP Neonatal	505	20.5	1.8	2.7	-0.1 0.8
In House	40	24.0	3.9	5.5	5.5 0.8
Lot 1352 - Enriched 50.0 ng/mL serum					
Siemens Healthcare Diagnostics	60	42.5	4.9	6.6	3.7 0.8
Neo-Genesis Accuwell	38	50.4	3.6	5.5	1.9 0.9
Delfia	333	39.7	4.4	6.6	-0.8 0.8
Delfia Neonatal 17-OHP (A024)	126	43.1	6.9	11.0	-2.4 0.9
AutoDelfia	475	43.5	4.2	6.3	-0.5 0.9
AutoDelfia Neonatal 17-OHP (B024)	740	42.0	4.1	5.2	0.2 0.8
Bio-Rad Quantase	178	42.4	9.8	14.4	1.3 0.8
TecnoSuma UMELISA	29	57.4	3.8	15.9	-2.2 1.2
LC-MS/MS	57	44.3	5.8	6.5	0.1 0.9
MP Biomedicals RIA	50	48.1	6.3	6.3	2.0 0.9
PerkinElmer GSP Neonatal	508	42.9	3.5	4.9	-0.1 0.8
In House	40	43.6	6.6	10.7	5.5 0.8
Lot 1353 - Enriched 100.0 ng/mL serum					
Siemens Healthcare Diagnostics	60	81.7	10.6	15.0	3.7 0.8
Neo-Genesis Accuwell	40	94.3	11.8	12.0	1.9 0.9
Delfia	337	79.1	10.1	15.9	-0.8 0.8
Delfia Neonatal 17-OHP (A024)	129	88.3	13.0	21.4	-2.4 0.9
AutoDelfia	475	85.8	8.8	13.7	-0.5 0.9
AutoDelfia Neonatal 17-OHP (B024)	729	81.5	8.1	10.2	0.2 0.8
Bio-Rad Quantase	176	83.4	19.8	32.2	1.3 0.8
TecnoSuma UMELISA	30	116.4	13.1	31.5	-2.2 1.2
LC-MS/MS	59	91.1	12.3	13.1	0.1 0.9
MP Biomedicals RIA	50	95.5	11.5	14.2	2.0 0.9
PerkinElmer GSP Neonatal	504	84.1	7.4	10.5	-0.1 0.8
In House	40	80.8	10.5	21.6	5.5 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 17b. 2014 Quality Control Data
Summaries of Statistical Analyses

THYROXINE ($\mu\text{g T}_4/\text{dL serum}$)

METHOD	N	Average			Y- Intercept*	Slope
		Mean	Lab SD	Total SD		
Lot 1301 - Assayed 1.6 $\mu\text{g}/\text{dL}$ serum						
Siemens Healthcare Diagnostics	39	2.3	0.5	0.6	0.3	1.2
Neo-Genesis Accuwell	40	1.2	0.3	0.5	-0.5	1.1
Delfia	186	1.8	0.3	0.4	0.3	1.0
AutoDelfia	411	1.6	0.3	0.4	0.1	1.0
Interscientific NeoMAP Multiplex	99	1.8	0.4	0.4	0.1	1.0
PerkinElmer GSP Neonatal	290	1.6	0.2	0.3	0.0	1.0
Lot 1302 - Assayed 6.1 $\mu\text{g}/\text{dL}$ serum						
Siemens Healthcare Diagnostics	39	7.8	0.9	0.9	0.3	1.2
Neo-Genesis Accuwell	40	6.0	0.9	0.9	-0.5	1.1
Delfia	187	6.1	0.8	0.8	0.3	1.0
AutoDelfia	423	6.1	0.6	0.7	0.1	1.0
Interscientific NeoMAP Multiplex	100	6.3	0.6	0.8	0.1	1.0
PerkinElmer GSP Neonatal	295	6.2	0.5	0.6	0.0	1.0
Lot 1303 - Assayed 9.5 $\mu\text{g}/\text{dL}$ serum						
Siemens Healthcare Diagnostics	40	12.1	1.2	1.2	0.3	1.2
Neo-Genesis Accuwell	40	9.6	1.2	1.5	-0.5	1.1
Delfia	188	9.5	1.3	1.4	0.3	1.0
AutoDelfia	421	9.3	0.9	1.0	0.1	1.0
Interscientific NeoMAP Multiplex	100	10.0	1.1	1.4	0.1	1.0
PerkinElmer GSP Neonatal	290	9.7	0.9	1.0	0.0	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 17c. 2014 Quality Control Data
Summaries of Statistical Analyses

THYROID-STIMULATING HORMONE (μ IU TSH/mL serum)

METHOD	N	Average Within		Y-Intercept*	Slope	
		Mean	Lab SD			
Lot 1311 - Enriched 25.0 μ IU/mL serum						
Siemens Healthcare Diagnostics	40	31.6	2.3	2.5	2.8	1.2
Neo-Genesis Accuwell	20	18.9	1.7	8.3	-10.4	1.2
Delfia	480	25.2	2.4	4.9	-0.1	1.0
AutoDelfia	908	26.1	2.2	2.8	0.3	1.0
Ani Labsystems	108	24.2	2.5	3.8	-0.8	1.0
Bio-Rad Quantase	97	25.3	3.4	9.4	4.9	0.9
TecnoSuma UMELISA	30	29.6	3.3	4.0	0.8	1.2
Bioclone ELISA	20	20.9	2.2	3.6	-1.4	0.9
DiaSorin	88	25.6	2.4	3.6	3.1	0.9
Interscientific NeoMAP Multiplex	40	22.2	2.6	3.9	-3.6	1.0
PerkinElmer GSP Neonatal	283	23.5	2.1	3.5	-0.3	0.9
In House	40	25.3	2.7	8.0	3.9	0.9
Lot 1312 - Enriched 40.0 μ IU/mL serum						
Siemens Healthcare Diagnostics	39	49.7	4.4	6.0	2.8	1.2
Neo-Genesis Accuwell	20	34.8	2.9	8.1	-10.4	1.2
Delfia	471	41.0	4.2	7.2	-0.1	1.0
AutoDelfia	913	42.0	3.5	4.8	0.3	1.0
Ani Labsystems	97	40.4	4.2	5.7	-0.8	1.0
Bio-Rad Quantase	100	41.4	6.8	14.0	4.9	0.9
TecnoSuma UMELISA	29	51.3	4.7	8.2	0.8	1.2
Bioclone ELISA	20	33.7	4.3	5.7	-1.4	0.9
DiaSorin	90	40.5	3.8	5.3	3.1	0.9
Interscientific NeoMAP Multiplex	40	35.8	2.8	6.0	-3.6	1.0
PerkinElmer GSP Neonatal	286	37.0	3.3	5.9	-0.3	0.9
In House	38	40.8	3.4	12.1	3.9	0.9
Lot 1313 - Enriched 80.0 μ IU/mL serum						
Siemens Healthcare Diagnostics	37	95.6	10.8	13.1	2.8	1.2
Neo-Genesis Accuwell	20	81.8	14.5	14.5	-10.4	1.2
Delfia	466	81.5	7.5	11.8	-0.1	1.0
AutoDelfia	906	83.2	6.9	10.7	0.3	1.0
Ani Labsystems	100	80.2	7.5	9.6	-0.8	1.0
Bio-Rad Quantase	100	74.0	12.3	25.8	4.9	0.9
TecnoSuma UMELISA	30	97.2	11.1	11.5	0.8	1.2
Bioclone ELISA	20	69.4	11.0	19.2	-1.4	0.9
DiaSorin	87	76.4	7.8	10.3	3.1	0.9
Interscientific NeoMAP Multiplex	39	77.1	5.5	10.2	-3.6	1.0
PerkinElmer GSP Neonatal	281	75.1	6.5	9.1	-0.3	0.9
In House	40	74.8	8.5	25.9	3.9	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.

THYROID-STIMULATING HORMONE (μ IU TSH/mL serum)

- continued -

METHOD	N	Average			Y- Intercept*	Slope
		Mean	Within Lab SD	Total SD		
Lot 1411 - Enriched 25.0 μ IU/mL serum						
Siemens Healthcare Diagnostics	40	35.0	3.6	6.1	-4.1	1.5
Neo-Genesis Accuwell	20	26.6	2.4	2.6	0.5	1.0
MP Biomedicals ELISA	10	23.7	3.0	3.0	8.6	0.7
Delfia	552	25.7	2.8	6.3	-0.7	1.1
AutoDelfia	805	28.5	2.2	2.9	0.6	1.1
Ani Labsystems	60	27.4	2.7	4.6	-2.9	1.2
Bio-Rad Quantase	85	26.1	2.6	6.2	-2.0	1.2
TecnoSuma UMELISA	19	33.2	4.8	8.1	-1.8	1.4
Bioclone ELISA	10	24.6	1.0	1.0	-3.4	1.1
DiaSorin	77	25.7	2.5	4.3	1.3	1.0
Interscientific NeoMAP Multiplex	50	25.8	1.9	2.1	-3.1	1.1
PerkinElmer GSP Neonatal	358	25.7	1.9	2.5	-0.7	1.1
In House	30	19.3	2.0	9.3	1.7	0.7
Lot 1412 - Enriched 40.0 μ IU/mL serum						
Siemens Healthcare Diagnostics	40	56.6	5.1	6.4	-4.1	1.5
Neo-Genesis Accuwell	20	41.6	4.0	4.6	0.5	1.0
MP Biomedicals ELISA	10	36.4	2.5	2.5	8.6	0.7
Delfia	551	41.6	4.4	10.5	-0.7	1.1
AutoDelfia	803	46.5	3.6	5.0	0.6	1.1
Ani Labsystems	59	47.0	3.5	5.3	-2.9	1.2
Bio-Rad Quantase	88	44.6	3.8	9.5	-2.0	1.2
TecnoSuma UMELISA	19	52.2	6.4	6.5	-1.8	1.4
Bioclone ELISA	10	42.1	1.7	1.7	-3.4	1.1
DiaSorin	79	41.2	3.8	6.9	1.3	1.0
Interscientific NeoMAP Multiplex	50	41.2	2.6	3.2	-3.1	1.1
PerkinElmer GSP Neonatal	361	41.4	3.1	3.9	-0.7	1.1
In House	30	30.8	3.5	13.4	1.7	0.7
Lot 1413 - Enriched 80.0 μ IU/mL serum						
Siemens Healthcare Diagnostics	40	119.2	10.5	14.2	-4.1	1.5
Neo-Genesis Accuwell	20	83.3	7.2	7.5	0.5	1.0
MP Biomedicals ELISA	10	60.4	5.3	5.3	8.6	0.7
Delfia	549	83.7	9.3	19.5	-0.7	1.1
AutoDelfia	804	91.0	6.5	9.9	0.6	1.1
Ani Labsystems	58	95.3	6.0	11.9	-2.9	1.2
Bio-Rad Quantase	89	89.6	8.4	21.6	-2.0	1.2
TecnoSuma UMELISA	19	108.3	13.3	14.3	-1.8	1.4
Bioclone ELISA	10	87.0	2.6	2.6	-3.4	1.1
DiaSorin	77	80.2	7.1	10.8	1.3	1.0
Interscientific NeoMAP Multiplex	50	87.5	7.1	8.8	-3.1	1.1
PerkinElmer GSP Neonatal	361	83.6	7.1	8.8	-0.7	1.1
In House	30	58.9	5.9	24.1	1.7	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 17d. 2014 Quality Control Data
Summaries of Statistical Analyses

TOTAL GALACTOSE (mg Gal/dL whole blood)

METHOD	N	Mean	Average		Y- Intercept*	Slope
			Within Lab SD	Total SD		
Lot 1325 - Enriched 5.0 mg/dL whole blood						
Siemens Healthcare Diagnostics	40	5.2	0.3	0.5	1.9	0.9
Fluorometric Manual	110	4.5	0.4	2.0	-0.6	0.9
Colorimetric	30	6.3	1.4	1.7	-0.2	1.3
PerkinElmer Neonatal Kit	240	5.0	0.5	0.6	1.6	0.8
Neo-Genesis Accuwell	20	5.8	0.6	1.1	0.4	1.1
Bio-Rad Quantase	169	6.2	1.1	1.6	-0.5	1.3
MP Biomedicals Enzyme Assay	30	8.0	1.9	3.5	1.9	1.3
Interscientific Enzyme	38	5.0	0.6	0.6	0.2	0.9
Astoria-Pacific 50 Hour Reagent Kit	110	6.3	0.6	0.9	1.3	1.0
TecnoSuma UMTEST	30	5.6	1.1	2.5	-1.1	1.3
R&D Diagnostics Greece	20	5.0	0.9	0.9	0.7	0.9
Lot 1326 - Enriched 10.0 mg/dL whole blood						
Siemens Healthcare Diagnostics	40	10.5	0.7	0.9	1.9	0.9
Fluorometric Manual	110	8.5	0.8	3.6	-0.6	0.9
Colorimetric	30	13.4	2.1	3.0	-0.2	1.3
PerkinElmer Neonatal Kit	251	9.5	0.9	1.5	1.6	0.8
Neo-Genesis Accuwell	20	11.7	0.9	1.6	0.4	1.1
Bio-Rad Quantase	165	12.3	1.5	2.8	-0.5	1.3
MP Biomedicals Enzyme Assay	29	15.3	2.0	5.4	1.9	1.3
Interscientific Enzyme	40	9.1	1.0	1.0	0.2	0.9
Astoria-Pacific 50 Hour Reagent Kit	109	11.3	0.8	1.6	1.3	1.0
TecnoSuma UMTEST	30	11.1	1.4	3.3	-1.1	1.3
R&D Diagnostics Greece	20	9.1	1.0	1.9	0.7	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.

TOTAL GALACTOSE (mg Gal/dL whole blood)

- continued -

METHOD	N	Mean	Average Within Lab SD	Total SD	Y- Intercept*	Slope
Lot 1327 - Enriched 15.0 mg/dL whole blood						
Siemens Healthcare Diagnostics	40	15.8	0.8	1.0	1.9	0.9
Fluorometric Manual	110	12.5	0.9	5.1	-0.6	0.9
Colorimetric	30	19.8	1.9	3.6	-0.2	1.3
PerkinElmer Neonatal Kit	246	13.2	1.2	1.6	1.6	0.8
Neo-Genesis Accuwell	20	16.5	1.2	1.7	0.4	1.1
Bio-Rad Quantase	167	18.8	2.7	4.7	-0.5	1.3
MP Biomedicals Enzyme Assay	30	23.4	3.7	8.2	1.9	1.3
Interscientific Enzyme	39	14.2	1.0	1.3	0.2	0.9
Astoria-Pacific 50 Hour Reagent Kit	106	16.1	1.4	2.2	1.3	1.0
TecnoSuma UMTEST	28	18.8	1.6	2.0	-1.1	1.3
R&D Diagnostics Greece	20	13.9	2.0	3.1	0.7	0.9
Lot 1328 - Enriched 30.0 mg/dL whole blood						
Siemens Healthcare Diagnostics	40	26.8	1.7	6.6	1.9	0.9
Fluorometric Manual	98	27.2	2.9	5.3	-0.6	0.9
Colorimetric	30	39.8	4.1	10.8	-0.2	1.3
PerkinElmer Neonatal Kit	249	24.3	2.2	3.3	1.6	0.8
Neo-Genesis Accuwell	20	33.3	2.0	3.5	0.4	1.1
Bio-Rad Quantase	168	38.6	4.6	8.9	-0.5	1.3
MP Biomedicals Enzyme Assay	30	41.8	4.1	12.1	1.9	1.3
Interscientific Enzyme	40	27.8	2.1	2.3	0.2	0.9
Astoria-Pacific 50 Hour Reagent Kit	105	31.2	2.3	3.6	1.3	1.0
TecnoSuma UMTEST	30	37.5	3.3	4.6	-1.1	1.3
R&D Diagnostics Greece	20	26.5	3.8	5.4	0.7	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.

TOTAL GALACTOSE (mg Gal/dL whole blood)
- continued -

METHOD	N	Average			Y- Intercept*	Slope
		Mean	Lab SD	Total SD		
Lot 1421 - Enriched 5.0 mg/dL whole blood						
Siemens Healthcare Diagnostics	40	5.3	0.3	0.8	1.8	0.8
Fluorometric Manual	90	5.1	0.7	1.7	0.2	1.0
Colorimetric	47	6.2	2.0	2.6	0.2	1.4
PerkinElmer Neonatal Kit	279	4.7	0.6	0.8	1.0	0.8
Neo-Genesis Accuwell	20	5.8	0.4	0.4	-0.2	1.2
Bio-Rad Quantase	148	6.4	1.0	1.6	-0.6	1.4
MP Biomedicals Enzyme Assay	20	8.7	1.0	1.2	-0.1	1.8
Interscientific Enzyme	29	5.3	0.7	0.8	0.4	1.0
Astoria-Pacific 50 Hour Reagent Kit	98	6.6	0.5	1.0	1.9	1.0
TecnoSuma UMTEST	30	6.5	1.6	1.7	0.3	1.2
R&D Diagnostics Greece	30	5.0	1.1	1.1	-0.1	1.1
Lot 1422 - Enriched 10.0 mg/dL whole blood						
Siemens Healthcare Diagnostics	40	10.5	0.5	0.6	1.8	0.8
Fluorometric Manual	86	10.0	1.1	2.2	0.2	1.0
Colorimetric	47	14.3	3.5	4.8	0.2	1.4
PerkinElmer Neonatal Kit	285	8.7	0.8	1.3	1.0	0.8
Neo-Genesis Accuwell	20	11.7	0.7	1.4	-0.2	1.2
Bio-Rad Quantase	146	12.9	1.7	3.3	-0.6	1.4
MP Biomedicals Enzyme Assay	20	18.6	1.9	1.9	-0.1	1.8
Interscientific Enzyme	29	10.0	1.1	1.1	0.4	1.0
Astoria-Pacific 50 Hour Reagent Kit	98	11.9	0.9	1.3	1.9	1.0
TecnoSuma UMTEST	30	11.9	1.5	2.6	0.3	1.2
R&D Diagnostics Greece	28	10.6	1.2	1.4	-0.1	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.

TOTAL GALACTOSE (mg Gal/dL whole blood)

- continued -

METHOD	N	Mean	Average		Y- Intercept*	Slope
			Within Lab SD	Total SD		
Lot 1423 - Enriched 15.0 mg/dL whole blood						
Siemens Healthcare Diagnostics	40	15.0	0.7	1.1	1.8	0.8
Fluorometric Manual	87	14.8	1.1	3.1	0.2	1.0
Colorimetric	50	21.5	2.6	6.0	0.2	1.4
PerkinElmer Neonatal Kit	286	13.0	1.2	1.9	1.0	0.8
Neo-Genesis Accuwell	20	17.1	1.2	1.8	-0.2	1.2
Bio-Rad Quantase	148	19.4	2.2	4.5	-0.6	1.4
MP Biomedicals Enzyme Assay	20	27.3	2.2	4.3	-0.1	1.8
Interscientific Enzyme	28	14.6	0.9	0.9	0.4	1.0
Astoria-Pacific 50 Hour Reagent Kit	97	16.4	1.1	1.8	1.9	1.0
TecnoSuma UMTEST	29	17.5	1.8	1.8	0.3	1.2
R&D Diagnostics Greece	27	15.8	1.3	1.5	-0.1	1.1
Lot 1424 - Enriched 30.0 mg/dL whole blood						
Siemens Healthcare Diagnostics	40	26.6	2.2	6.8	1.8	0.8
Fluorometric Manual	88	29.5	1.9	5.3	0.2	1.0
Colorimetric	50	40.7	6.2	9.5	0.2	1.4
PerkinElmer Neonatal Kit	279	24.1	2.5	3.3	1.0	0.8
Neo-Genesis Accuwell	20	35.3	2.0	4.9	-0.2	1.2
Bio-Rad Quantase	149	40.1	4.7	9.6	-0.6	1.4
MP Biomedicals Enzyme Assay	19	54.5	3.3	4.7	-0.1	1.8
Interscientific Enzyme	29	29.2	1.8	1.8	0.4	1.0
Astoria-Pacific 50 Hour Reagent Kit	100	31.1	2.1	3.3	1.9	1.0
TecnoSuma UMTEST	29	35.9	2.7	5.2	0.3	1.2
R&D Diagnostics Greece	30	31.3	3.6	5.0	-0.1	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 17e. 2014 Quality Control Data
Summaries of Statistical Analyses

GALACTOSE-1-PHOSPHATE URIDYLTRANSFERASE (GALT U/g Hb)

METHOD	N	Average			Y- Intercept*	Slope
		Mean	Lab SD	Total SD		
Lot 1331 - Assayed 1.5 U/g Hb						
Quantitative Fluorometric Assay	10	0.0	0.0	0.0	-0.9	0.6
PerkinElmer Neonatal Kit	268	1.1	0.3	0.5	-0.1	0.8
Bio-Rad Quantase	10	1.0	0.1	0.1	-0.1	0.8
Astoria-Pacific Microplate Reagent Kit	50	0.6	0.1	0.2	-0.3	0.6
Lot 1332 - Assayed 3.5 U/g Hb						
Quantitative Fluorometric Assay	10	0.9	0.1	0.1	-0.9	0.6
PerkinElmer Neonatal Kit	251	2.7	0.3	0.5	-0.1	0.8
Bio-Rad Quantase	10	2.9	0.1	0.1	-0.1	0.8
Astoria-Pacific Microplate Reagent Kit	50	1.9	0.3	0.5	-0.3	0.6
Lot 1333 - Assayed 8.2 U/g Hb						
Quantitative Fluorometric Assay	10	3.7	0.5	0.5	-0.9	0.6
PerkinElmer Neonatal Kit	248	6.4	0.7	1.1	-0.1	0.8
Bio-Rad Quantase	10	6.5	0.2	0.2	-0.1	0.8
Astoria-Pacific Microplate Reagent Kit	50	4.7	0.6	1.2	-0.3	0.6

METHODS REPORTED IN UNITS OTHER THAN U/g Hb (≥ 3 PARTICIPANTS)*

1331	34 Astoria-Pacific 50 Hour Reagent Kit ($\mu\text{mol/L}$ blood)	80	12.6	2.0	3.0	6.3	21.6
	62 Perkin Elmer GSP Neonatal (U/dL blood)	96	0.6	0.1	0.8	0.0	2.5
1332	34 Astoria-Pacific 50 Hour Reagent Kit ($\mu\text{mol/L}$ blood)	80	54.0	6.8	11.2	33.1	89.9
	62 Perkin Elmer GSP Neonatal (U/dL blood)	100	1.5	0.2	1.0	0.4	4.1
1333	34 Astoria-Pacific 50 Hour Reagent Kit ($\mu\text{mol/L}$ blood)	80	123.0	22.6	38.2	48.3	196.4
	62 Perkin Elmer GSP Neonatal (U/dL blood)	110	7.3	0.8	1.0	4.8	10.9

* For further information, please see Quality Control, page 23.

*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 17f. 2014 Quality Control Data
Summaries of Statistical Analyses

IMMUNOREACTIVE TRYPSINOGEN (ng IRT/mL whole blood)

METHOD	N	Mean	Average		Y- Intercept*	Slope
			Within Lab SD	Total SD		
Lot 1391 - Assayed 16.9 ng/mL whole blood						
MP Biomedicals ELISA	60	21.8	3.1	8.3	0.0	1.5
Delfia	211	14.5	1.7	2.2	-0.0	0.9
AutoDelfia	717	15.2	1.1	1.5	0.4	0.9
Bio-Rad Quantase	20	29.1	3.5	15.3	12.6	1.2
PerkinElmer GSP Neonatal	226	15.4	1.0	1.2	-1.3	0.9
Lot 1392 - Assayed 54.4 ng/mL whole blood						
MP Biomedicals ELISA	59	77.3	9.6	22.4	0.0	1.5
Delfia	216	45.9	5.2	6.5	-0.0	0.9
AutoDelfia	717	47.8	3.3	4.5	0.4	0.9
Bio-Rad Quantase	20	76.0	6.9	39.7	12.6	1.2
PerkinElmer GSP Neonatal	216	47.1	2.9	3.5	-1.3	0.9
Lot 1393 - Assayed 107.3 ng/mL whole blood						
MP Biomedicals ELISA	59	181.1	22.8	58.2	0.0	1.5
Delfia	219	93.8	9.4	12.0	-0.0	0.9
AutoDelfia	734	100.2	6.7	9.0	0.4	0.9
Bio-Rad Quantase	20	144.2	11.3	54.8	12.6	1.2
PerkinElmer GSP Neonatal	218	98.8	5.6	7.1	-1.3	0.9
Lot 1394 - Assayed 188.6 ng/mL whole blood						
MP Biomedicals ELISA	60	279.3	37.1	88.3	0.0	1.5
Delfia	212	161.7	14.0	16.9	-0.0	0.9
AutoDelfia	736	168.8	10.3	13.5	0.4	0.9
Bio-Rad Quantase	20	228.6	20.2	44.8	12.6	1.2
PerkinElmer GSP Neonatal	223	173.1	9.3	11.0	-1.3	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.

IMMUNOREACTIVE TRYPSINOGEN (ng IRT/mL whole blood)

- continued -

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 1491 - Assayed 19.7 ng/mL whole blood						
MP Biomedicals ELISA	40	22.8	3.3	7.7	15.9	1.5
Delfia	184	19.1	2.0	3.5	1.1	0.9
AutoDelfia	631	19.4	1.4	1.9	0.5	1.0
Bio-Rad Quantase	20	40.9	5.9	32.2	49.9	0.6
PerkinElmer GSP Neonatal	292	19.0	1.4	1.9	-1.8	1.1
Lot 1492 - Assayed 70.3 ng/mL whole blood						
MP Biomedicals ELISA	38	117.1	13.8	19.0	15.9	1.5
Delfia	179	67.1	6.5	8.1	1.1	0.9
AutoDelfia	630	71.0	4.7	6.2	0.5	1.0
Bio-Rad Quantase	20	106.5	9.1	50.5	49.9	0.6
PerkinElmer GSP Neonatal	282	72.8	4.6	5.6	-1.8	1.1
Lot 1493 - Assayed 145.6 ng/mL whole blood						
MP Biomedicals ELISA	39	274.5	41.8	125.0	15.9	1.5
Delfia	178	139.6	14.1	18.5	1.1	0.9
AutoDelfia	630	146.3	9.7	11.9	0.5	1.0
Bio-Rad Quantase	20	161.7	9.2	22.0	49.9	0.6
PerkinElmer GSP Neonatal	285	148.9	8.9	12.5	-1.8	1.1
Lot 1494 - Assayed 259.3 ng/mL whole blood						
MP Biomedicals ELISA	30	359.0	47.6	238.2	15.9	1.5
Delfia	178	244.6	25.8	32.6	1.1	0.9
AutoDelfia	634	258.3	17.6	21.3	0.5	1.0
Bio-Rad Quantase	20	194.6	0.0	26.5	49.9	0.6
PerkinElmer GSP Neonatal	285	270.9	16.6	19.0	-1.8	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 17g. 2014 Quality Control Data
Summaries of Statistical Analyses

ALANINE ($\mu\text{mol Ala/L}$ whole blood)

METHOD	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 1325 - Nonenriched 0 $\mu\text{mol/L}$ whole blood						
Derivatized - MS/MS non-kit	645	282.9	27.6	81.8	289.7	0.6
Non-derivatized - MS/MS non-kit	148	329.7	29.3	81.2	332.4	0.6
Derivatized - MS/MS PE NeoGram Kit	78	340.5	31.6	65.8	342.9	0.7
Non-derivatized - MS/MS PE NeoBase Kit	385	384.2	32.3	71.8	395.4	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	89	293.4	26.6	41.2	298.9	0.6
Non-derivatized - MS/MS Chromsystems MassChrom Kit	70	263.3	19.7	67.7	266.1	0.5
Lot 1326 - Enriched 200.0 $\mu\text{mol/L}$ whole blood						
Derivatized - MS/MS non-kit	651	411.9	41.3	115.7	289.7	0.6
Non-derivatized - MS/MS non-kit	150	467.8	38.7	116.9	332.4	0.6
Derivatized - MS/MS PE NeoGram Kit	80	481.2	43.4	117.6	342.9	0.7
Non-derivatized - MS/MS PE NeoBase Kit	395	563.4	43.7	99.3	395.4	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	89	425.6	36.6	64.2	298.9	0.6
Non-derivatized - MS/MS Chromsystems MassChrom Kit	70	379.0	22.4	97.1	266.1	0.5
Lot 1327 - Enriched 400.0 $\mu\text{mol/L}$ whole blood						
Derivatized - MS/MS non-kit	650	522.6	50.4	142.6	289.7	0.6
Non-derivatized - MS/MS non-kit	149	583.9	51.1	150.8	332.4	0.6
Derivatized - MS/MS PE NeoGram Kit	80	623.9	79.5	151.6	342.9	0.7
Non-derivatized - MS/MS PE NeoBase Kit	395	722.6	53.7	127.9	395.4	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	87	531.0	48.8	69.9	298.9	0.6
Non-derivatized - MS/MS Chromsystems MassChrom Kit	70	484.3	31.3	123.5	266.1	0.5
Lot 1328 - Enriched 600.0 $\mu\text{mol/L}$ whole blood						
Derivatized - MS/MS non-kit	651	626.9	60.4	173.3	289.7	0.6
Non-derivatized - MS/MS non-kit	149	719.4	65.8	172.4	332.4	0.6
Derivatized - MS/MS PE NeoGram Kit	80	751.7	72.5	184.1	342.9	0.7
Non-derivatized - MS/MS PE NeoBase Kit	396	856.7	67.0	157.2	395.4	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	87	648.9	52.6	94.6	298.9	0.6
Non-derivatized - MS/MS Chromsystems MassChrom Kit	70	590.9	46.0	145.6	266.1	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.

ALANINE ($\mu\text{mol Ala/L}$ whole blood)
- continued -

METHOD	N	Average		Y- Intercept*	Slope
		Mean	Within Lab SD		
Lot 1421 - Nonenriched 0 $\mu\text{mol/L}$ whole blood					
Derivatized - MS/MS non-kit	546	297.1	26.6	48.0	301.9 0.6
Non-derivatized - MS/MS non-kit	128	304.8	30.1	55.5	305.8 0.6
Derivatized - MS/MS PE NeoGram Kit	80	346.0	43.6	96.0	346.7 0.7
Non-derivatized - MS/MS PE NeoBase Kit	442	377.6	29.1	58.4	388.4 0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	116	318.2	32.1	45.8	316.7 0.7
Non-derivatized - MS/MS Chromsystems MassChrom Kit	60	257.6	15.6	62.2	258.4 0.6
Lot 1422 - Enriched 200.0 $\mu\text{mol/L}$ whole blood					
Derivatized - MS/MS non-kit	547	425.6	38.8	81.0	301.9 0.6
Non-derivatized - MS/MS non-kit	130	432.2	43.8	86.3	305.8 0.6
Derivatized - MS/MS PE NeoGram Kit	80	486.6	56.3	116.3	346.7 0.7
Non-derivatized - MS/MS PE NeoBase Kit	444	563.0	41.5	100.3	388.4 0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	115	446.4	35.7	68.1	316.7 0.7
Non-derivatized - MS/MS Chromsystems MassChrom Kit	60	375.6	36.0	88.5	258.4 0.6
Lot 1423 - Enriched 400.0 $\mu\text{mol/L}$ whole blood					
Derivatized - MS/MS non-kit	547	550.7	48.0	85.1	301.9 0.6
Non-derivatized - MS/MS non-kit	130	561.3	53.3	103.9	305.8 0.6
Derivatized - MS/MS PE NeoGram Kit	78	647.9	69.1	156.2	346.7 0.7
Non-derivatized - MS/MS PE NeoBase Kit	446	730.6	58.7	128.9	388.4 0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	113	580.2	54.4	93.7	316.7 0.7
Non-derivatized - MS/MS Chromsystems MassChrom Kit	60	491.6	39.1	129.8	258.4 0.6
Lot 1424 - Enriched 600.0 $\mu\text{mol/L}$ whole blood					
Derivatized - MS/MS non-kit	551	656.8	53.8	117.7	301.9 0.6
Non-derivatized - MS/MS non-kit	127	683.1	63.2	128.0	305.8 0.6
Derivatized - MS/MS PE NeoGram Kit	79	774.9	61.1	187.9	346.7 0.7
Non-derivatized - MS/MS PE NeoBase Kit	446	871.0	64.6	144.4	388.4 0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	117	713.3	42.7	91.6	316.7 0.7
Non-derivatized - MS/MS Chromsystems MassChrom Kit	60	606.4	47.4	146.9	258.4 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.

Table 17h. 2014 Quality Control Data
Summaries of Statistical Analyses

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

METHOD	N	Mean	Average Within		Y-Intercept*	Slope
			Lab SD	Total SD		
Lot 1325 - Nonenriched 0 $\mu\text{mol/L}$ whole blood						
Derivatized - MS/MS non-kit	685	8.5	1.6	4.7	8.6	0.6
Non-derivatized - MS/MS non-kit	145	6.8	1.1	2.6	5.6	0.7
Derivatized - MS/MS PE NeoGram Kit	125	8.3	1.2	2.0	7.6	0.7
Non-derivatized - MS/MS PE NeoBase Kit	471	7.8	0.9	1.9	7.2	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	80	10.8	1.8	3.1	11.8	0.9
Non-derivatized - MS/MS Chromsystems MassChrom Kit	68	7.5	0.8	2.1	9.5	0.7
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	30	5.1	0.5	1.6	5.1	0.5
Lot 1326 - Enriched 100.0 $\mu\text{mol/L}$ whole blood						
Derivatized - MS/MS non-kit	713	67.4	7.8	31.7	8.6	0.6
Non-derivatized - MS/MS non-kit	144	69.0	8.6	20.8	5.6	0.7
Derivatized - MS/MS PE NeoGram Kit	123	79.6	5.6	10.5	7.6	0.7
Non-derivatized - MS/MS PE NeoBase Kit	466	90.0	6.4	10.5	7.2	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	89	106.5	9.4	25.7	11.8	0.9
Non-derivatized - MS/MS Chromsystems MassChrom Kit	70	79.6	7.7	13.6	9.5	0.7
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	30	51.8	3.8	4.7	5.1	0.5
Lot 1327 - Enriched 200.0 $\mu\text{mol/L}$ whole blood						
Derivatized - MS/MS non-kit	707	127.6	13.1	60.2	8.6	0.6
Non-derivatized - MS/MS non-kit	144	133.7	18.1	42.8	5.6	0.7
Derivatized - MS/MS PE NeoGram Kit	124	156.6	12.6	22.0	7.6	0.7
Non-derivatized - MS/MS PE NeoBase Kit	468	175.3	12.1	19.1	7.2	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	90	199.1	21.2	47.5	11.8	0.9
Non-derivatized - MS/MS Chromsystems MassChrom Kit	70	147.7	10.4	26.0	9.5	0.7
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	30	100.9	6.4	8.8	5.1	0.5
Lot 1328 - Enriched 300.0 $\mu\text{mol/L}$ whole blood						
Derivatized - MS/MS non-kit	705	185.6	19.4	85.8	8.6	0.6
Non-derivatized - MS/MS non-kit	144	200.8	24.1	62.2	5.6	0.7
Derivatized - MS/MS PE NeoGram Kit	126	228.7	20.7	38.4	7.6	0.7
Non-derivatized - MS/MS PE NeoBase Kit	480	258.9	19.0	31.4	7.2	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	90	291.6	26.3	69.3	11.8	0.9
Non-derivatized - MS/MS Chromsystems MassChrom Kit	70	211.8	19.0	34.9	9.5	0.7
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	30	146.4	11.8	13.0	5.1	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.

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

METHOD	N	Average		Y- Intercept*	Slope
		Mean	Within Lab SD		
Lot 1421 - Nonenriched 0 $\mu\text{mol/L}$ whole blood					
Derivatized - MS/MS non-kit	630	8.2	1.4	3.6	9.6 0.6
Non-derivatized - MS/MS non-kit	152	7.1	1.6	3.3	7.6 0.7
Derivatized - MS/MS PE NeoGram Kit	104	9.0	1.3	2.1	7.8 0.9
Non-derivatized - MS/MS PE NeoBase Kit	510	7.6	0.8	1.6	8.5 0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	115	10.5	1.2	2.8	12.7 0.9
Non-derivatized - MS/MS Chromsystems MassChrom Kit	68	7.5	0.8	1.2	11.3 0.8
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	30	12.1	4.5	12.9	9.9 0.5
Lot 1422 - Enriched 100.0 $\mu\text{mol/L}$ whole blood					
Derivatized - MS/MS non-kit	659	73.1	8.0	29.6	9.6 0.6
Non-derivatized - MS/MS non-kit	160	79.2	7.6	18.9	7.6 0.7
Derivatized - MS/MS PE NeoGram Kit	104	95.0	7.8	17.5	7.8 0.9
Non-derivatized - MS/MS PE NeoBase Kit	502	95.7	6.8	12.8	8.5 0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	117	103.0	9.8	23.4	12.7 0.9
Non-derivatized - MS/MS Chromsystems MassChrom Kit	70	89.8	7.1	20.3	11.3 0.8
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	28	54.9	3.5	5.0	9.9 0.5
Lot 1423 - Enriched 200.0 $\mu\text{mol/L}$ whole blood					
Derivatized - MS/MS non-kit	659	136.2	13.6	55.6	9.6 0.6
Non-derivatized - MS/MS non-kit	156	151.9	12.5	37.4	7.6 0.7
Derivatized - MS/MS PE NeoGram Kit	103	183.9	12.8	30.0	7.8 0.9
Non-derivatized - MS/MS PE NeoBase Kit	512	181.5	14.1	27.8	8.5 0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	116	190.6	17.0	42.5	12.7 0.9
Non-derivatized - MS/MS Chromsystems MassChrom Kit	70	163.8	13.9	37.0	11.3 0.8
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	30	105.9	11.1	14.5	9.9 0.5
Lot 1424 - Enriched 300.0 $\mu\text{mol/L}$ whole blood					
Derivatized - MS/MS non-kit	653	195.0	20.6	82.8	9.6 0.6
Non-derivatized - MS/MS non-kit	159	221.0	20.0	53.0	7.6 0.7
Derivatized - MS/MS PE NeoGram Kit	108	274.5	19.9	54.8	7.8 0.9
Non-derivatized - MS/MS PE NeoBase Kit	509	265.9	19.0	35.4	8.5 0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	117	274.8	21.1	49.7	12.7 0.9
Non-derivatized - MS/MS Chromsystems MassChrom Kit	70	231.6	19.6	47.6	11.3 0.8
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	28	156.0	10.7	15.1	9.9 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. 2014 Quality Control Data
Summaries of Statistical Analyses

CITRULLINE ($\mu\text{mol Cit/L}$ whole blood)

METHOD	N	Mean	Average Within		Y- Intercept*	Slope
			Lab SD	Total SD		
Lot 1325 - Nonenriched 0 $\mu\text{mol/L}$ whole blood						
Derivatized - MS/MS non-kit	803	26.1	2.7	5.7	28.0	0.8
Non-derivatized - MS/MS non-kit	217	28.9	3.4	4.9	30.1	0.9
Derivatized - MS/MS PE NeoGram Kit	140	26.9	2.3	3.2	27.5	0.8
Non-derivatized - MS/MS PE NeoBase Kit	547	28.7	2.8	3.5	30.0	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	84	28.2	2.9	5.7	29.7	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	70	29.4	3.4	5.3	30.4	0.8
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	50	27.4	1.9	3.1	29.1	0.8
Lot 1326 - Enriched 25.0 $\mu\text{mol/L}$ whole blood						
Derivatized - MS/MS non-kit	817	47.5	4.9	11.3	28.0	0.8
Non-derivatized - MS/MS non-kit	213	52.3	5.3	9.2	30.1	0.9
Derivatized - MS/MS PE NeoGram Kit	137	47.4	3.4	4.9	27.5	0.8
Non-derivatized - MS/MS PE NeoBase Kit	540	52.3	4.5	5.8	30.0	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	89	53.3	6.0	12.2	29.7	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	70	50.9	4.4	7.8	30.4	0.8
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	50	49.8	3.9	5.8	29.1	0.8
Lot 1327 - Enriched 100.0 $\mu\text{mol/L}$ whole blood						
Derivatized - MS/MS non-kit	812	106.9	10.1	23.5	28.0	0.8
Non-derivatized - MS/MS non-kit	216	117.9	12.5	20.6	30.1	0.9
Derivatized - MS/MS PE NeoGram Kit	140	108.8	8.4	12.1	27.5	0.8
Non-derivatized - MS/MS PE NeoBase Kit	544	118.5	8.6	11.8	30.0	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	80	110.2	11.6	16.5	29.7	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	68	115.5	8.1	12.9	30.4	0.8
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	50	112.9	6.5	11.2	29.1	0.8
Lot 1328 - Enriched 250.0 $\mu\text{mol/L}$ whole blood						
Derivatized - MS/MS non-kit	810	217.7	20.2	45.8	28.0	0.8
Non-derivatized - MS/MS non-kit	214	246.5	21.5	35.8	30.1	0.9
Derivatized - MS/MS PE NeoGram Kit	150	227.7	15.0	27.5	27.5	0.8
Non-derivatized - MS/MS PE NeoBase Kit	550	247.6	19.4	27.2	30.0	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	85	237.6	19.8	48.6	29.7	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	68	236.9	19.1	33.5	30.4	0.8
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	50	231.8	12.9	16.1	29.1	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.

CITRULLINE ($\mu\text{mol Cit/L}$ whole blood)

- continued -

METHOD	N	Mean	Average Within		Y-Intercept*	Slope
			Lab SD	Total SD		
Lot 1421 - Nonenriched 0 $\mu\text{mol/L}$ whole blood						
Derivatized - MS/MS non-kit	720	25.6	2.8	5.3	26.5	0.8
Non-derivatized - MS/MS non-kit	216	27.3	3.2	4.7	27.2	0.9
Derivatized - MS/MS PE NeoGram Kit	127	28.2	2.1	3.4	28.3	0.9
Non-derivatized - MS/MS PE NeoBase Kit	578	27.8	2.8	3.5	29.7	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	116	27.6	2.8	4.5	27.7	0.9
Non-derivatized - MS/MS Chromsystems MassChrom Kit	80	26.8	2.8	4.3	27.5	0.9
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	60	27.8	2.8	3.7	27.7	0.9
Lot 1422 - Enriched 25.0 $\mu\text{mol/L}$ whole blood						
Derivatized - MS/MS non-kit	717	46.9	4.4	9.8	26.5	0.8
Non-derivatized - MS/MS non-kit	207	49.6	5.4	8.3	27.2	0.9
Derivatized - MS/MS PE NeoGram Kit	127	50.7	4.4	6.6	28.3	0.9
Non-derivatized - MS/MS PE NeoBase Kit	589	54.4	4.8	6.9	29.7	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	117	51.0	4.8	9.6	27.7	0.9
Non-derivatized - MS/MS Chromsystems MassChrom Kit	78	50.5	4.6	6.9	27.5	0.9
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	59	50.4	3.4	5.3	27.7	0.9
Lot 1423 - Enriched 100.0 $\mu\text{mol/L}$ whole blood						
Derivatized - MS/MS non-kit	721	107.4	9.1	22.1	26.5	0.8
Non-derivatized - MS/MS non-kit	210	113.8	13.0	19.4	27.2	0.9
Derivatized - MS/MS PE NeoGram Kit	127	117.8	9.0	13.6	28.3	0.9
Non-derivatized - MS/MS PE NeoBase Kit	580	122.3	10.1	15.4	29.7	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	116	114.8	10.0	21.3	27.7	0.9
Non-derivatized - MS/MS Chromsystems MassChrom Kit	80	116.5	9.8	17.8	27.5	0.9
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	57	111.8	7.9	13.0	27.7	0.9
Lot 1424 - Enriched 250.0 $\mu\text{mol/L}$ whole blood						
Derivatized - MS/MS non-kit	716	226.3	19.7	45.8	26.5	0.8
Non-derivatized - MS/MS non-kit	211	246.4	25.8	50.5	27.2	0.9
Derivatized - MS/MS PE NeoGram Kit	129	252.1	19.6	29.3	28.3	0.9
Non-derivatized - MS/MS PE NeoBase Kit	590	259.4	20.3	30.6	29.7	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	116	249.9	18.7	29.0	27.7	0.9
Non-derivatized - MS/MS Chromsystems MassChrom Kit	80	249.8	21.8	35.7	27.5	0.9
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	59	244.2	14.8	30.4	27.7	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.

Table 17j. 2014 Quality Control Data
Summaries of Statistical Analyses

LEUCINE ($\mu\text{mol Leu/L}$ whole blood)

METHOD	N	Mean	Average		Y- Intercept*	Slope
			Within Lab SD	Total SD		
Lot 1325 - Nonenriched 0 $\mu\text{mol/L}$ whole blood						
Derivatized - MS/MS non-kit	813	133.5	10.8	24.2	138.1	0.8
Non-derivatized - MS/MS non-kit	266	157.1	12.8	21.8	160.1	0.9
Derivatized - MS/MS PE NeoGram Kit	147	126.4	11.2	13.0	128.1	0.9
Non-derivatized - MS/MS PE NeoBase Kit	548	155.4	11.2	17.9	158.3	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	83	133.3	11.7	15.5	135.8	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	70	145.4	9.7	26.5	146.4	0.8
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	49	160.2	7.7	18.1	169.0	0.9
Lot 1326 - Enriched 100.0 $\mu\text{mol/L}$ whole blood						
Derivatized - MS/MS non-kit	809	223.6	19.4	38.4	138.1	0.8
Non-derivatized - MS/MS non-kit	265	251.4	18.6	34.2	160.1	0.9
Derivatized - MS/MS PE NeoGram Kit	150	215.3	18.0	21.8	128.1	0.9
Non-derivatized - MS/MS PE NeoBase Kit	553	246.0	17.4	29.9	158.3	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	85	218.0	20.6	26.7	135.8	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	70	229.7	12.8	39.5	146.4	0.8
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	50	258.7	19.1	30.0	169.0	0.9
Lot 1327 - Enriched 250.0 $\mu\text{mol/L}$ whole blood						
Derivatized - MS/MS non-kit	804	347.7	28.5	54.1	138.1	0.8
Non-derivatized - MS/MS non-kit	269	384.2	31.8	59.6	160.1	0.9
Derivatized - MS/MS PE NeoGram Kit	148	347.1	27.6	32.5	128.1	0.9
Non-derivatized - MS/MS PE NeoBase Kit	552	380.3	25.6	40.1	158.3	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	88	329.9	19.5	25.2	135.8	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	70	356.2	17.8	57.9	146.4	0.8
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	50	397.3	22.4	41.5	169.0	0.9
Lot 1328 - Enriched 500.0 $\mu\text{mol/L}$ whole blood						
Derivatized - MS/MS non-kit	812	546.7	47.2	87.3	138.1	0.8
Non-derivatized - MS/MS non-kit	268	603.1	48.8	85.4	160.1	0.9
Derivatized - MS/MS PE NeoGram Kit	148	559.7	42.5	63.0	128.1	0.9
Non-derivatized - MS/MS PE NeoBase Kit	556	590.9	39.2	65.4	158.3	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	90	527.1	39.4	47.9	135.8	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	70	561.2	35.8	79.6	146.4	0.8
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	48	594.6	35.2	45.9	169.0	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.

LEUCINE ($\mu\text{mol Leu/L}$ whole blood)
- continued -

METHOD	N	Mean	Average Within Lab SD	Total SD	Y- Intercept*	Slope
Lot 1421 - Nonenriched 0 $\mu\text{mol/L}$ whole blood						
HPLC	10	152.3	8.2	8.2	155.1	1.4
Derivatized - MS/MS non-kit	726	126.5	10.8	21.7	130.2	0.8
Non-derivatized - MS/MS non-kit	266	152.6	11.3	21.6	153.1	0.9
Derivatized - MS/MS PE NeoGram Kit	127	124.8	11.1	13.6	123.9	0.9
Non-derivatized - MS/MS PE NeoBase Kit	570	152.0	10.8	15.9	156.6	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	114	128.2	10.3	15.0	130.1	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	80	137.0	9.5	17.7	139.2	0.8
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	60	153.6	10.1	19.0	153.7	0.9
Lot 1422 - Enriched 100.0 $\mu\text{mol/L}$ whole blood						
HPLC	10	292.9	16.1	16.1	155.1	1.4
Derivatized - MS/MS non-kit	746	212.6	17.8	38.5	130.2	0.8
Non-derivatized - MS/MS non-kit	268	242.6	18.8	37.8	153.1	0.9
Derivatized - MS/MS PE NeoGram Kit	127	210.4	16.9	22.5	123.9	0.9
Non-derivatized - MS/MS PE NeoBase Kit	582	249.3	18.1	27.3	156.6	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	116	209.7	19.7	30.3	130.1	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	79	220.6	17.4	24.8	139.2	0.8
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	58	244.5	16.7	27.4	153.7	0.9
Lot 1423 - Enriched 250.0 $\mu\text{mol/L}$ whole blood						
HPLC	10	495.6	21.8	21.8	155.1	1.4
Derivatized - MS/MS non-kit	742	329.6	28.0	55.6	130.2	0.8
Non-derivatized - MS/MS non-kit	265	367.8	27.8	53.8	153.1	0.9
Derivatized - MS/MS PE NeoGram Kit	125	342.2	29.7	41.2	123.9	0.9
Non-derivatized - MS/MS PE NeoBase Kit	588	381.6	28.5	46.8	156.6	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	114	318.0	27.7	47.7	130.1	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	80	343.7	24.7	39.0	139.2	0.8
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	60	373.6	31.6	53.6	153.7	0.9
Lot 1424 - Enriched 500.0 $\mu\text{mol/L}$ whole blood						
HPLC	10	830.9	33.6	33.6	155.1	1.4
Derivatized - MS/MS non-kit	746	523.8	45.5	89.4	130.2	0.8
Non-derivatized - MS/MS non-kit	268	589.4	44.8	100.5	153.1	0.9
Derivatized - MS/MS PE NeoGram Kit	127	561.8	43.6	61.5	123.9	0.9
Non-derivatized - MS/MS PE NeoBase Kit	581	598.8	44.3	65.8	156.6	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	117	510.4	34.3	63.2	130.1	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	79	540.4	36.9	65.2	139.2	0.8
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	60	599.4	40.8	88.3	153.7	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.

Table 17k. 2014 Quality Control Data
Summaries of Statistical Analyses

METHIONINE ($\mu\text{mol Met/L}$ whole blood)

METHOD	N	Mean	Average		Y- Intercept*	Slope
			Within Lab SD	Total SD		
Lot 1325 - Nonenriched 0 $\mu\text{mol/L}$ whole blood						
Derivatized - MS/MS non-kit	814	18.8	2.3	3.5	19.4	0.8
Non-derivatized - MS/MS non-kit	266	17.2	1.8	2.9	16.2	0.8
Derivatized - MS/MS PE NeoGram Kit	138	20.3	2.4	2.7	20.1	0.8
Non-derivatized - MS/MS PE NeoBase Kit	557	16.2	1.5	2.2	15.1	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	87	15.4	3.4	5.0	16.2	0.6
Non-derivatized - MS/MS Chromsystems MassChrom Kit	67	12.6	1.4	2.8	10.3	0.7
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	49	17.4	0.9	2.8	16.9	0.8
Lot 1326 - Enriched 50.0 $\mu\text{mol/L}$ whole blood						
Derivatized - MS/MS non-kit	819	59.1	5.5	9.2	19.4	0.8
Non-derivatized - MS/MS non-kit	268	57.3	4.5	8.8	16.2	0.8
Derivatized - MS/MS PE NeoGram Kit	137	61.4	5.4	6.3	20.1	0.8
Non-derivatized - MS/MS PE NeoBase Kit	559	54.0	3.7	6.2	15.1	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	87	46.4	6.7	12.2	16.2	0.6
Non-derivatized - MS/MS Chromsystems MassChrom Kit	68	42.1	3.9	7.1	10.3	0.7
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	48	57.1	3.5	7.5	16.9	0.8
Lot 1327 - Enriched 150.0 $\mu\text{mol/L}$ whole blood						
Derivatized - MS/MS non-kit	822	137.8	11.9	20.4	19.4	0.8
Non-derivatized - MS/MS non-kit	270	137.9	11.1	21.7	16.2	0.8
Derivatized - MS/MS PE NeoGram Kit	135	145.0	14.1	15.9	20.1	0.8
Non-derivatized - MS/MS PE NeoBase Kit	563	132.8	9.4	15.1	15.1	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	90	102.0	15.5	27.7	16.2	0.6
Non-derivatized - MS/MS Chromsystems MassChrom Kit	69	104.7	8.7	16.8	10.3	0.7
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	50	141.2	5.7	18.3	16.9	0.8
Lot 1328 - Enriched 250.0 $\mu\text{mol/L}$ whole blood						
Derivatized - MS/MS non-kit	824	215.5	19.0	32.6	19.4	0.8
Non-derivatized - MS/MS non-kit	273	223.8	17.6	32.0	16.2	0.8
Derivatized - MS/MS PE NeoGram Kit	135	227.9	18.2	24.3	20.1	0.8
Non-derivatized - MS/MS PE NeoBase Kit	565	214.1	16.2	26.7	15.1	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	90	160.8	28.1	46.1	16.2	0.6
Non-derivatized - MS/MS Chromsystems MassChrom Kit	70	176.2	14.1	23.3	10.3	0.7
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	50	222.4	14.5	25.1	16.9	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.

METHIONINE ($\mu\text{mol Met/L}$ whole blood)
- continued -

METHOD	N	Average		Y- Intercept*	Slope
		Mean	Within Lab SD		
Lot 1421 - Nonenriched 0 $\mu\text{mol/L}$ whole blood					
Derivatized - MS/MS non-kit	746	20.3	2.2	3.7	21.2 0.8
Non-derivatized - MS/MS non-kit	258	20.8	1.9	3.4	20.4 0.9
Derivatized - MS/MS PE NeoGram Kit	116	21.0	2.8	3.2	20.0 0.9
Non-derivatized - MS/MS PE NeoBase Kit	575	20.7	1.8	3.1	21.0 0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	117	15.9	3.3	5.8	15.1 0.7
Non-derivatized - MS/MS Chromsystems MassChrom Kit	77	15.6	1.5	2.8	15.3 0.7
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	59	20.6	1.5	2.2	19.4 0.9
Lot 1422 - Enriched 50.0 $\mu\text{mol/L}$ whole blood					
Derivatized - MS/MS non-kit	741	60.7	5.5	9.8	21.2 0.8
Non-derivatized - MS/MS non-kit	268	64.5	6.4	10.8	20.4 0.9
Derivatized - MS/MS PE NeoGram Kit	118	62.8	6.2	8.0	20.0 0.9
Non-derivatized - MS/MS PE NeoBase Kit	597	65.3	5.4	9.1	21.0 0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	119	47.7	6.9	14.6	15.1 0.7
Non-derivatized - MS/MS Chromsystems MassChrom Kit	80	51.5	5.0	8.0	15.3 0.7
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	59	64.4	3.9	6.1	19.4 0.9
Lot 1423 - Enriched 150.0 $\mu\text{mol/L}$ whole blood					
Derivatized - MS/MS non-kit	749	141.7	12.1	22.6	21.2 0.8
Non-derivatized - MS/MS non-kit	266	149.7	13.2	25.3	20.4 0.9
Derivatized - MS/MS PE NeoGram Kit	117	150.1	13.7	19.2	20.0 0.9
Non-derivatized - MS/MS PE NeoBase Kit	589	153.0	11.7	21.4	21.0 0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	116	111.6	14.4	35.6	15.1 0.7
Non-derivatized - MS/MS Chromsystems MassChrom Kit	80	125.7	11.2	17.4	15.3 0.7
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	57	148.9	10.3	14.3	19.4 0.9
Lot 1424 - Enriched 250.0 $\mu\text{mol/L}$ whole blood					
Derivatized - MS/MS non-kit	740	217.2	17.6	32.6	21.2 0.8
Non-derivatized - MS/MS non-kit	259	240.1	18.9	42.4	20.4 0.9
Derivatized - MS/MS PE NeoGram Kit	120	238.9	23.6	34.7	20.0 0.9
Non-derivatized - MS/MS PE NeoBase Kit	596	240.7	18.3	31.5	21.0 0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	119	179.6	24.3	50.8	15.1 0.7
Non-derivatized - MS/MS Chromsystems MassChrom Kit	79	198.9	15.8	34.1	15.3 0.7
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	60	244.1	12.5	28.0	19.4 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 17I. 2014 Quality Control Data
Summaries of Statistical Analyses

PHENYLALANINE ($\mu\text{mol Phe/L}$ whole blood)

METHOD	N	Average		Y- Intercept*	Slope
		Mean	Within Lab SD		
Lot 1325 - Nonenriched 0 $\mu\text{mol/L}$ whole blood					
Fluorometric Manual	100	95.9	12.1	31.3	93.7 1.1
PerkinElmer Neonatal Kit	262	78.2	9.6	15.8	80.5 0.9
Ani Labsystems	104	82.3	12.9	18.4	83.6 1.3
Bio-Rad Quantase	50	74.9	18.6	51.0	72.3 0.8
MP Biomedicals Enzyme Assay	20	68.8	25.0	26.4	58.2 1.2
Interscientific Enzyme	80	73.1	8.4	19.3	76.7 0.9
IBL International Neonatal Screening Kit	80	72.7	14.6	34.3	69.9 1.2
Astoria-Pacific	20	80.5	3.7	21.3	82.1 1.0
Derivatized - MS/MS non-kit	871	66.5	5.2	9.0	68.9 0.9
Non-derivatized - MS/MS non-kit	350	68.9	4.5	8.2	70.7 1.0
Derivatized - MS/MS PE NeoGram Kit	149	63.2	5.2	6.9	64.4 0.9
Non-derivatized - MS/MS PE NeoBase Kit	574	65.0	4.7	6.9	66.5 0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	78	65.7	6.1	6.4	69.3 0.9
Non-derivatized - MS/MS Chromsystems MassChrom Kit	80	70.5	5.2	12.7	71.8 1.0
TecnoSuma UMTEST	30	133.8	25.5	50.7	126.6 1.3
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	50	67.6	3.7	7.0	70.5 0.9
Lot 1326 - Enriched 100.0 $\mu\text{mol/L}$ whole blood					
Fluorometric Manual	96	210.9	21.1	46.0	93.7 1.1
PerkinElmer Neonatal Kit	265	170.7	15.2	28.4	80.5 0.9
Ani Labsystems	110	212.7	20.4	38.7	83.6 1.3
Bio-Rad Quantase	48	151.4	26.0	96.5	72.3 0.8
MP Biomedicals Enzyme Assay	20	176.8	30.8	47.2	58.2 1.2
Interscientific Enzyme	80	169.4	13.6	33.2	76.7 0.9
IBL International Neonatal Screening Kit	80	177.9	14.7	80.2	69.9 1.2
Astoria-Pacific	20	177.9	8.0	24.6	82.1 1.0
Derivatized - MS/MS non-kit	863	156.4	12.4	21.2	68.9 0.9
Non-derivatized - MS/MS non-kit	356	164.9	11.4	22.0	70.7 1.0
Derivatized - MS/MS PE NeoGram Kit	149	148.6	10.7	15.6	64.4 0.9
Non-derivatized - MS/MS PE NeoBase Kit	579	153.2	11.0	17.6	66.5 0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	79	154.0	12.3	13.7	69.3 0.9
Non-derivatized - MS/MS Chromsystems MassChrom Kit	78	166.1	11.9	29.8	71.8 1.0
TecnoSuma UMTEST	29	237.5	34.7	65.8	126.6 1.3
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	50	160.8	10.5	15.4	70.5 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.

Table 17I. 2014 Quality Control Data
Summaries of Statistical Analyses

PHENYLALANINE ($\mu\text{mol Phe/L}$ whole blood)

METHOD	N	Average		Y- Intercept*	Slope
		Mean	Within Lab SD		
Lot 1327 - Enriched 200.0 $\mu\text{mol/L}$ whole blood					
Fluorometric Manual	100	299.8	24.4	121.8	93.7 1.1
PerkinElmer Neonatal Kit	258	269.6	23.4	45.8	80.5 0.9
Ani Labsystems	108	342.0	27.5	55.1	83.6 1.3
Bio-Rad Quantase	50	241.1	26.5	144.5	72.3 0.8
MP Biomedicals Enzyme Assay	19	257.1	35.8	35.9	58.2 1.2
Interscientific Enzyme	77	270.5	18.3	36.1	76.7 0.9
IBL International Neonatal Screening Kit	80	307.6	26.1	138.1	69.9 1.2
Astoria-Pacific	19	278.3	10.5	16.5	82.1 1.0
Derivatized - MS/MS non-kit	868	256.5	20.4	36.8	68.9 0.9
Non-derivatized - MS/MS non-kit	357	270.7	17.9	37.6	70.7 1.0
Derivatized - MS/MS PE NeoGram Kit	150	245.7	20.7	27.3	64.4 0.9
Non-derivatized - MS/MS PE NeoBase Kit	579	254.0	18.6	28.2	66.5 0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	78	250.9	19.7	21.4	69.3 0.9
Non-derivatized - MS/MS Chromsystems MassChrom Kit	80	277.0	17.7	48.7	71.8 1.0
TecnoSuma UMTEST	30	412.1	33.0	108.5	126.6 1.3
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	48	263.1	11.1	18.6	70.5 0.9
Lot 1328 - Enriched 300.0 $\mu\text{mol/L}$ whole blood					
Fluorometric Manual	100	438.1	34.5	65.9	93.7 1.1
PerkinElmer Neonatal Kit	264	347.4	28.7	52.4	80.5 0.9
Ani Labsystems	110	466.5	36.1	83.5	83.6 1.3
Bio-Rad Quantase	50	324.5	36.5	181.9	72.3 0.8
MP Biomedicals Enzyme Assay	20	432.8	76.1	83.0	58.2 1.2
Interscientific Enzyme	79	345.9	25.5	39.3	76.7 0.9
IBL International Neonatal Screening Kit	80	414.8	33.9	187.5	69.9 1.2
Astoria-Pacific	20	366.1	28.9	35.8	82.1 1.0
Derivatized - MS/MS non-kit	869	329.1	26.7	46.6	68.9 0.9
Non-derivatized - MS/MS non-kit	355	353.2	21.4	42.9	70.7 1.0
Derivatized - MS/MS PE NeoGram Kit	149	319.2	21.5	40.2	64.4 0.9
Non-derivatized - MS/MS PE NeoBase Kit	580	328.7	25.6	38.4	66.5 0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	76	316.8	22.7	24.8	69.3 0.9
Non-derivatized - MS/MS Chromsystems MassChrom Kit	80	358.3	28.3	56.2	71.8 1.0
TecnoSuma UMTEST	30	518.0	49.7	132.1	126.6 1.3
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	50	337.4	20.3	30.8	70.5 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.

PHENYLALANINE ($\mu\text{mol Phe/L}$ whole blood)

- continued -

METHOD	N	Mean	Average Within Lab SD	Total SD	Y- Intercept*	Slope
Lot 1421 - Nonenriched 0 $\mu\text{mol/L}$ whole blood						
Fluorometric Manual	104	102.6	11.8	28.7	102.1	1.1
PerkinElmer Neonatal Kit	235	74.0	10.3	13.2	74.6	0.9
Neo-Genesis Accuwell	10	75.1	10.0	10.0	71.6	1.0
Ani Labsystems	96	82.5	8.9	15.7	82.8	1.2
Bio-Rad Quantase	20	51.2	24.9	50.1	64.1	1.1
MP Biomedicals Enzyme Assay	20	73.0	16.2	41.6	56.4	1.2
Interscientific Enzyme	10	67.9	8.5	8.5	67.6	1.0
IBL International Neonatal Screening Kit	80	88.2	12.0	13.0	85.8	1.5
Astoria-Pacific 50 Hour Reagent Kit	20	94.0	6.2	30.9	97.0	0.9
HPLC	10	88.3	3.8	3.8	85.0	1.0
Derivatized - MS/MS non-kit	789	67.7	6.0	10.4	70.0	0.9
Non-derivatized - MS/MS non-kit	366	71.2	6.4	10.7	72.2	1.0
Derivatized - MS/MS PE NeoGram Kit	139	71.0	6.3	8.3	70.3	0.9
Non-derivatized - MS/MS PE NeoBase Kit	593	68.3	5.0	7.8	70.8	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	103	69.5	6.3	11.4	69.7	0.9
Non-derivatized - MS/MS Chromsystems MassChrom Kit	80	73.4	4.7	12.1	74.1	1.0
TecnoSuma UMTEST	10	82.9	7.7	7.7	75.8	1.2
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	59	70.3	4.2	4.7	70.6	0.9
Lot 1422 - Enriched 100.0 $\mu\text{mol/L}$ whole blood						
Fluorometric Manual	107	212.1	19.3	35.5	102.1	1.1
PerkinElmer Neonatal Kit	236	168.7	15.3	25.5	74.6	0.9
Neo-Genesis Accuwell	10	164.2	8.3	8.3	71.6	1.0
Ani Labsystems	99	211.6	20.3	35.0	82.8	1.2
Bio-Rad Quantase	20	192.9	27.7	47.9	64.1	1.1
MP Biomedicals Enzyme Assay	30	149.8	31.2	65.2	56.4	1.2
Interscientific Enzyme	10	159.4	12.5	12.5	67.6	1.0
IBL International Neonatal Screening Kit	80	240.3	24.0	36.9	85.8	1.5
Astoria-Pacific 50 Hour Reagent Kit	20	193.3	19.0	55.3	97.0	0.9
HPLC	10	189.4	11.0	11.0	85.0	1.0
Derivatized - MS/MS non-kit	805	159.8	13.5	25.3	70.0	0.9
Non-derivatized - MS/MS non-kit	367	170.3	11.3	24.9	72.2	1.0
Derivatized - MS/MS PE NeoGram Kit	140	162.0	12.8	17.7	70.3	0.9
Non-derivatized - MS/MS PE NeoBase Kit	592	164.5	11.5	18.6	70.8	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	100	159.1	15.6	22.0	69.7	0.9
Non-derivatized - MS/MS Chromsystems MassChrom Kit	80	175.7	13.3	24.5	74.1	1.0
TecnoSuma UMTEST	10	167.5	16.9	16.9	75.8	1.2
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	59	165.0	11.3	11.6	70.6	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.

PHENYLALANINE ($\mu\text{mol Phe/L}$ whole blood)

- continued -

METHOD	N	Mean	Average Within Lab SD	Total SD	Y- Intercept*	Slope
Lot 1423 - Enriched 200.0 $\mu\text{mol/L}$ whole blood						
Fluorometric Manual	100	328.9	28.3	48.9	102.1	1.1
PerkinElmer Neonatal Kit	235	261.5	23.8	36.1	74.6	0.9
Neo-Genesis Accuwell	10	276.9	19.4	19.4	71.6	1.0
Ani Labsystems	100	323.6	27.1	48.3	82.8	1.2
Bio-Rad Quantase	20	301.3	40.0	94.3	64.1	1.1
MP Biomedicals Enzyme Assay	30	298.9	55.8	77.1	56.4	1.2
Interscientific Enzyme	10	262.4	20.8	20.8	67.6	1.0
IBL International Neonatal Screening Kit	80	381.1	28.0	60.1	85.8	1.5
Astoria-Pacific 50 Hour Reagent Kit	20	284.7	29.5	58.1	97.0	0.9
HPLC	10	277.9	14.5	14.5	85.0	1.0
Derivatized - MS/MS non-kit	803	250.2	21.3	39.9	70.0	0.9
Non-derivatized - MS/MS non-kit	358	266.2	17.7	41.2	72.2	1.0
Derivatized - MS/MS PE NeoGram Kit	137	255.8	20.7	23.9	70.3	0.9
Non-derivatized - MS/MS PE NeoBase Kit	595	256.3	19.3	33.0	70.8	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	101	247.5	23.1	36.5	69.7	0.9
Non-derivatized - MS/MS Chromsystems MassChrom Kit	79	276.5	19.7	39.1	74.1	1.0
TecnoSuma UMTEST	10	353.1	18.0	18.0	75.8	1.2
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	60	257.8	19.3	26.3	70.6	0.9
Lot 1424 - Enriched 300.0 $\mu\text{mol/L}$ whole blood						
Fluorometric Manual	110	437.0	37.4	55.2	102.1	1.1
PerkinElmer Neonatal Kit	234	354.3	25.5	54.5	74.6	0.9
Neo-Genesis Accuwell	10	372.1	21.0	21.0	71.6	1.0
Ani Labsystems	100	459.5	28.9	78.5	82.8	1.2
Bio-Rad Quantase	20	395.2	49.0	129.3	64.1	1.1
MP Biomedicals Enzyme Assay	30	403.4	44.0	112.6	56.4	1.2
Interscientific Enzyme	10	349.7	15.9	15.9	67.6	1.0
IBL International Neonatal Screening Kit	80	551.1	33.9	90.7	85.8	1.5
Astoria-Pacific 50 Hour Reagent Kit	20	372.9	21.6	83.0	97.0	0.9
HPLC	10	401.6	32.6	32.6	85.0	1.0
Derivatized - MS/MS non-kit	795	331.7	26.1	50.2	70.0	0.9
Non-derivatized - MS/MS non-kit	359	362.1	25.9	57.9	72.2	1.0
Derivatized - MS/MS PE NeoGram Kit	138	349.1	25.3	34.9	70.3	0.9
Non-derivatized - MS/MS PE NeoBase Kit	598	342.2	26.5	41.9	70.8	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	103	336.7	23.2	37.8	69.7	0.9
Non-derivatized - MS/MS Chromsystems MassChrom Kit	79	376.4	26.3	56.3	74.1	1.0
TecnoSuma UMTEST	10	422.6	15.3	15.3	75.8	1.2
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	60	351.8	20.3	23.9	70.6	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 17m. 2014 Quality Control Data
Summaries of Statistical Analyses

SUCCINYLLACETONE ($\mu\text{mol SUAC/L}$ whole blood)

METHOD	N	Mean	Average		Y- Intercept*	Slope
			Within Lab SD	Total SD		
Lot 1325 - Nonenriched 0 $\mu\text{mol/L}$ whole blood						
Derivatized - MS/MS non-kit	219	0.8	0.2	0.5	0.8	0.5
Non-derivatized - MS/MS non-kit	80	1.5	0.6	1.3	1.7	0.6
Non-derivatized - MS/MS PE NeoBase Kit	317	0.5	0.1	0.3	0.5	0.2
Derivatized - MS/MS Chromsystems MassChrom Kit	40	0.6	0.2	0.5	0.7	0.3
Lot 1326 - Enriched 2.5 $\mu\text{mol/L}$ whole blood						
Derivatized - MS/MS non-kit	216	2.0	0.3	1.0	0.8	0.5
Non-derivatized - MS/MS non-kit	80	3.1	0.6	1.8	1.7	0.6
Non-derivatized - MS/MS PE NeoBase Kit	313	1.0	0.2	0.4	0.5	0.2
Derivatized - MS/MS Chromsystems MassChrom Kit	40	1.4	0.5	0.7	0.7	0.3
Lot 1327 - Enriched 7.5 $\mu\text{mol/L}$ whole blood						
Derivatized - MS/MS non-kit	218	4.6	0.5	2.7	0.8	0.5
Non-derivatized - MS/MS non-kit	80	6.3	1.4	3.9	1.7	0.6
Non-derivatized - MS/MS PE NeoBase Kit	311	1.9	0.3	0.7	0.5	0.2
Derivatized - MS/MS Chromsystems MassChrom Kit	39	2.7	0.5	0.9	0.7	0.3
Lot 1328 - Enriched 15.0 $\mu\text{mol/L}$ whole blood						
Derivatized - MS/MS non-kit	218	8.2	1.0	5.0	0.8	0.5
Non-derivatized - MS/MS non-kit	79	10.3	2.1	6.6	1.7	0.6
Non-derivatized - MS/MS PE NeoBase Kit	319	3.3	0.4	1.1	0.5	0.2
Derivatized - MS/MS Chromsystems MassChrom Kit	40	4.6	0.7	1.2	0.7	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.

SUCCINYLLACETONE ($\mu\text{mol SUAC/L}$ whole blood)

- continued -

METHOD	N	Mean	Average		Y- Intercept*	Slope
			Within Lab SD	Total SD		
Lot 1421 - Nonenriched 0 $\mu\text{mol/L}$ whole blood						
Derivatized - MS/MS non-kit	213	0.8	0.2	0.5	0.8	0.6
Non-derivatized - MS/MS non-kit	64	0.8	0.2	0.5	0.4	0.7
Non-derivatized - MS/MS PE NeoBase Kit	369	0.6	0.1	0.4	0.5	0.3
Derivatized - MS/MS Chromsystems MassChrom Kit	49	0.5	0.1	0.4	0.5	0.4
Lot 1422 - Enriched 2.5 $\mu\text{mol/L}$ whole blood						
Derivatized - MS/MS non-kit	215	2.3	0.3	1.1	0.8	0.6
Non-derivatized - MS/MS non-kit	64	2.2	0.4	0.9	0.4	0.7
Non-derivatized - MS/MS PE NeoBase Kit	368	1.2	0.2	0.6	0.5	0.3
Derivatized - MS/MS Chromsystems MassChrom Kit	48	1.5	0.2	0.4	0.5	0.4
Lot 1423 - Enriched 7.5 $\mu\text{mol/L}$ whole blood						
Derivatized - MS/MS non-kit	219	5.2	0.6	2.6	0.8	0.6
Non-derivatized - MS/MS non-kit	66	4.9	1.1	2.6	0.4	0.7
Non-derivatized - MS/MS PE NeoBase Kit	374	2.5	0.4	1.1	0.5	0.3
Derivatized - MS/MS Chromsystems MassChrom Kit	49	3.2	0.4	0.7	0.5	0.4
Lot 1424 - Enriched 15.0 $\mu\text{mol/L}$ whole blood						
Derivatized - MS/MS non-kit	217	9.6	1.0	4.8	0.8	0.6
Non-derivatized - MS/MS non-kit	70	11.1	2.2	5.8	0.4	0.7
Non-derivatized - MS/MS PE NeoBase Kit	382	5.0	0.6	1.9	0.5	0.3
Derivatized - MS/MS Chromsystems MassChrom Kit	50	6.1	1.0	1.7	0.5	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. 2014 Quality Control Data
Summaries of Statistical Analyses

TYROSINE ($\mu\text{mol Tyr/L}$ whole blood)

METHOD	N	Average		Y- Intercept*	Slope	
		Mean	Within Lab SD			
Lot 1325 - Nonenriched 0 $\mu\text{mol/L}$ whole blood						
Derivatized - MS/MS non-kit	842	50.0	4.1	7.1	50.1	0.8
Non-derivatized - MS/MS non-kit	312	51.2	4.6	8.1	51.6	0.8
Derivatized - MS/MS PE NeoGram Kit	150	51.9	4.6	6.7	50.4	0.8
Non-derivatized - MS/MS PE NeoBase Kit	544	56.0	4.4	7.3	55.0	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	88	56.8	5.7	7.0	58.3	0.9
Non-derivatized - MS/MS Chromsystems MassChrom Kit	76	61.2	4.9	12.8	59.4	1.0
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	40	52.0	3.1	5.0	53.7	0.8
Lot 1326 - Enriched 200.0 $\mu\text{mol/L}$ whole blood						
Derivatized - MS/MS non-kit	844	211.3	17.5	29.8	50.1	0.8
Non-derivatized - MS/MS non-kit	311	220.1	16.8	31.7	51.6	0.8
Derivatized - MS/MS PE NeoGram Kit	146	215.8	16.8	20.5	50.4	0.8
Non-derivatized - MS/MS PE NeoBase Kit	540	235.9	18.0	30.1	55.0	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	89	244.3	20.9	27.6	58.3	0.9
Non-derivatized - MS/MS Chromsystems MassChrom Kit	76	253.9	17.9	48.9	59.4	1.0
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	39	222.5	11.1	16.7	53.7	0.8
Lot 1327 - Enriched 400.0 $\mu\text{mol/L}$ whole blood						
Derivatized - MS/MS non-kit	842	369.4	28.9	48.3	50.1	0.8
Non-derivatized - MS/MS non-kit	311	390.8	26.6	54.9	51.6	0.8
Derivatized - MS/MS PE NeoGram Kit	148	381.8	28.5	37.9	50.4	0.8
Non-derivatized - MS/MS PE NeoBase Kit	552	414.8	30.6	53.8	55.0	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	89	418.0	34.2	43.1	58.3	0.9
Non-derivatized - MS/MS Chromsystems MassChrom Kit	74	449.8	27.5	74.2	59.4	1.0
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	40	394.8	18.7	37.0	53.7	0.8
Lot 1328 - Enriched 600.0 $\mu\text{mol/L}$ whole blood						
Derivatized - MS/MS non-kit	859	531.5	45.2	75.1	50.1	0.8
Non-derivatized - MS/MS non-kit	311	556.5	39.3	75.5	51.6	0.8
Derivatized - MS/MS PE NeoGram Kit	146	552.0	43.1	62.8	50.4	0.8
Non-derivatized - MS/MS PE NeoBase Kit	549	600.0	43.8	76.8	55.0	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	89	605.2	48.9	58.7	58.3	0.9
Non-derivatized - MS/MS Chromsystems MassChrom Kit	76	650.0	52.0	124.7	59.4	1.0
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	40	555.9	38.3	43.5	53.7	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.

TYROSINE ($\mu\text{mol Tyr/L}$ whole blood)
- continued -

METHOD	N	Average		Y- Intercept*	Slope
		Mean	Within Lab SD		
Lot 1421 - Nonenriched 0 $\mu\text{mol/L}$ whole blood					
HPLC	10	75.3	3.1	69.8	1.0
Derivatized - MS/MS non-kit	766	50.1	4.6	53.6	0.8
Non-derivatized - MS/MS non-kit	314	52.5	4.6	51.6	0.9
Derivatized - MS/MS PE NeoGram Kit	126	53.9	5.0	53.1	0.9
Non-derivatized - MS/MS PE NeoBase Kit	594	56.4	4.7	58.3	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	115	58.5	7.0	60.7	0.9
Non-derivatized - MS/MS Chromsystems MassChrom Kit	80	57.9	4.4	56.9	1.0
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	49	51.9	3.4	50.9	0.9
Lot 1422 - Enriched 200.0 $\mu\text{mol/L}$ whole blood					
HPLC	10	273.9	14.2	69.8	1.0
Derivatized - MS/MS non-kit	787	217.2	18.7	53.6	0.8
Non-derivatized - MS/MS non-kit	329	224.0	17.4	51.6	0.9
Derivatized - MS/MS PE NeoGram Kit	130	231.8	17.9	53.1	0.9
Non-derivatized - MS/MS PE NeoBase Kit	600	247.0	17.8	58.3	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	115	249.5	27.9	60.7	0.9
Non-derivatized - MS/MS Chromsystems MassChrom Kit	78	250.5	21.0	56.9	1.0
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	49	224.8	13.1	50.9	0.9
Lot 1423 - Enriched 400.0 $\mu\text{mol/L}$ whole blood					
HPLC	10	441.4	19.9	69.8	1.0
Derivatized - MS/MS non-kit	777	372.1	30.4	53.6	0.8
Non-derivatized - MS/MS non-kit	325	390.9	29.3	51.6	0.9
Derivatized - MS/MS PE NeoGram Kit	129	401.9	40.4	53.1	0.9
Non-derivatized - MS/MS PE NeoBase Kit	598	428.0	33.0	58.3	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	113	429.8	52.6	60.7	0.9
Non-derivatized - MS/MS Chromsystems MassChrom Kit	77	440.4	31.8	56.9	1.0
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	50	391.0	26.6	50.9	0.9
Lot 1424 - Enriched 600.0 $\mu\text{mol/L}$ whole blood					
HPLC	10	683.1	52.4	69.8	1.0
Derivatized - MS/MS non-kit	773	528.0	41.8	53.6	0.8
Non-derivatized - MS/MS non-kit	329	569.1	42.1	51.6	0.9
Derivatized - MS/MS PE NeoGram Kit	128	587.8	44.8	53.1	0.9
Non-derivatized - MS/MS PE NeoBase Kit	598	614.2	48.1	58.3	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	114	615.0	46.7	60.7	0.9
Non-derivatized - MS/MS Chromsystems MassChrom Kit	77	639.7	48.5	56.9	1.0
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	50	572.5	31.4	50.9	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 17o. 2014 Quality Control Data
Summaries of Statistical Analyses

VALINE ($\mu\text{mol Val/L}$ whole blood)

METHOD	N	Mean	Average Within		Y- Intercept*	Slope
			Lab SD	Total SD		
Lot 1325 - Nonenriched 0 $\mu\text{mol/L}$ whole blood						
Derivatized - MS/MS non-kit	773	141.8	13.7	28.7	141.1	0.7
Non-derivatized - MS/MS non-kit	217	141.5	11.8	31.2	139.3	0.8
Derivatized - MS/MS PE NeoGram Kit	140	159.3	18.2	24.0	157.7	0.8
Non-derivatized - MS/MS PE NeoBase Kit	546	151.5	12.2	19.7	151.3	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	86	121.6	13.0	18.4	123.8	0.6
Non-derivatized - MS/MS Chromsystems MassChrom Kit	70	104.5	7.5	23.0	102.1	0.6
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	49	154.7	9.8	29.8	157.8	0.9
Lot 1326 - Enriched 200.0 $\mu\text{mol/L}$ whole blood						
Derivatized - MS/MS non-kit	786	290.4	27.0	51.6	141.1	0.7
Non-derivatized - MS/MS non-kit	219	302.9	23.7	68.1	139.3	0.8
Derivatized - MS/MS PE NeoGram Kit	136	321.1	29.3	36.0	157.7	0.8
Non-derivatized - MS/MS PE NeoBase Kit	547	330.2	29.7	51.9	151.3	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	89	254.2	25.6	32.7	123.8	0.6
Non-derivatized - MS/MS Chromsystems MassChrom Kit	70	223.9	12.1	39.4	102.1	0.6
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	50	338.8	21.7	62.2	157.8	0.9
Lot 1327 - Enriched 350.0 $\mu\text{mol/L}$ whole blood						
Derivatized - MS/MS non-kit	782	395.4	35.4	71.8	141.1	0.7
Non-derivatized - MS/MS non-kit	220	416.3	38.9	97.7	139.3	0.8
Derivatized - MS/MS PE NeoGram Kit	137	444.3	52.5	61.3	157.7	0.8
Non-derivatized - MS/MS PE NeoBase Kit	547	463.3	38.4	63.0	151.3	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	90	348.1	34.9	51.7	123.8	0.6
Non-derivatized - MS/MS Chromsystems MassChrom Kit	70	315.6	20.9	62.8	102.1	0.6
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	50	468.1	18.8	82.3	157.8	0.9
Lot 1328 - Enriched 500.0 $\mu\text{mol/L}$ whole blood						
Derivatized - MS/MS non-kit	792	514.1	49.5	94.4	141.1	0.7
Non-derivatized - MS/MS non-kit	220	552.4	48.2	129.5	139.3	0.8
Derivatized - MS/MS PE NeoGram Kit	138	572.3	57.4	74.9	157.7	0.8
Non-derivatized - MS/MS PE NeoBase Kit	545	599.1	54.5	90.6	151.3	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	86	440.5	43.6	68.1	123.8	0.6
Non-derivatized - MS/MS Chromsystems MassChrom Kit	70	415.7	34.9	80.5	102.1	0.6
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	50	596.6	41.0	91.6	157.8	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.

VALINE ($\mu\text{mol Val/L}$ whole blood)
- continued -

METHOD	N	Mean	Average Within Lab SD	Total SD	Y- Intercept*	Slope
Lot 1421 - Nonenriched 0 $\mu\text{mol/L}$ whole blood						
Derivatized - MS/MS non-kit	670	139.9	14.0	30.3	141.3	0.7
Non-derivatized - MS/MS non-kit	215	136.9	10.3	23.1	134.0	0.8
Derivatized - MS/MS PE NeoGram Kit	118	154.8	17.6	25.1	153.3	0.8
Non-derivatized - MS/MS PE NeoBase Kit	572	155.2	12.8	24.9	156.8	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	114	120.6	16.9	25.1	118.6	0.6
Non-derivatized - MS/MS Chromsystems MassChrom Kit	70	104.0	7.4	27.6	102.2	0.6
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	60	152.9	9.9	12.2	149.4	0.9
Lot 1422 - Enriched 200.0 $\mu\text{mol/L}$ whole blood						
Derivatized - MS/MS non-kit	678	278.4	26.9	59.6	141.3	0.7
Non-derivatized - MS/MS non-kit	218	283.1	20.3	51.9	134.0	0.8
Derivatized - MS/MS PE NeoGram Kit	118	313.1	32.0	44.8	153.3	0.8
Non-derivatized - MS/MS PE NeoBase Kit	577	337.8	29.2	54.8	156.8	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	113	240.4	26.5	41.7	118.6	0.6
Non-derivatized - MS/MS Chromsystems MassChrom Kit	70	224.0	22.8	53.2	102.2	0.6
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	57	320.3	20.2	21.7	149.4	0.9
Lot 1423 - Enriched 350.0 $\mu\text{mol/L}$ whole blood						
Derivatized - MS/MS non-kit	675	374.3	36.2	71.9	141.3	0.7
Non-derivatized - MS/MS non-kit	213	397.7	28.0	70.8	134.0	0.8
Derivatized - MS/MS PE NeoGram Kit	120	433.7	50.1	69.6	153.3	0.8
Non-derivatized - MS/MS PE NeoBase Kit	573	465.6	41.1	77.3	156.8	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	112	338.8	39.2	58.1	118.6	0.6
Non-derivatized - MS/MS Chromsystems MassChrom Kit	68	311.2	23.9	68.3	102.2	0.6
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	60	445.9	34.7	46.7	149.4	0.9
Lot 1424 - Enriched 500.0 $\mu\text{mol/L}$ whole blood						
Derivatized - MS/MS non-kit	684	476.3	46.5	88.1	141.3	0.7
Non-derivatized - MS/MS non-kit	220	518.2	37.4	94.1	134.0	0.8
Derivatized - MS/MS PE NeoGram Kit	119	558.6	58.3	82.0	153.3	0.8
Non-derivatized - MS/MS PE NeoBase Kit	575	600.1	52.1	101.8	156.8	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	114	433.6	33.5	66.3	118.6	0.6
Non-derivatized - MS/MS Chromsystems MassChrom Kit	69	411.7	32.2	88.1	102.2	0.6
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	60	588.6	38.2	48.2	149.4	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 17p. 2014 Quality Control Data
Summaries of Statistical Analyses

FREE CARNITINE ($\mu\text{mol C0/L}$ whole blood)

METHOD	N	Mean	Average		Y- Intercept*	Slope
			Within Lab SD	Total SD		
Lot 1365 - Nonenriched 0 $\mu\text{mol/L}$ whole blood						
Derivatized - MS/MS non-kit	915	18.49	2.01	3.72	15.80	1.3
Non-derivatized - MS/MS non-kit	241	16.97	1.52	3.24	14.53	0.9
Derivatized - MS/MS PE NeoGram Kit	150	21.71	2.37	4.36	18.64	1.6
Non-derivatized - MS/MS PE NeoBase Kit	553	16.32	1.48	2.43	14.05	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	104	16.86	2.99	4.24	14.71	1.0
Non-derivatized - MS/MS Chromsystems MassChrom Kit	70	14.16	1.12	2.28	11.94	0.8
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	57	16.99	0.95	2.30	14.43	1.0
Lot 1366 - Enriched 10.0 $\mu\text{mol/L}$ whole blood						
Derivatized - MS/MS non-kit	904	24.80	2.44	4.89	15.80	1.3
Non-derivatized - MS/MS non-kit	242	20.14	1.88	3.61	14.53	0.9
Derivatized - MS/MS PE NeoGram Kit	150	30.80	2.92	5.52	18.64	1.6
Non-derivatized - MS/MS PE NeoBase Kit	538	19.32	1.47	2.63	14.05	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	107	21.46	2.77	5.74	14.71	1.0
Non-derivatized - MS/MS Chromsystems MassChrom Kit	70	16.42	1.17	2.62	11.94	0.8
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	60	20.06	1.15	2.20	14.43	1.0
Lot 1367 - Enriched 20.0 $\mu\text{mol/L}$ whole blood						
Derivatized - MS/MS non-kit	916	40.99	4.11	8.24	15.80	1.3
Non-derivatized - MS/MS non-kit	240	33.04	2.56	5.54	14.53	0.9
Derivatized - MS/MS PE NeoGram Kit	150	50.31	5.36	9.82	18.64	1.6
Non-derivatized - MS/MS PE NeoBase Kit	551	32.97	2.65	4.69	14.05	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	107	35.40	4.42	7.75	14.71	1.0
Non-derivatized - MS/MS Chromsystems MassChrom Kit	70	28.30	2.09	4.91	11.94	0.8
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	60	34.59	2.28	4.95	14.43	1.0
Lot 1368 - Enriched 30.0 $\mu\text{mol/L}$ whole blood						
Derivatized - MS/MS non-kit	921	55.86	5.39	11.65	15.80	1.3
Non-derivatized - MS/MS non-kit	239	43.54	3.50	7.60	14.53	0.9
Derivatized - MS/MS PE NeoGram Kit	149	69.56	6.69	13.62	18.64	1.6
Non-derivatized - MS/MS PE NeoBase Kit	539	42.25	3.49	6.05	14.05	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	105	45.89	6.54	10.49	14.71	1.0
Non-derivatized - MS/MS Chromsystems MassChrom Kit	70	36.84	2.22	6.03	11.94	0.8
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	60	44.27	3.50	5.51	14.43	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.

FREE CARNITINE ($\mu\text{mol C0/L}$ whole blood)

- continued -

METHOD	N	Average		Y- Intercept*	Slope
		Mean	Within Lab SD		
Lot 1461 - Nonenriched 0 $\mu\text{mol/L}$ whole blood					
Derivatized - MS/MS non-kit	824	19.13	2.13	4.37	18.41 1.5
Non-derivatized - MS/MS non-kit	240	15.99	1.43	2.54	15.69 1.1
Derivatized - MS/MS PE NeoGram Kit	129	24.90	1.84	3.48	23.80 2.1
Non-derivatized - MS/MS PE NeoBase Kit	575	16.14	1.38	2.72	15.91 1.1
Derivatized - MS/MS Chromsystems MassChrom Kit	128	17.56	2.85	4.86	16.67 1.3
Non-derivatized - MS/MS Chromsystems MassChrom Kit	60	14.45	1.00	2.77	13.93 1.0
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	59	17.18	0.91	1.86	17.24 1.2
Lot 1462 - Enriched 10.0 $\mu\text{mol/L}$ whole blood					
Derivatized - MS/MS non-kit	822	32.37	3.26	7.16	18.41 1.5
Non-derivatized - MS/MS non-kit	238	26.24	2.00	3.94	15.69 1.1
Derivatized - MS/MS PE NeoGram Kit	129	43.59	2.97	6.05	23.80 2.1
Non-derivatized - MS/MS PE NeoBase Kit	578	26.42	2.26	4.16	15.91 1.1
Derivatized - MS/MS Chromsystems MassChrom Kit	126	28.41	3.63	6.75	16.67 1.3
Non-derivatized - MS/MS Chromsystems MassChrom Kit	60	23.12	1.62	4.40	13.93 1.0
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	60	28.96	1.81	3.12	17.24 1.2
Lot 1463 - Enriched 20.0 $\mu\text{mol/L}$ whole blood					
Derivatized - MS/MS non-kit	826	47.54	4.89	11.42	18.41 1.5
Non-derivatized - MS/MS non-kit	238	36.94	3.11	5.87	15.69 1.1
Derivatized - MS/MS PE NeoGram Kit	129	64.23	6.08	9.16	23.80 2.1
Non-derivatized - MS/MS PE NeoBase Kit	584	37.63	3.02	6.04	15.91 1.1
Derivatized - MS/MS Chromsystems MassChrom Kit	127	41.79	5.73	10.90	16.67 1.3
Non-derivatized - MS/MS Chromsystems MassChrom Kit	59	33.10	1.87	6.59	13.93 1.0
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	57	39.92	2.17	3.08	17.24 1.2
Lot 1464 - Enriched 30.0 $\mu\text{mol/L}$ whole blood					
Derivatized - MS/MS non-kit	828	63.43	6.70	14.92	18.41 1.5
Non-derivatized - MS/MS non-kit	234	48.47	3.42	6.75	15.69 1.1
Derivatized - MS/MS PE NeoGram Kit	128	87.44	6.55	13.37	23.80 2.1
Non-derivatized - MS/MS PE NeoBase Kit	576	48.58	3.63	7.58	15.91 1.1
Derivatized - MS/MS Chromsystems MassChrom Kit	127	55.88	8.46	15.24	16.67 1.3
Non-derivatized - MS/MS Chromsystems MassChrom Kit	59	43.72	3.55	9.73	13.93 1.0
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	60	51.80	2.77	4.78	17.24 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 17q. 2014 Quality Control Data
Summaries of Statistical Analyses

ACETYLCARNITINE ($\mu\text{mol C2/L}$ whole blood)

METHOD	N	Mean	Average		Y- Intercept*	Slope
			Within Lab SD	Total SD		
Lot 1365 - Nonenriched 0 $\mu\text{mol/L}$ whole blood						
Derivatized - MS/MS non-kit	859	12.62	1.49	3.71	12.48	0.9
Non-derivatized - MS/MS non-kit	213	10.77	0.87	1.93	10.56	1.0
Derivatized - MS/MS PE NeoGram Kit	147	13.11	1.03	1.76	13.01	0.8
Non-derivatized - MS/MS PE NeoBase Kit	547	9.75	0.70	1.24	9.70	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	102	11.06	1.18	2.05	11.15	0.9
Non-derivatized - MS/MS Chromsystems MassChrom Kit	70	9.06	0.63	0.82	8.86	0.9
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	50	11.71	0.79	1.56	11.86	1.1
Lot 1366 - Enriched 10.0 $\mu\text{mol/L}$ whole blood						
Derivatized - MS/MS non-kit	853	21.95	2.26	5.16	12.48	0.9
Non-derivatized - MS/MS non-kit	210	20.92	1.70	2.93	10.56	1.0
Derivatized - MS/MS PE NeoGram Kit	149	20.52	1.38	2.10	13.01	0.8
Non-derivatized - MS/MS PE NeoBase Kit	549	18.91	1.21	2.15	9.70	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	110	20.89	1.77	2.99	11.15	0.9
Non-derivatized - MS/MS Chromsystems MassChrom Kit	70	17.60	1.16	1.80	8.86	0.9
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	50	22.97	1.14	3.16	11.86	1.1
Lot 1367 - Enriched 20.0 $\mu\text{mol/L}$ whole blood						
Derivatized - MS/MS non-kit	864	30.69	3.36	7.33	12.48	0.9
Non-derivatized - MS/MS non-kit	207	30.65	2.67	4.66	10.56	1.0
Derivatized - MS/MS PE NeoGram Kit	146	27.65	2.13	3.14	13.01	0.8
Non-derivatized - MS/MS PE NeoBase Kit	533	27.89	1.88	2.94	9.70	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	108	29.60	2.55	4.15	11.15	0.9
Non-derivatized - MS/MS Chromsystems MassChrom Kit	69	26.73	1.70	2.54	8.86	0.9
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	50	34.40	2.01	6.00	11.86	1.1
Lot 1368 - Enriched 30.0 $\mu\text{mol/L}$ whole blood						
Derivatized - MS/MS non-kit	857	41.02	4.16	9.57	12.48	0.9
Non-derivatized - MS/MS non-kit	213	42.04	3.32	6.57	10.56	1.0
Derivatized - MS/MS PE NeoGram Kit	147	35.72	2.64	4.00	13.01	0.8
Non-derivatized - MS/MS PE NeoBase Kit	535	37.40	2.51	4.37	9.70	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	108	39.55	3.67	4.49	11.15	0.9
Non-derivatized - MS/MS Chromsystems MassChrom Kit	70	35.99	2.04	3.08	8.86	0.9
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	50	44.84	3.04	4.93	11.86	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.

ACETYLCARNITINE ($\mu\text{mol C2/L}$ whole blood)

- continued -

METHOD	N	Mean	Average Within		Y- Intercept*	Slope
			Lab SD	Total SD		
Lot 1461 - Nonenriched 0 $\mu\text{mol/L}$ whole blood						
Derivatized - MS/MS non-kit	794	13.89	1.48	3.35	13.69	1.0
Non-derivatized - MS/MS non-kit	218	11.91	0.76	1.69	11.57	1.1
Derivatized - MS/MS PE NeoGram Kit	125	14.58	1.14	1.79	14.72	0.8
Non-derivatized - MS/MS PE NeoBase Kit	581	11.25	0.83	1.38	10.82	1.0
Derivatized - MS/MS Chromsystems MassChrom Kit	121	12.91	1.42	2.87	12.50	0.9
Non-derivatized - MS/MS Chromsystems MassChrom Kit	60	9.90	0.50	1.10	9.42	0.9
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	60	14.19	0.90	2.54	13.91	1.2
Lot 1462 - Enriched 10.0 $\mu\text{mol/L}$ whole blood						
Derivatized - MS/MS non-kit	782	23.23	2.39	4.72	13.69	1.0
Non-derivatized - MS/MS non-kit	219	21.77	1.57	2.89	11.57	1.1
Derivatized - MS/MS PE NeoGram Kit	127	23.20	1.63	2.44	14.72	0.8
Non-derivatized - MS/MS PE NeoBase Kit	572	20.13	1.45	2.32	10.82	1.0
Derivatized - MS/MS Chromsystems MassChrom Kit	123	21.37	2.06	3.60	12.50	0.9
Non-derivatized - MS/MS Chromsystems MassChrom Kit	60	17.43	1.18	2.39	9.42	0.9
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	60	25.61	1.42	4.51	13.91	1.2
Lot 1463 - Enriched 20.0 $\mu\text{mol/L}$ whole blood						
Derivatized - MS/MS non-kit	791	33.25	3.33	6.65	13.69	1.0
Non-derivatized - MS/MS non-kit	219	32.38	2.28	4.14	11.57	1.1
Derivatized - MS/MS PE NeoGram Kit	127	31.08	2.31	3.12	14.72	0.8
Non-derivatized - MS/MS PE NeoBase Kit	578	30.60	2.09	3.47	10.82	1.0
Derivatized - MS/MS Chromsystems MassChrom Kit	122	30.33	2.45	5.19	12.50	0.9
Non-derivatized - MS/MS Chromsystems MassChrom Kit	59	27.79	2.06	3.29	9.42	0.9
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	60	38.63	2.28	6.63	13.91	1.2
Lot 1464 - Enriched 30.0 $\mu\text{mol/L}$ whole blood						
Derivatized - MS/MS non-kit	796	43.23	4.40	8.87	13.69	1.0
Non-derivatized - MS/MS non-kit	218	43.58	2.97	5.18	11.57	1.1
Derivatized - MS/MS PE NeoGram Kit	126	39.39	2.07	3.05	14.72	0.8
Non-derivatized - MS/MS PE NeoBase Kit	581	40.83	3.09	5.08	10.82	1.0
Derivatized - MS/MS Chromsystems MassChrom Kit	126	40.55	3.80	6.95	12.50	0.9
Non-derivatized - MS/MS Chromsystems MassChrom Kit	58	36.33	2.52	4.39	9.42	0.9
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	60	50.65	2.61	9.14	13.91	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 17r. 2014 Quality Control Data
Summaries of Statistical Analyses

PROPIONYLCARNITINE ($\mu\text{mol C3/L}$ whole blood)

METHOD	N	Mean	Average		Y- Intercept*	Slope
			Within Lab SD	Total SD		
Lot 1365 - Nonenriched 0 $\mu\text{mol/L}$ whole blood						
Derivatized - MS/MS non-kit	873	1.28	0.18	0.30	1.21	0.9
Non-derivatized - MS/MS non-kit	228	1.25	0.14	0.25	1.24	0.9
Derivatized - MS/MS PE NeoGram Kit	143	1.05	0.11	0.15	1.02	0.8
Non-derivatized - MS/MS PE NeoBase Kit	546	1.03	0.08	0.13	1.03	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	96	1.19	0.17	0.22	1.15	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	63	1.00	0.07	0.09	0.95	0.8
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	50	1.31	0.08	0.11	1.36	1.0
Lot 1366 - Enriched 3.0 $\mu\text{mol/L}$ whole blood						
Derivatized - MS/MS non-kit	871	4.00	0.49	0.81	1.21	0.9
Non-derivatized - MS/MS non-kit	227	4.05	0.44	0.61	1.24	0.9
Derivatized - MS/MS PE NeoGram Kit	146	3.41	0.26	0.35	1.02	0.8
Non-derivatized - MS/MS PE NeoBase Kit	563	3.43	0.21	0.37	1.03	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	99	3.60	0.41	0.44	1.15	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	70	3.29	0.19	0.29	0.95	0.8
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	50	4.39	0.24	0.34	1.36	1.0
Lot 1367 - Enriched 7.5 $\mu\text{mol/L}$ whole blood						
Derivatized - MS/MS non-kit	877	7.85	0.96	1.53	1.21	0.9
Non-derivatized - MS/MS non-kit	227	7.87	0.79	1.18	1.24	0.9
Derivatized - MS/MS PE NeoGram Kit	148	6.74	0.53	0.77	1.02	0.8
Non-derivatized - MS/MS PE NeoBase Kit	563	6.88	0.50	0.79	1.03	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	97	7.26	0.74	0.83	1.15	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	69	6.69	0.44	0.57	0.95	0.8
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	50	8.79	0.54	1.18	1.36	1.0
Lot 1368 - Enriched 12.0 $\mu\text{mol/L}$ whole blood						
Derivatized - MS/MS non-kit	905	12.38	1.43	3.05	1.21	0.9
Non-derivatized - MS/MS non-kit	228	12.28	1.13	1.64	1.24	0.9
Derivatized - MS/MS PE NeoGram Kit	148	10.48	0.81	1.17	1.02	0.8
Non-derivatized - MS/MS PE NeoBase Kit	552	10.51	0.65	1.29	1.03	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	95	11.06	1.11	1.24	1.15	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	69	10.38	0.60	0.77	0.95	0.8
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	50	13.23	0.92	1.01	1.36	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.

PROPIONYLCARNITINE ($\mu\text{mol C3/L}$ whole blood)

- continued -

METHOD	N	Average		Y- Intercept*	Slope	
		Mean	Within Lab SD			
Lot 1461 - Nonenriched 0 $\mu\text{mol/L}$ whole blood						
Derivatized - MS/MS non-kit	790	1.24	0.15	0.22	1.18	1.0
Non-derivatized - MS/MS non-kit	233	1.20	0.12	0.17	1.10	1.1
Derivatized - MS/MS PE NeoGram Kit	125	1.09	0.09	0.11	1.02	0.9
Non-derivatized - MS/MS PE NeoBase Kit	589	1.05	0.08	0.12	0.95	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	121	1.15	0.15	0.21	0.92	0.9
Non-derivatized - MS/MS Chromsystems MassChrom Kit	59	0.98	0.05	0.07	0.83	0.9
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	60	1.33	0.09	0.20	1.27	1.2
Lot 1462 - Enriched 3.0 $\mu\text{mol/L}$ whole blood						
Derivatized - MS/MS non-kit	813	4.20	0.51	0.88	1.18	1.0
Non-derivatized - MS/MS non-kit	236	4.18	0.34	0.54	1.10	1.1
Derivatized - MS/MS PE NeoGram Kit	127	3.78	0.24	0.39	1.02	0.9
Non-derivatized - MS/MS PE NeoBase Kit	584	3.58	0.24	0.37	0.95	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	126	3.54	0.37	0.52	0.92	0.9
Non-derivatized - MS/MS Chromsystems MassChrom Kit	59	3.20	0.21	0.33	0.83	0.9
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	60	4.61	0.29	0.64	1.27	1.2
Lot 1463 - Enriched 7.5 $\mu\text{mol/L}$ whole blood						
Derivatized - MS/MS non-kit	793	8.79	0.93	1.63	1.18	1.0
Non-derivatized - MS/MS non-kit	233	8.79	0.62	1.17	1.10	1.1
Derivatized - MS/MS PE NeoGram Kit	124	7.88	0.66	0.79	1.02	0.9
Non-derivatized - MS/MS PE NeoBase Kit	582	7.75	0.53	0.83	0.95	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	123	7.77	0.86	1.03	0.92	0.9
Non-derivatized - MS/MS Chromsystems MassChrom Kit	57	7.32	0.55	0.64	0.83	0.9
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	60	9.87	0.66	1.37	1.27	1.2
Lot 1464 - Enriched 12.0 $\mu\text{mol/L}$ whole blood						
Derivatized - MS/MS non-kit	788	13.50	1.46	2.54	1.18	1.0
Non-derivatized - MS/MS non-kit	230	13.76	1.07	1.91	1.10	1.1
Derivatized - MS/MS PE NeoGram Kit	128	12.24	0.85	1.28	1.02	0.9
Non-derivatized - MS/MS PE NeoBase Kit	582	12.00	0.85	1.35	0.95	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	123	12.37	1.18	1.50	0.92	0.9
Non-derivatized - MS/MS Chromsystems MassChrom Kit	55	11.17	0.79	1.10	0.83	0.9
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	60	15.03	0.85	1.97	1.27	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 17s. 2014 Quality Control Data
Summaries of Statistical Analyses

MALONYLCARNITINE ($\mu\text{mol C3DC/L}$ whole blood)

METHOD	N	Mean	Average Within Lab SD	Total SD	Y- Intercept*	Slope
Lot 1365 - Nonenriched 0 $\mu\text{mol/L}$ whole blood						
Derivatized - MS/MS non-kit	797	0.03	0.02	0.03	0.04	0.5
Derivatized - MS/MS PE NeoGram Kit	122	0.03	0.01	0.01	0.03	1.3
Derivatized - MS/MS Chromsystems MassChrom Kit	87	0.05	0.02	0.03	0.06	0.7
Lot 1366 - Enriched 0.5 $\mu\text{mol/L}$ whole blood						
Derivatized - MS/MS non-kit	796	0.31	0.07	0.13	0.04	0.5
Derivatized - MS/MS PE NeoGram Kit	123	0.70	0.07	0.13	0.03	1.3
Derivatized - MS/MS Chromsystems MassChrom Kit	89	0.42	0.09	0.17	0.06	0.7
Lot 1367 - Enriched 1.5 $\mu\text{mol/L}$ whole blood						
Derivatized - MS/MS non-kit	784	0.81	0.13	0.25	0.04	0.5
Derivatized - MS/MS PE NeoGram Kit	125	1.91	0.18	0.40	0.03	1.3
Derivatized - MS/MS Chromsystems MassChrom Kit	87	1.08	0.18	0.36	0.06	0.7
Lot 1368 - Enriched 3.0 $\mu\text{mol/L}$ whole blood						
Derivatized - MS/MS non-kit	779	1.59	0.26	0.50	0.04	0.5
Derivatized - MS/MS PE NeoGram Kit	123	3.92	0.37	0.75	0.03	1.3
Derivatized - MS/MS Chromsystems MassChrom Kit	85	2.14	0.36	0.68	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.

MALONYLCARNITINE ($\mu\text{mol C3DC/L}$ whole blood)

- continued -

METHOD	N	Mean	Average Within Lab SD	Total SD	Y- Intercept*	Slope
Lot 1461 - Nonenriched 0 $\mu\text{mol/L}$ whole blood						
Derivatized - MS/MS non-kit	714	0.03	0.02	0.02	0.04	0.6
Derivatized - MS/MS PE NeoGram Kit	96	0.04	0.01	0.02	0.04	1.4
Derivatized - MS/MS Chromsystems MassChrom Kit	107	0.04	0.02	0.03	0.04	0.7
Lot 1462 - Enriched 0.5 $\mu\text{mol/L}$ whole blood						
Derivatized - MS/MS non-kit	729	0.35	0.07	0.15	0.04	0.6
Derivatized - MS/MS PE NeoGram Kit	95	0.73	0.08	0.16	0.04	1.4
Derivatized - MS/MS Chromsystems MassChrom Kit	108	0.37	0.06	0.18	0.04	0.7
Lot 1463 - Enriched 1.5 $\mu\text{mol/L}$ whole blood						
Derivatized - MS/MS non-kit	711	0.97	0.16	0.36	0.04	0.6
Derivatized - MS/MS PE NeoGram Kit	98	2.22	0.35	0.61	0.04	1.4
Derivatized - MS/MS Chromsystems MassChrom Kit	106	1.01	0.14	0.47	0.04	0.7
Lot 1464 - Enriched 3.0 $\mu\text{mol/L}$ whole blood						
Derivatized - MS/MS non-kit	710	1.87	0.30	0.74	0.04	0.6
Derivatized - MS/MS PE NeoGram Kit	97	4.32	0.41	1.22	0.04	1.4
Derivatized - MS/MS Chromsystems MassChrom Kit	109	2.01	0.27	0.91	0.04	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. 2014 Quality Control Data
Summaries of Statistical Analyses

MALONYLCARNITINE + HYDROXYBUTYRYLCARNITINE
($\mu\text{mol C3DC+C4OH/L}$ whole blood)

METHOD	N	Mean	Average Within Lab SD	Total SD	Y- Intercept*	Slope
Lot 1365 - Nonenriched 0 $\mu\text{mol/L}$ whole blood						
Non-derivatized - MS/MS non-kit	94	0.15	0.04	0.08	0.18	0.6
Non-derivatized - MS/MS PE NeoBase Kit	430	0.10	0.02	0.06	0.10	0.4
Non-derivatized - MS/MS Chromsystems MassChrom Kit	39	0.22	0.12	0.26	0.18	0.7
Lot 1366 - Enriched 1.0 $\mu\text{mol/L}$ whole blood						
Non-derivatized - MS/MS non-kit	97	0.78	0.12	0.49	0.18	0.6
Non-derivatized - MS/MS PE NeoBase Kit	448	0.55	0.05	0.35	0.10	0.4
Non-derivatized - MS/MS Chromsystems MassChrom Kit	40	0.90	0.12	1.04	0.18	0.7
Lot 1367 - Enriched 2.5 $\mu\text{mol/L}$ whole blood						
Non-derivatized - MS/MS non-kit	96	1.52	0.20	0.98	0.18	0.6
Non-derivatized - MS/MS PE NeoBase Kit	426	0.94	0.08	0.54	0.10	0.4
Non-derivatized - MS/MS Chromsystems MassChrom Kit	40	1.92	0.36	2.26	0.18	0.7
Lot 1368 - Enriched 5.5 $\mu\text{mol/L}$ whole blood						
Non-derivatized - MS/MS non-kit	94	3.21	0.36	1.87	0.18	0.6
Non-derivatized - MS/MS PE NeoBase Kit	442	2.23	0.17	1.43	0.10	0.4
Non-derivatized - MS/MS Chromsystems MassChrom Kit	40	4.17	0.21	4.65	0.18	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.

MALONYLCARNITINE + HYDROXYBUTYRYLCARNITINE

(μmol C3DC+C4OH/L whole blood)

- continued -

METHOD	N	Mean	Average Within Lab SD	Total SD	Y- Intercept*	Slope
Lot 1461 - Nonenriched 0 μmol/L whole blood						
Non-derivatized - MS/MS non-kit	122	0.10	0.03	0.05	0.08	0.5
Non-derivatized - MS/MS PE NeoBase Kit	321	0.07	0.01	0.03	0.06	0.3
Non-derivatized - MS/MS Chromsystems MassChrom Kit	40	0.15	0.05	0.20	0.12	0.7
Lot 1462 - Enriched 1.0 μmol/L whole blood						
Non-derivatized - MS/MS non-kit	122	0.58	0.10	0.25	0.08	0.5
Non-derivatized - MS/MS PE NeoBase Kit	309	0.36	0.04	0.08	0.06	0.3
Non-derivatized - MS/MS Chromsystems MassChrom Kit	40	0.82	0.15	1.04	0.12	0.7
Lot 1463 - Enriched 2.5 μmol/L whole blood						
Non-derivatized - MS/MS non-kit	121	1.29	0.13	0.62	0.08	0.5
Non-derivatized - MS/MS PE NeoBase Kit	309	0.76	0.08	0.13	0.06	0.3
Non-derivatized - MS/MS Chromsystems MassChrom Kit	40	1.83	0.46	2.33	0.12	0.7
Lot 1464 - Enriched 5.5 μmol/L whole blood						
Non-derivatized - MS/MS non-kit	121	2.86	0.28	1.25	0.08	0.5
Non-derivatized - MS/MS PE NeoBase Kit	310	1.71	0.17	0.41	0.06	0.3
Non-derivatized - MS/MS Chromsystems MassChrom Kit	40	4.00	1.03	5.08	0.12	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 17u. 2014 Quality Control Data
Summaries of Statistical Analyses

BUTYRYLCARNITINE ($\mu\text{mol C4/L}$ whole blood)

METHOD	N	Average		Y- Intercept*	Slope
		Mean	Within Lab SD		
Lot 1365 - Nonenriched 0 $\mu\text{mol/L}$ whole blood					
Derivatized - MS/MS non-kit	877	0.19	0.04	0.06	0.17 0.8
Non-derivatized - MS/MS non-kit	196	0.17	0.03	0.04	0.15 0.9
Derivatized - MS/MS PE NeoGram Kit	136	0.18	0.04	0.04	0.16 0.7
Non-derivatized - MS/MS PE NeoBase Kit	530	0.16	0.02	0.04	0.15 0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	92	0.16	0.04	0.05	0.10 0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	68	0.14	0.01	0.01	0.10 0.7
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	40	0.15	0.01	0.03	0.14 0.8
Lot 1366 - Enriched 1.0 $\mu\text{mol/L}$ whole blood					
Derivatized - MS/MS non-kit	867	1.00	0.14	0.19	0.17 0.8
Non-derivatized - MS/MS non-kit	200	1.03	0.11	0.14	0.15 0.9
Derivatized - MS/MS PE NeoGram Kit	137	0.91	0.15	0.17	0.16 0.7
Non-derivatized - MS/MS PE NeoBase Kit	536	0.91	0.07	0.10	0.15 0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	90	0.88	0.14	0.15	0.10 0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	70	0.81	0.06	0.08	0.10 0.7
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	40	0.91	0.06	0.16	0.14 0.8
Lot 1367 - Enriched 2.5 $\mu\text{mol/L}$ whole blood					
Derivatized - MS/MS non-kit	882	2.14	0.26	0.43	0.17 0.8
Non-derivatized - MS/MS non-kit	201	2.21	0.19	0.29	0.15 0.9
Derivatized - MS/MS PE NeoGram Kit	136	1.97	0.23	0.27	0.16 0.7
Non-derivatized - MS/MS PE NeoBase Kit	540	2.00	0.14	0.22	0.15 0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	93	1.89	0.23	0.39	0.10 0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	69	1.84	0.11	0.14	0.10 0.7
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	40	2.09	0.10	0.33	0.14 0.8
Lot 1368 - Enriched 5.0 $\mu\text{mol/L}$ whole blood					
Derivatized - MS/MS non-kit	880	4.27	0.48	0.79	0.17 0.8
Non-derivatized - MS/MS non-kit	199	4.45	0.33	0.55	0.15 0.9
Derivatized - MS/MS PE NeoGram Kit	137	3.91	0.47	0.58	0.16 0.7
Non-derivatized - MS/MS PE NeoBase Kit	527	3.93	0.24	0.40	0.15 0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	97	4.00	0.56	0.58	0.10 0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	70	3.71	0.22	0.30	0.10 0.7
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	40	4.04	0.28	0.65	0.14 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.

BUTYRYLCARNITINE ($\mu\text{mol C4/L}$ whole blood)

- continued -

METHOD	N	Mean	Average Within		Y-Intercept*	Slope
			Lab SD	Total SD		
Lot 1461 - Nonenriched 0 $\mu\text{mol/L}$ whole blood						
Derivatized - MS/MS non-kit	770	0.15	0.03	0.04	0.10	0.9
Non-derivatized - MS/MS non-kit	199	0.12	0.02	0.02	0.07	1.0
Derivatized - MS/MS PE NeoGram Kit	116	0.16	0.05	0.07	0.14	0.9
Non-derivatized - MS/MS PE NeoBase Kit	548	0.13	0.02	0.03	0.07	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	119	0.14	0.05	0.08	0.08	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	59	0.10	0.01	0.01	0.05	0.8
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	40	0.13	0.01	0.02	0.07	1.0
Lot 1462 - Enriched 1.0 $\mu\text{mol/L}$ whole blood						
Derivatized - MS/MS non-kit	793	1.00	0.13	0.19	0.10	0.9
Non-derivatized - MS/MS non-kit	202	1.00	0.09	0.12	0.07	1.0
Derivatized - MS/MS PE NeoGram Kit	118	0.97	0.15	0.17	0.14	0.9
Non-derivatized - MS/MS PE NeoBase Kit	554	0.91	0.07	0.10	0.07	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	121	0.84	0.12	0.16	0.08	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	60	0.79	0.07	0.12	0.05	0.8
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	40	1.01	0.06	0.10	0.07	1.0
Lot 1463 - Enriched 2.5 $\mu\text{mol/L}$ whole blood						
Derivatized - MS/MS non-kit	783	2.42	0.29	0.43	0.10	0.9
Non-derivatized - MS/MS non-kit	204	2.44	0.17	0.26	0.07	1.0
Derivatized - MS/MS PE NeoGram Kit	116	2.28	0.33	0.36	0.14	0.9
Non-derivatized - MS/MS PE NeoBase Kit	556	2.25	0.16	0.25	0.07	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	123	2.11	0.31	0.38	0.08	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	59	2.06	0.18	0.24	0.05	0.8
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	40	2.61	0.20	0.34	0.07	1.0
Lot 1464 - Enriched 5.0 $\mu\text{mol/L}$ whole blood						
Derivatized - MS/MS non-kit	780	4.79	0.55	0.83	0.10	0.9
Non-derivatized - MS/MS non-kit	202	4.93	0.35	0.56	0.07	1.0
Derivatized - MS/MS PE NeoGram Kit	115	4.42	0.47	0.57	0.14	0.9
Non-derivatized - MS/MS PE NeoBase Kit	558	4.51	0.31	0.52	0.07	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	127	4.21	0.49	0.68	0.08	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	56	4.09	0.23	0.42	0.05	0.8
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	40	5.12	0.32	0.69	0.07	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. 2014 Quality Control Data
Summaries of Statistical Analyses

HYDROXYBUTYRYLCARNITINE ($\mu\text{mol C4OH/L}$ whole blood)

METHOD	N	Mean	Average Within		Y-Intercept*	Slope
			Lab SD	Total SD		
Lot 1365 - Nonenriched 0 $\mu\text{mol/L}$ whole blood						
Derivatized - MS/MS non-kit	703	0.11	0.03	0.04	0.11	0.6
Derivatized - MS/MS PE NeoGram Kit	108	0.12	0.03	0.05	0.13	0.7
Derivatized - MS/MS Chromsystems MassChrom Kit	66	0.11	0.03	0.04	0.11	0.7
Lot 1366 - Enriched 0.5 $\mu\text{mol/L}$ whole blood						
Derivatized - MS/MS non-kit	695	0.43	0.07	0.11	0.11	0.6
Derivatized - MS/MS PE NeoGram Kit	109	0.50	0.09	0.19	0.13	0.7
Derivatized - MS/MS Chromsystems MassChrom Kit	66	0.44	0.06	0.08	0.11	0.7
Lot 1367 - Enriched 1.0 $\mu\text{mol/L}$ whole blood						
Derivatized - MS/MS non-kit	702	0.75	0.11	0.20	0.11	0.6
Derivatized - MS/MS PE NeoGram Kit	100	0.82	0.13	0.25	0.13	0.7
Derivatized - MS/MS Chromsystems MassChrom Kit	68	0.81	0.12	0.16	0.11	0.7
Lot 1368 - Enriched 2.5 $\mu\text{mol/L}$ whole blood						
Derivatized - MS/MS non-kit	718	1.72	0.23	0.44	0.11	0.6
Derivatized - MS/MS PE NeoGram Kit	106	1.92	0.28	0.76	0.13	0.7
Derivatized - MS/MS Chromsystems MassChrom Kit	67	1.82	0.24	0.30	0.11	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.

HYDROXYBUTYRYLCARNITINE ($\mu\text{mol C4OH/L}$ whole blood)

- continued -

METHOD	N	Mean	Average Within Lab SD	Total SD	Y- Intercept*	Slope
Lot 1461 - Nonenriched 0 $\mu\text{mol/L}$ whole blood						
Derivatized - MS/MS non-kit	667	0.09	0.03	0.04	0.09	0.7
Derivatized - MS/MS PE NeoGram Kit	97	0.12	0.03	0.04	0.11	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	77	0.08	0.02	0.03	0.07	0.7
Lot 1462 - Enriched 0.5 $\mu\text{mol/L}$ whole blood						
Derivatized - MS/MS non-kit	664	0.40	0.06	0.12	0.09	0.7
Derivatized - MS/MS PE NeoGram Kit	94	0.52	0.08	0.14	0.11	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	81	0.36	0.06	0.10	0.07	0.7
Lot 1463 - Enriched 1.0 $\mu\text{mol/L}$ whole blood						
Derivatized - MS/MS non-kit	654	0.76	0.10	0.22	0.09	0.7
Derivatized - MS/MS PE NeoGram Kit	89	0.91	0.15	0.18	0.11	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	87	0.76	0.10	0.19	0.07	0.7
Lot 1464 - Enriched 2.5 $\mu\text{mol/L}$ whole blood						
Derivatized - MS/MS non-kit	661	1.71	0.22	0.46	0.09	0.7
Derivatized - MS/MS PE NeoGram Kit	90	2.14	0.38	0.42	0.11	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	88	1.69	0.17	0.29	0.07	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. 2014 Quality Control Data
Summaries of Statistical Analyses

ISOVALERYLCARNITINE ($\mu\text{mol C5/L}$ whole blood)

METHOD	N	Mean	Average Within		Y- Intercept*	Slope
			Lab SD	Total SD		
Lot 1365 - Nonenriched 0 $\mu\text{mol/L}$ whole blood						
Derivatized - MS/MS non-kit	915	0.11	0.02	0.03	0.11	0.9
Non-derivatized - MS/MS non-kit	254	0.09	0.01	0.01	0.08	0.9
Derivatized - MS/MS PE NeoGram Kit	145	0.09	0.02	0.02	0.10	0.8
Non-derivatized - MS/MS PE NeoBase Kit	557	0.09	0.01	0.02	0.08	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	97	0.12	0.03	0.05	0.11	0.9
Non-derivatized - MS/MS Chromsystems MassChrom Kit	70	0.08	0.01	0.02	0.07	0.8
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	50	0.10	0.01	0.02	0.12	0.9
Lot 1366 - Enriched 0.5 $\mu\text{mol/L}$ whole blood						
Derivatized - MS/MS non-kit	906	0.54	0.07	0.10	0.11	0.9
Non-derivatized - MS/MS non-kit	262	0.54	0.05	0.07	0.08	0.9
Derivatized - MS/MS PE NeoGram Kit	143	0.51	0.07	0.09	0.10	0.8
Non-derivatized - MS/MS PE NeoBase Kit	565	0.49	0.03	0.06	0.08	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	91	0.54	0.06	0.07	0.11	0.9
Non-derivatized - MS/MS Chromsystems MassChrom Kit	70	0.45	0.03	0.09	0.07	0.8
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	50	0.58	0.04	0.08	0.12	0.9
Lot 1367 - Enriched 1.5 $\mu\text{mol/L}$ whole blood						
Derivatized - MS/MS non-kit	910	1.38	0.15	0.23	0.11	0.9
Non-derivatized - MS/MS non-kit	261	1.40	0.12	0.21	0.08	0.9
Derivatized - MS/MS PE NeoGram Kit	150	1.30	0.18	0.23	0.10	0.8
Non-derivatized - MS/MS PE NeoBase Kit	570	1.27	0.09	0.18	0.08	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	96	1.39	0.17	0.23	0.11	0.9
Non-derivatized - MS/MS Chromsystems MassChrom Kit	70	1.21	0.09	0.22	0.07	0.8
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	50	1.52	0.09	0.27	0.12	0.9
Lot 1368 - Enriched 3.0 $\mu\text{mol/L}$ whole blood						
Derivatized - MS/MS non-kit	928	2.69	0.30	0.45	0.11	0.9
Non-derivatized - MS/MS non-kit	258	2.77	0.21	0.32	0.08	0.9
Derivatized - MS/MS PE NeoGram Kit	148	2.50	0.30	0.38	0.10	0.8
Non-derivatized - MS/MS PE NeoBase Kit	570	2.49	0.16	0.37	0.08	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	98	2.73	0.37	0.39	0.11	0.9
Non-derivatized - MS/MS Chromsystems MassChrom Kit	69	2.36	0.14	0.45	0.07	0.8
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	50	2.85	0.20	0.34	0.12	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.

ISOVALERYLCARNITINE ($\mu\text{mol C5/L}$ whole blood)

- continued -

METHOD	N	Average			Y- Intercept*	Slope
		Mean	Within Lab SD	Total SD		
Lot 1461 - Nonenriched 0 $\mu\text{mol/L}$ whole blood						
Derivatized - MS/MS non-kit	789	0.09	0.02	0.03	0.08	0.9
Non-derivatized - MS/MS non-kit	254	0.07	0.01	0.02	0.05	1.0
Derivatized - MS/MS PE NeoGram Kit	123	0.09	0.02	0.02	0.07	0.9
Non-derivatized - MS/MS PE NeoBase Kit	589	0.08	0.01	0.02	0.07	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	121	0.11	0.03	0.05	0.08	0.9
Non-derivatized - MS/MS Chromsystems MassChrom Kit	68	0.07	0.01	0.01	0.06	0.8
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	58	0.09	0.01	0.02	0.09	0.9
Lot 1462 - Enriched 0.5 $\mu\text{mol/L}$ whole blood						
Derivatized - MS/MS non-kit	824	0.52	0.07	0.11	0.08	0.9
Non-derivatized - MS/MS non-kit	262	0.53	0.04	0.06	0.05	1.0
Derivatized - MS/MS PE NeoGram Kit	128	0.52	0.07	0.09	0.07	0.9
Non-derivatized - MS/MS PE NeoBase Kit	595	0.50	0.04	0.07	0.07	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	123	0.52	0.07	0.08	0.08	0.9
Non-derivatized - MS/MS Chromsystems MassChrom Kit	69	0.44	0.03	0.06	0.06	0.8
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	60	0.55	0.03	0.07	0.09	0.9
Lot 1463 - Enriched 1.5 $\mu\text{mol/L}$ whole blood						
Derivatized - MS/MS non-kit	810	1.40	0.16	0.25	0.08	0.9
Non-derivatized - MS/MS non-kit	265	1.47	0.10	0.17	0.05	1.0
Derivatized - MS/MS PE NeoGram Kit	128	1.38	0.15	0.21	0.07	0.9
Non-derivatized - MS/MS PE NeoBase Kit	589	1.40	0.11	0.19	0.07	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	122	1.44	0.19	0.24	0.08	0.9
Non-derivatized - MS/MS Chromsystems MassChrom Kit	59	1.30	0.07	0.19	0.06	0.8
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	60	1.52	0.09	0.15	0.09	0.9
Lot 1464 - Enriched 3.0 $\mu\text{mol/L}$ whole blood						
Derivatized - MS/MS non-kit	821	2.75	0.31	0.50	0.08	0.9
Non-derivatized - MS/MS non-kit	262	2.96	0.21	0.33	0.05	1.0
Derivatized - MS/MS PE NeoGram Kit	128	2.76	0.31	0.42	0.07	0.9
Non-derivatized - MS/MS PE NeoBase Kit	595	2.74	0.19	0.37	0.07	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	123	2.88	0.35	0.41	0.08	0.9
Non-derivatized - MS/MS Chromsystems MassChrom Kit	69	2.47	0.16	0.43	0.06	0.8
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	60	2.91	0.14	0.26	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.

Table 17x. 2014 Quality Control Data
Summaries of Statistical Analyses

GLUTARYLCARNITINE ($\mu\text{mol C5DC/L}$ whole blood)

METHOD	N	Average		Y- Intercept*	Slope	
		Mean	Within Lab SD			
Lot 1365 - Nonenriched 0 $\mu\text{mol/L}$ whole blood						
Derivatized - MS/MS non-kit	896	0.02	0.01	0.02	0.03	0.6
Non-derivatized - MS/MS non-kit	243	0.05	0.02	0.03	0.05	0.8
Derivatized - MS/MS PE NeoGram Kit	135	0.03	0.01	0.01	0.03	1.0
Non-derivatized - MS/MS PE NeoBase Kit	532	0.05	0.02	0.03	0.06	1.0
Derivatized - MS/MS Chromsystems MassChrom Kit	96	0.05	0.02	0.05	0.06	1.3
Non-derivatized - MS/MS Chromsystems MassChrom Kit	69	0.08	0.02	0.03	0.07	1.4
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	50	0.07	0.01	0.01	0.08	0.9
Lot 1366 - Enriched 0.5 $\mu\text{mol/L}$ whole blood						
Derivatized - MS/MS non-kit	896	0.32	0.06	0.14	0.03	0.6
Non-derivatized - MS/MS non-kit	249	0.48	0.06	0.18	0.05	0.8
Derivatized - MS/MS PE NeoGram Kit	144	0.53	0.04	0.06	0.03	1.0
Non-derivatized - MS/MS PE NeoBase Kit	530	0.53	0.05	0.09	0.06	1.0
Derivatized - MS/MS Chromsystems MassChrom Kit	97	0.71	0.15	0.16	0.06	1.3
Non-derivatized - MS/MS Chromsystems MassChrom Kit	69	0.78	0.08	0.17	0.07	1.4
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	50	0.55	0.03	0.08	0.08	0.9
Lot 1367 - Enriched 1.0 $\mu\text{mol/L}$ whole blood						
Derivatized - MS/MS non-kit	907	0.59	0.09	0.25	0.03	0.6
Non-derivatized - MS/MS non-kit	248	0.90	0.10	0.34	0.05	0.8
Derivatized - MS/MS PE NeoGram Kit	145	0.99	0.09	0.13	0.03	1.0
Non-derivatized - MS/MS PE NeoBase Kit	533	1.01	0.09	0.18	0.06	1.0
Derivatized - MS/MS Chromsystems MassChrom Kit	96	1.37	0.22	0.28	0.06	1.3
Non-derivatized - MS/MS Chromsystems MassChrom Kit	70	1.50	0.13	0.36	0.07	1.4
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	50	1.04	0.07	0.18	0.08	0.9
Lot 1368 - Enriched 2.5 $\mu\text{mol/L}$ whole blood						
Derivatized - MS/MS non-kit	909	1.44	0.20	0.59	0.03	0.6
Non-derivatized - MS/MS non-kit	250	2.16	0.20	0.81	0.05	0.8
Derivatized - MS/MS PE NeoGram Kit	145	2.47	0.21	0.31	0.03	1.0
Non-derivatized - MS/MS PE NeoBase Kit	533	2.42	0.19	0.40	0.06	1.0
Derivatized - MS/MS Chromsystems MassChrom Kit	93	3.29	0.46	0.56	0.06	1.3
Non-derivatized - MS/MS Chromsystems MassChrom Kit	70	3.65	0.36	0.90	0.07	1.4
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	50	2.43	0.15	0.32	0.08	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.

GLUTARYLCARNITINE ($\mu\text{mol C5DC/L}$ whole blood)

- continued -

METHOD	N	Average			Y- Intercept*	Slope
		Mean	Within Lab SD	Total SD		
Lot 1461 - Nonenriched 0 $\mu\text{mol/L}$ whole blood						
Derivatized - MS/MS non-kit	799	0.02	0.01	0.02	0.02	0.7
Non-derivatized - MS/MS non-kit	253	0.05	0.01	0.03	0.04	1.0
Derivatized - MS/MS PE NeoGram Kit	124	0.04	0.01	0.02	0.03	1.2
Non-derivatized - MS/MS PE NeoBase Kit	531	0.07	0.01	0.03	0.05	1.1
Derivatized - MS/MS Chromsystems MassChrom Kit	117	0.05	0.03	0.04	0.05	1.4
Non-derivatized - MS/MS Chromsystems MassChrom Kit	69	0.09	0.02	0.03	0.06	1.7
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	58	0.08	0.01	0.01	0.08	1.1
Lot 1462 - Enriched 0.5 $\mu\text{mol/L}$ whole blood						
Derivatized - MS/MS non-kit	824	0.34	0.06	0.17	0.02	0.7
Non-derivatized - MS/MS non-kit	260	0.51	0.07	0.19	0.04	1.0
Derivatized - MS/MS PE NeoGram Kit	125	0.59	0.05	0.07	0.03	1.2
Non-derivatized - MS/MS PE NeoBase Kit	545	0.61	0.06	0.09	0.05	1.1
Derivatized - MS/MS Chromsystems MassChrom Kit	125	0.70	0.16	0.27	0.05	1.4
Non-derivatized - MS/MS Chromsystems MassChrom Kit	70	0.85	0.09	0.18	0.06	1.7
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	60	0.61	0.04	0.08	0.08	1.1
Lot 1463 - Enriched 1.0 $\mu\text{mol/L}$ whole blood						
Derivatized - MS/MS non-kit	816	0.68	0.10	0.32	0.02	0.7
Non-derivatized - MS/MS non-kit	259	1.00	0.13	0.37	0.04	1.0
Derivatized - MS/MS PE NeoGram Kit	121	1.20	0.09	0.12	0.03	1.2
Non-derivatized - MS/MS PE NeoBase Kit	549	1.20	0.10	0.18	0.05	1.1
Derivatized - MS/MS Chromsystems MassChrom Kit	125	1.45	0.31	0.56	0.05	1.4
Non-derivatized - MS/MS Chromsystems MassChrom Kit	69	1.75	0.16	0.33	0.06	1.7
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	60	1.16	0.09	0.16	0.08	1.1
Lot 1464 - Enriched 2.5 $\mu\text{mol/L}$ whole blood						
Derivatized - MS/MS non-kit	822	1.66	0.23	0.80	0.02	0.7
Non-derivatized - MS/MS non-kit	260	2.44	0.27	0.89	0.04	1.0
Derivatized - MS/MS PE NeoGram Kit	122	2.94	0.21	0.30	0.03	1.2
Non-derivatized - MS/MS PE NeoBase Kit	548	2.91	0.23	0.45	0.05	1.1
Derivatized - MS/MS Chromsystems MassChrom Kit	127	3.40	0.61	1.23	0.05	1.4
Non-derivatized - MS/MS Chromsystems MassChrom Kit	69	4.24	0.40	0.80	0.06	1.7
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	60	2.75	0.18	0.41	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.

Table 17y. 2014 Quality Control Data
Summaries of Statistical Analyses

HYDROXYISOVALERYLCARNITINE ($\mu\text{mol C5OH/L}$ whole blood)

METHOD	N	Average		Y- Intercept*	Slope
		Mean	Within Lab SD		
Lot 1365 - Nonenriched 0 $\mu\text{mol/L}$ whole blood					
Derivatized - MS/MS non-kit	901	0.45	0.06	0.10	0.45 0.8
Non-derivatized - MS/MS non-kit	219	0.57	0.05	0.13	0.57 0.7
Derivatized - MS/MS PE NeoGram Kit	148	0.42	0.07	0.08	0.42 0.7
Non-derivatized - MS/MS PE NeoBase Kit	441	0.47	0.04	0.11	0.46 0.5
Derivatized - MS/MS Chromsystems MassChrom Kit	88	0.45	0.08	0.10	0.45 0.7
Non-derivatized - MS/MS Chromsystems MassChrom Kit	58	0.76	0.08	1.24	0.78 1.2
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	50	0.66	0.04	0.06	0.68 0.9
Lot 1366 - Enriched 0.5 $\mu\text{mol/L}$ whole blood					
Derivatized - MS/MS non-kit	892	0.84	0.11	0.17	0.45 0.8
Non-derivatized - MS/MS non-kit	222	0.96	0.07	0.22	0.57 0.7
Derivatized - MS/MS PE NeoGram Kit	149	0.79	0.12	0.16	0.42 0.7
Non-derivatized - MS/MS PE NeoBase Kit	450	0.74	0.05	0.17	0.46 0.5
Derivatized - MS/MS Chromsystems MassChrom Kit	87	0.81	0.14	0.18	0.45 0.7
Non-derivatized - MS/MS Chromsystems MassChrom Kit	60	1.38	0.13	2.02	0.78 1.2
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	50	1.15	0.07	0.11	0.68 0.9
Lot 1367 - Enriched 1.5 $\mu\text{mol/L}$ whole blood					
Derivatized - MS/MS non-kit	898	1.58	0.19	0.31	0.45 0.8
Non-derivatized - MS/MS non-kit	222	1.63	0.16	0.42	0.57 0.7
Derivatized - MS/MS PE NeoGram Kit	147	1.44	0.18	0.27	0.42 0.7
Non-derivatized - MS/MS PE NeoBase Kit	455	1.26	0.08	0.29	0.46 0.5
Derivatized - MS/MS Chromsystems MassChrom Kit	84	1.49	0.19	0.25	0.45 0.7
Non-derivatized - MS/MS Chromsystems MassChrom Kit	60	2.57	0.32	3.93	0.78 1.2
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	50	2.07	0.11	0.22	0.68 0.9
Lot 1368 - Enriched 2.5 $\mu\text{mol/L}$ whole blood					
Derivatized - MS/MS non-kit	898	2.41	0.29	0.48	0.45 0.8
Non-derivatized - MS/MS non-kit	221	2.44	0.19	0.60	0.57 0.7
Derivatized - MS/MS PE NeoGram Kit	150	2.17	0.30	0.41	0.42 0.7
Non-derivatized - MS/MS PE NeoBase Kit	450	1.83	0.14	0.43	0.46 0.5
Derivatized - MS/MS Chromsystems MassChrom Kit	87	2.23	0.29	0.40	0.45 0.7
Non-derivatized - MS/MS Chromsystems MassChrom Kit	60	3.71	0.25	5.58	0.78 1.2
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	50	2.96	0.19	0.39	0.68 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.

HYDROXYISOVALERYLCARNITINE ($\mu\text{mol C5OH/L}$ whole blood)

- continued -

METHOD	N	Average Within			Y- Intercept*	Slope
		Mean	Lab SD	Total SD		
Lot 1461 - Nonenriched 0 $\mu\text{mol/L}$ whole blood						
Derivatized - MS/MS non-kit	799	0.46	0.07	0.10	0.45	0.8
Non-derivatized - MS/MS non-kit	217	0.64	0.06	0.14	0.64	0.9
Derivatized - MS/MS PE NeoGram Kit	126	0.45	0.07	0.08	0.44	0.8
Non-derivatized - MS/MS PE NeoBase Kit	456	0.54	0.05	0.11	0.52	0.6
Derivatized - MS/MS Chromsystems MassChrom Kit	114	0.48	0.08	0.10	0.45	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	50	1.14	0.16	1.70	1.00	1.4
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	60	0.73	0.05	0.05	0.73	1.0
Lot 1462 - Enriched 0.5 $\mu\text{mol/L}$ whole blood						
Derivatized - MS/MS non-kit	812	0.86	0.11	0.20	0.45	0.8
Non-derivatized - MS/MS non-kit	219	1.08	0.10	0.26	0.64	0.9
Derivatized - MS/MS PE NeoGram Kit	129	0.85	0.12	0.15	0.44	0.8
Non-derivatized - MS/MS PE NeoBase Kit	466	0.83	0.07	0.17	0.52	0.6
Derivatized - MS/MS Chromsystems MassChrom Kit	114	0.82	0.12	0.15	0.45	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	50	1.73	0.25	2.58	1.00	1.4
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	59	1.24	0.07	0.09	0.73	1.0
Lot 1463 - Enriched 1.5 $\mu\text{mol/L}$ whole blood						
Derivatized - MS/MS non-kit	797	1.69	0.20	0.36	0.45	0.8
Non-derivatized - MS/MS non-kit	220	1.94	0.17	0.45	0.64	0.9
Derivatized - MS/MS PE NeoGram Kit	124	1.60	0.19	0.23	0.44	0.8
Non-derivatized - MS/MS PE NeoBase Kit	458	1.44	0.12	0.27	0.52	0.6
Derivatized - MS/MS Chromsystems MassChrom Kit	117	1.59	0.22	0.28	0.45	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	48	2.77	0.32	4.55	1.00	1.4
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	59	2.30	0.15	0.18	0.73	1.0
Lot 1464 - Enriched 2.5 $\mu\text{mol/L}$ whole blood						
Derivatized - MS/MS non-kit	813	2.56	0.30	0.57	0.45	0.8
Non-derivatized - MS/MS non-kit	220	2.85	0.25	0.70	0.64	0.9
Derivatized - MS/MS PE NeoGram Kit	124	2.43	0.29	0.35	0.44	0.8
Non-derivatized - MS/MS PE NeoBase Kit	459	2.10	0.17	0.41	0.52	0.6
Derivatized - MS/MS Chromsystems MassChrom Kit	118	2.41	0.25	0.43	0.45	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	50	4.81	1.03	7.35	1.00	1.4
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	56	3.29	0.18	0.29	0.73	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 17z. 2014 Quality Control Data
Summaries of Statistical Analyses

HEXANOYLCARNITINE ($\mu\text{mol C6/L}$ whole blood)

METHOD	N	Average			Y- Intercept*	Slope
		Mean	Lab SD	Total SD		
Lot 1365 - Nonenriched 0 $\mu\text{mol/L}$ whole blood						
Derivatized - MS/MS non-kit	877	0.04	0.02	0.03	0.04	0.8
Non-derivatized - MS/MS non-kit	213	0.02	0.01	0.01	0.02	0.8
Derivatized - MS/MS PE NeoGram Kit	142	0.04	0.02	0.02	0.08	0.6
Non-derivatized - MS/MS PE NeoBase Kit	509	0.03	0.01	0.01	0.03	0.7
Derivatized - MS/MS Chromsystems MassChrom Kit	95	0.06	0.04	0.06	0.08	0.6
Non-derivatized - MS/MS Chromsystems MassChrom Kit	68	0.02	0.00	0.01	0.02	0.7
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	39	0.02	0.00	0.00	0.02	0.7
Lot 1366 - Enriched 0.5 $\mu\text{mol/L}$ whole blood						
Derivatized - MS/MS non-kit	868	0.42	0.06	0.10	0.04	0.8
Non-derivatized - MS/MS non-kit	222	0.44	0.05	0.09	0.02	0.8
Derivatized - MS/MS PE NeoGram Kit	142	0.39	0.06	0.06	0.08	0.6
Non-derivatized - MS/MS PE NeoBase Kit	535	0.41	0.03	0.05	0.03	0.7
Derivatized - MS/MS Chromsystems MassChrom Kit	92	0.41	0.08	0.09	0.08	0.6
Non-derivatized - MS/MS Chromsystems MassChrom Kit	69	0.39	0.03	0.04	0.02	0.7
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	40	0.39	0.03	0.06	0.02	0.7
Lot 1367 - Enriched 1.0 $\mu\text{mol/L}$ whole blood						
Derivatized - MS/MS non-kit	906	0.78	0.10	0.19	0.04	0.8
Non-derivatized - MS/MS non-kit	226	0.83	0.09	0.18	0.02	0.8
Derivatized - MS/MS PE NeoGram Kit	149	0.67	0.09	0.11	0.08	0.6
Non-derivatized - MS/MS PE NeoBase Kit	541	0.76	0.06	0.09	0.03	0.7
Derivatized - MS/MS Chromsystems MassChrom Kit	93	0.68	0.12	0.16	0.08	0.6
Non-derivatized - MS/MS Chromsystems MassChrom Kit	69	0.73	0.05	0.07	0.02	0.7
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	40	0.76	0.05	0.13	0.02	0.7
Lot 1368 - Enriched 2.5 $\mu\text{mol/L}$ whole blood						
Derivatized - MS/MS non-kit	880	1.91	0.23	0.44	0.04	0.8
Non-derivatized - MS/MS non-kit	223	2.06	0.19	0.39	0.02	0.8
Derivatized - MS/MS PE NeoGram Kit	148	1.48	0.18	0.24	0.08	0.6
Non-derivatized - MS/MS PE NeoBase Kit	530	1.87	0.13	0.23	0.03	0.7
Derivatized - MS/MS Chromsystems MassChrom Kit	97	1.59	0.28	0.31	0.08	0.6
Non-derivatized - MS/MS Chromsystems MassChrom Kit	70	1.83	0.09	0.17	0.02	0.7
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	40	1.87	0.13	0.36	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.

HEXANOYLCARNITINE ($\mu\text{mol C6/L}$ whole blood)

- continued -

METHOD	N	Average Within			Y- Intercept*	Slope
		Mean	Lab SD	Total SD		
Lot 1461 - Nonenriched 0 $\mu\text{mol/L}$ whole blood						
Derivatized - MS/MS non-kit	784	0.04	0.01	0.02	0.03	0.9
Non-derivatized - MS/MS non-kit	215	0.02	0.01	0.01	0.00	0.9
Derivatized - MS/MS PE NeoGram Kit	121	0.04	0.02	0.03	0.07	0.7
Non-derivatized - MS/MS PE NeoBase Kit	562	0.02	0.01	0.02	0.02	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	119	0.07	0.04	0.05	0.09	0.7
Non-derivatized - MS/MS Chromsystems MassChrom Kit	59	0.02	0.00	0.01	0.01	0.8
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	39	0.02	0.00	0.00	0.00	0.9
Lot 1462 - Enriched 0.5 $\mu\text{mol/L}$ whole blood						
Derivatized - MS/MS non-kit	810	0.44	0.06	0.10	0.03	0.9
Non-derivatized - MS/MS non-kit	226	0.45	0.06	0.10	0.00	0.9
Derivatized - MS/MS PE NeoGram Kit	127	0.43	0.08	0.08	0.07	0.7
Non-derivatized - MS/MS PE NeoBase Kit	557	0.42	0.04	0.05	0.02	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	122	0.44	0.08	0.10	0.09	0.7
Non-derivatized - MS/MS Chromsystems MassChrom Kit	60	0.40	0.03	0.07	0.01	0.8
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	40	0.42	0.03	0.07	0.00	0.9
Lot 1463 - Enriched 1.0 $\mu\text{mol/L}$ whole blood						
Derivatized - MS/MS non-kit	806	0.88	0.12	0.19	0.03	0.9
Non-derivatized - MS/MS non-kit	226	0.92	0.11	0.19	0.00	0.9
Derivatized - MS/MS PE NeoGram Kit	125	0.75	0.10	0.10	0.07	0.7
Non-derivatized - MS/MS PE NeoBase Kit	559	0.87	0.06	0.09	0.02	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	124	0.76	0.11	0.15	0.09	0.7
Non-derivatized - MS/MS Chromsystems MassChrom Kit	58	0.85	0.06	0.11	0.01	0.8
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	40	0.88	0.05	0.14	0.00	0.9
Lot 1464 - Enriched 2.5 $\mu\text{mol/L}$ whole blood						
Derivatized - MS/MS non-kit	810	2.15	0.25	0.45	0.03	0.9
Non-derivatized - MS/MS non-kit	226	2.35	0.24	0.50	0.00	0.9
Derivatized - MS/MS PE NeoGram Kit	125	1.72	0.23	0.30	0.07	0.7
Non-derivatized - MS/MS PE NeoBase Kit	563	2.11	0.14	0.22	0.02	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	129	1.77	0.20	0.30	0.09	0.7
Non-derivatized - MS/MS Chromsystems MassChrom Kit	59	2.05	0.14	0.31	0.01	0.8
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	40	2.18	0.14	0.39	0.00	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 17 aa. 2014 Quality Control Data
Summaries of Statistical Analyses

OCTANOYLCARNITINE ($\mu\text{mol C8/L}$ whole blood)

METHOD	N	Average		Y- Intercept*	Slope
		Mean	Within Lab SD		
Lot 1365 - Nonenriched 0 $\mu\text{mol/L}$ whole blood					
Derivatized - MS/MS non-kit	905	0.04	0.02	0.03	0.9
Non-derivatized - MS/MS non-kit	278	0.03	0.01	0.02	1.0
Derivatized - MS/MS PE NeoGram Kit	144	0.03	0.02	0.02	0.9
Non-derivatized - MS/MS PE NeoBase Kit	552	0.03	0.01	0.01	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	95	0.04	0.02	0.04	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	76	0.03	0.01	0.01	0.8
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	50	0.04	0.00	0.01	0.9
Lot 1366 - Enriched 0.5 $\mu\text{mol/L}$ whole blood					
Derivatized - MS/MS non-kit	889	0.50	0.07	0.12	0.9
Non-derivatized - MS/MS non-kit	281	0.51	0.05	0.08	1.0
Derivatized - MS/MS PE NeoGram Kit	144	0.49	0.08	0.08	0.9
Non-derivatized - MS/MS PE NeoBase Kit	563	0.47	0.04	0.06	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	94	0.46	0.06	0.08	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	80	0.40	0.03	0.04	0.8
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	50	0.52	0.03	0.08	0.9
Lot 1367 - Enriched 1.0 $\mu\text{mol/L}$ whole blood					
Derivatized - MS/MS non-kit	899	0.93	0.11	0.20	0.9
Non-derivatized - MS/MS non-kit	272	0.98	0.08	0.13	1.0
Derivatized - MS/MS PE NeoGram Kit	146	0.89	0.15	0.17	0.9
Non-derivatized - MS/MS PE NeoBase Kit	568	0.92	0.07	0.12	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	96	0.85	0.13	0.15	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	80	0.79	0.06	0.09	0.8
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	50	0.99	0.06	0.20	0.9
Lot 1368 - Enriched 2.5 $\mu\text{mol/L}$ whole blood					
Derivatized - MS/MS non-kit	901	2.34	0.28	0.43	0.9
Non-derivatized - MS/MS non-kit	276	2.43	0.20	0.30	1.0
Derivatized - MS/MS PE NeoGram Kit	146	2.24	0.31	0.36	0.9
Non-derivatized - MS/MS PE NeoBase Kit	556	2.26	0.16	0.28	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	99	2.14	0.24	0.26	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	76	1.96	0.13	0.23	0.8
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	50	2.38	0.18	0.29	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.

OCTANOYLCARNITINE ($\mu\text{mol C8/L}$ whole blood)

- continued -

METHOD	N	Average			Y- Intercept*	Slope
		Mean	Within Lab SD	Total SD		
Lot 1461 - Nonenriched 0 $\mu\text{mol/L}$ whole blood						
Derivatized - MS/MS non-kit	807	0.04	0.01	0.02	0.03	1.0
Non-derivatized - MS/MS non-kit	297	0.03	0.01	0.01	0.02	1.1
Derivatized - MS/MS PE NeoGram Kit	125	0.03	0.02	0.02	0.02	1.0
Non-derivatized - MS/MS PE NeoBase Kit	582	0.02	0.01	0.01	0.01	1.0
Derivatized - MS/MS Chromsystems MassChrom Kit	122	0.04	0.02	0.03	0.03	0.9
Non-derivatized - MS/MS Chromsystems MassChrom Kit	64	0.02	0.00	0.01	0.00	0.8
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	56	0.03	0.01	0.01	0.03	1.1
Lot 1462 - Enriched 0.5 $\mu\text{mol/L}$ whole blood						
Derivatized - MS/MS non-kit	827	0.52	0.07	0.11	0.03	1.0
Non-derivatized - MS/MS non-kit	293	0.53	0.05	0.07	0.02	1.1
Derivatized - MS/MS PE NeoGram Kit	127	0.53	0.09	0.10	0.02	1.0
Non-derivatized - MS/MS PE NeoBase Kit	573	0.49	0.04	0.06	0.01	1.0
Derivatized - MS/MS Chromsystems MassChrom Kit	125	0.46	0.08	0.09	0.03	0.9
Non-derivatized - MS/MS Chromsystems MassChrom Kit	69	0.41	0.04	0.06	0.00	0.8
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	60	0.57	0.04	0.05	0.03	1.1
Lot 1463 - Enriched 1.0 $\mu\text{mol/L}$ whole blood						
Derivatized - MS/MS non-kit	813	1.05	0.13	0.21	0.03	1.0
Non-derivatized - MS/MS non-kit	299	1.07	0.09	0.15	0.02	1.1
Derivatized - MS/MS PE NeoGram Kit	125	1.02	0.15	0.16	0.02	1.0
Non-derivatized - MS/MS PE NeoBase Kit	587	1.00	0.07	0.11	0.01	1.0
Derivatized - MS/MS Chromsystems MassChrom Kit	126	0.93	0.12	0.15	0.03	0.9
Non-derivatized - MS/MS Chromsystems MassChrom Kit	68	0.85	0.06	0.11	0.00	0.8
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	60	1.17	0.07	0.10	0.03	1.1
Lot 1464 - Enriched 2.5 $\mu\text{mol/L}$ whole blood						
Derivatized - MS/MS non-kit	808	2.54	0.27	0.46	0.03	1.0
Non-derivatized - MS/MS non-kit	293	2.65	0.19	0.31	0.02	1.1
Derivatized - MS/MS PE NeoGram Kit	127	2.54	0.36	0.39	0.02	1.0
Non-derivatized - MS/MS PE NeoBase Kit	586	2.47	0.18	0.27	0.01	1.0
Derivatized - MS/MS Chromsystems MassChrom Kit	124	2.26	0.25	0.30	0.03	0.9
Non-derivatized - MS/MS Chromsystems MassChrom Kit	68	2.12	0.17	0.30	0.00	0.8
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	60	2.81	0.17	0.27	0.03	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. 2014 Quality Control Data
Summaries of Statistical Analyses

DECANOYLCARNITINE ($\mu\text{mol C10/L}$ whole blood)

METHOD	N	Average Within			Y- Intercept*	Slope
		Mean	Lab SD	Total SD		
Lot 1365 - Nonenriched 0 $\mu\text{mol/L}$ whole blood						
Derivatized - MS/MS non-kit	877	0.03	0.02	0.02	0.02	0.9
Non-derivatized - MS/MS non-kit	257	0.02	0.01	0.01	0.00	1.0
Derivatized - MS/MS PE NeoGram Kit	143	0.02	0.01	0.02	0.02	0.7
Non-derivatized - MS/MS PE NeoBase Kit	550	0.02	0.01	0.01	0.00	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	97	0.03	0.02	0.03	0.01	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	80	0.02	0.01	0.01	-0.01	0.7
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	50	0.02	0.00	0.01	0.01	1.1
Lot 1366 - Enriched 0.5 $\mu\text{mol/L}$ whole blood						
Derivatized - MS/MS non-kit	882	0.47	0.07	0.11	0.02	0.9
Non-derivatized - MS/MS non-kit	265	0.48	0.06	0.09	0.00	1.0
Derivatized - MS/MS PE NeoGram Kit	146	0.38	0.06	0.07	0.02	0.7
Non-derivatized - MS/MS PE NeoBase Kit	579	0.40	0.03	0.05	0.00	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	89	0.37	0.05	0.05	0.01	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	78	0.35	0.03	0.03	-0.01	0.7
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	50	0.53	0.04	0.16	0.01	1.1
Lot 1367 - Enriched 1.0 $\mu\text{mol/L}$ whole blood						
Derivatized - MS/MS non-kit	893	0.93	0.13	0.22	0.02	0.9
Non-derivatized - MS/MS non-kit	259	0.96	0.10	0.18	0.00	1.0
Derivatized - MS/MS PE NeoGram Kit	147	0.74	0.12	0.13	0.02	0.7
Non-derivatized - MS/MS PE NeoBase Kit	572	0.79	0.06	0.11	0.00	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	97	0.74	0.10	0.12	0.01	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	80	0.69	0.06	0.07	-0.01	0.7
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	50	1.07	0.07	0.38	0.01	1.1
Lot 1368 - Enriched 2.5 $\mu\text{mol/L}$ whole blood						
Derivatized - MS/MS non-kit	888	2.33	0.30	0.53	0.02	0.9
Non-derivatized - MS/MS non-kit	253	2.46	0.22	0.43	0.00	1.0
Derivatized - MS/MS PE NeoGram Kit	147	1.85	0.22	0.25	0.02	0.7
Non-derivatized - MS/MS PE NeoBase Kit	564	2.04	0.15	0.27	0.00	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	96	1.90	0.25	0.25	0.01	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	79	1.82	0.13	0.19	-0.01	0.7
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	50	2.67	0.21	0.68	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.

DECANOYLCARNITINE ($\mu\text{mol C10/L}$ whole blood)

- continued -

METHOD	N	Mean	Average		Y- Intercept*	Slope
			Within Lab SD	Total SD		
Lot 1461 - Nonenriched 0 $\mu\text{mol/L}$ whole blood						
Derivatized - MS/MS non-kit	769	0.03	0.01	0.02	0.02	1.0
Non-derivatized - MS/MS non-kit	277	0.02	0.01	0.01	0.00	1.1
Derivatized - MS/MS PE NeoGram Kit	127	0.03	0.02	0.02	0.02	0.8
Non-derivatized - MS/MS PE NeoBase Kit	581	0.03	0.01	0.01	0.00	1.0
Derivatized - MS/MS Chromsystems MassChrom Kit	121	0.03	0.01	0.03	0.02	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	69	0.03	0.01	0.01	0.00	0.8
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	59	0.03	0.00	0.01	0.01	1.2
Lot 1462 - Enriched 0.5 $\mu\text{mol/L}$ whole blood						
Derivatized - MS/MS non-kit	786	0.55	0.08	0.13	0.02	1.0
Non-derivatized - MS/MS non-kit	288	0.58	0.06	0.11	0.00	1.1
Derivatized - MS/MS PE NeoGram Kit	126	0.45	0.09	0.09	0.02	0.8
Non-derivatized - MS/MS PE NeoBase Kit	585	0.48	0.04	0.06	0.00	1.0
Derivatized - MS/MS Chromsystems MassChrom Kit	125	0.43	0.07	0.08	0.02	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	68	0.39	0.03	0.06	0.00	0.8
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	60	0.61	0.05	0.13	0.01	1.2
Lot 1463 - Enriched 1.0 $\mu\text{mol/L}$ whole blood						
Derivatized - MS/MS non-kit	767	1.01	0.13	0.21	0.02	1.0
Non-derivatized - MS/MS non-kit	286	1.08	0.11	0.20	0.00	1.1
Derivatized - MS/MS PE NeoGram Kit	127	0.82	0.14	0.14	0.02	0.8
Non-derivatized - MS/MS PE NeoBase Kit	584	0.91	0.07	0.09	0.00	1.0
Derivatized - MS/MS Chromsystems MassChrom Kit	121	0.80	0.09	0.12	0.02	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	68	0.78	0.06	0.09	0.00	0.8
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	60	1.15	0.09	0.24	0.01	1.2
Lot 1464 - Enriched 2.5 $\mu\text{mol/L}$ whole blood						
Derivatized - MS/MS non-kit	771	2.60	0.31	0.52	0.02	1.0
Non-derivatized - MS/MS non-kit	284	2.85	0.26	0.48	0.00	1.1
Derivatized - MS/MS PE NeoGram Kit	126	2.11	0.25	0.27	0.02	0.8
Non-derivatized - MS/MS PE NeoBase Kit	600	2.44	0.18	0.29	0.00	1.0
Derivatized - MS/MS Chromsystems MassChrom Kit	126	2.07	0.25	0.28	0.02	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	68	2.02	0.15	0.26	0.00	0.8
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	60	2.97	0.20	0.63	0.01	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 17cc. 2014 Quality Control Data
Summaries of Statistical Analyses

DODECANOYL CARNITINE ($\mu\text{mol C12/L}$ whole blood)

METHOD	N	Average			Y- Intercept*	Slope
		Mean	Lab SD	Total SD		
Lot 1365 - Nonenriched 0 $\mu\text{mol/L}$ whole blood						
Derivatized - MS/MS non-kit	774	0.04	0.02	0.03	-0.02	1.0
Non-derivatized - MS/MS non-kit	181	0.01	0.01	0.01	-0.04	0.9
Derivatized - MS/MS PE NeoGram Kit	134	0.03	0.02	0.02	-0.01	0.9
Non-derivatized - MS/MS PE NeoBase Kit	491	0.01	0.00	0.01	-0.05	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	97	0.06	0.02	0.04	0.02	1.0
Non-derivatized - MS/MS Chromsystems MassChrom Kit	61	0.01	0.00	0.00	-0.07	0.9
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	37	0.01	0.00	0.00	-0.04	1.0
Lot 1366 - Enriched 0.5 $\mu\text{mol/L}$ whole blood						
Derivatized - MS/MS non-kit	752	0.45	0.07	0.11	-0.02	1.0
Non-derivatized - MS/MS non-kit	178	0.41	0.06	0.11	-0.04	0.9
Derivatized - MS/MS PE NeoGram Kit	134	0.43	0.06	0.08	-0.01	0.9
Non-derivatized - MS/MS PE NeoBase Kit	515	0.38	0.03	0.05	-0.05	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	98	0.48	0.07	0.10	0.02	1.0
Non-derivatized - MS/MS Chromsystems MassChrom Kit	70	0.35	0.03	0.04	-0.07	0.9
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	40	0.43	0.03	0.06	-0.04	1.0
Lot 1367 - Enriched 1.0 $\mu\text{mol/L}$ whole blood						
Derivatized - MS/MS non-kit	774	0.90	0.13	0.23	-0.02	1.0
Non-derivatized - MS/MS non-kit	177	0.80	0.09	0.18	-0.04	0.9
Derivatized - MS/MS PE NeoGram Kit	137	0.87	0.13	0.16	-0.01	0.9
Non-derivatized - MS/MS PE NeoBase Kit	512	0.75	0.06	0.10	-0.05	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	97	0.96	0.14	0.23	0.02	1.0
Non-derivatized - MS/MS Chromsystems MassChrom Kit	68	0.69	0.05	0.07	-0.07	0.9
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	40	0.88	0.06	0.17	-0.04	1.0
Lot 1368 - Enriched 2.5 $\mu\text{mol/L}$ whole blood						
Derivatized - MS/MS non-kit	777	2.46	0.33	0.59	-0.02	1.0
Non-derivatized - MS/MS non-kit	178	2.31	0.25	0.60	-0.04	0.9
Derivatized - MS/MS PE NeoGram Kit	139	2.34	0.26	0.35	-0.01	0.9
Non-derivatized - MS/MS PE NeoBase Kit	514	2.20	0.16	0.29	-0.05	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	97	2.44	0.30	0.38	0.02	1.0
Non-derivatized - MS/MS Chromsystems MassChrom Kit	68	2.12	0.13	0.21	-0.07	0.9
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	38	2.43	0.13	0.23	-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.

DODECANOYL CARNITINE ($\mu\text{mol C12/L}$ whole blood)

- continued -

METHOD	N	Average Within			Y-Intercept*	Slope
		Mean	Lab SD	Total SD		
Lot 1461 - Nonenriched 0 $\mu\text{mol/L}$ whole blood						
Derivatized - MS/MS non-kit	707	0.04	0.02	0.03	0.05	0.9
Non-derivatized - MS/MS non-kit	193	0.01	0.01	0.01	0.02	0.9
Derivatized - MS/MS PE NeoGram Kit	120	0.03	0.02	0.02	0.05	0.9
Non-derivatized - MS/MS PE NeoBase Kit	557	0.02	0.00	0.01	0.01	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	124	0.09	0.03	0.06	0.12	0.9
Non-derivatized - MS/MS Chromsystems MassChrom Kit	60	0.01	0.00	0.00	0.00	0.8
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	40	0.01	0.00	0.00	0.01	1.0
Lot 1462 - Enriched 0.5 $\mu\text{mol/L}$ whole blood						
Derivatized - MS/MS non-kit	727	0.50	0.08	0.14	0.05	0.9
Non-derivatized - MS/MS non-kit	196	0.48	0.05	0.11	0.02	0.9
Derivatized - MS/MS PE NeoGram Kit	118	0.51	0.08	0.10	0.05	0.9
Non-derivatized - MS/MS PE NeoBase Kit	562	0.45	0.03	0.05	0.01	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	125	0.56	0.10	0.15	0.12	0.9
Non-derivatized - MS/MS Chromsystems MassChrom Kit	60	0.39	0.04	0.05	0.00	0.8
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	40	0.52	0.04	0.04	0.01	1.0
Lot 1463 - Enriched 1.0 $\mu\text{mol/L}$ whole blood						
Derivatized - MS/MS non-kit	710	1.00	0.14	0.25	0.05	0.9
Non-derivatized - MS/MS non-kit	196	0.95	0.11	0.24	0.02	0.9
Derivatized - MS/MS PE NeoGram Kit	115	1.00	0.14	0.14	0.05	0.9
Non-derivatized - MS/MS PE NeoBase Kit	569	0.90	0.07	0.11	0.01	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	123	1.15	0.18	0.32	0.12	0.9
Non-derivatized - MS/MS Chromsystems MassChrom Kit	59	0.80	0.06	0.10	0.00	0.8
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	40	1.04	0.08	0.10	0.01	1.0
Lot 1464 - Enriched 2.5 $\mu\text{mol/L}$ whole blood						
Derivatized - MS/MS non-kit	711	2.35	0.31	0.51	0.05	0.9
Non-derivatized - MS/MS non-kit	184	2.30	0.25	0.45	0.02	0.9
Derivatized - MS/MS PE NeoGram Kit	118	2.36	0.25	0.30	0.05	0.9
Non-derivatized - MS/MS PE NeoBase Kit	566	2.24	0.16	0.27	0.01	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	126	2.44	0.31	0.56	0.12	0.9
Non-derivatized - MS/MS Chromsystems MassChrom Kit	57	1.99	0.13	0.20	0.00	0.8
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	40	2.58	0.20	0.24	0.01	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 17dd. 2014 Quality Control Data
Summaries of Statistical Analyses

MYRISTOYL CARNITINE ($\mu\text{mol C14/L}$ whole blood)

METHOD	N	Average			Y- Intercept*	Slope
		Mean	Within Lab SD	Total SD		
Lot 1365 - Nonenriched 0 $\mu\text{mol/L}$ whole blood						
Derivatized - MS/MS non-kit	856	0.06	0.02	0.03	0.04	0.9
Non-derivatized - MS/MS non-kit	210	0.05	0.01	0.01	0.03	0.9
Derivatized - MS/MS PE NeoGram Kit	143	0.06	0.02	0.02	0.05	0.8
Non-derivatized - MS/MS PE NeoBase Kit	511	0.04	0.01	0.01	0.03	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	95	0.08	0.02	0.04	0.07	0.7
Non-derivatized - MS/MS Chromsystems MassChrom Kit	68	0.03	0.00	0.01	0.01	0.7
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	40	0.04	0.00	0.01	0.05	0.9
Lot 1366 - Enriched 0.5 $\mu\text{mol/L}$ whole blood						
Derivatized - MS/MS non-kit	867	0.48	0.07	0.11	0.04	0.9
Non-derivatized - MS/MS non-kit	211	0.47	0.05	0.08	0.03	0.9
Derivatized - MS/MS PE NeoGram Kit	144	0.46	0.07	0.08	0.05	0.8
Non-derivatized - MS/MS PE NeoBase Kit	533	0.42	0.03	0.05	0.03	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	94	0.45	0.08	0.11	0.07	0.7
Non-derivatized - MS/MS Chromsystems MassChrom Kit	68	0.34	0.03	0.03	0.01	0.7
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	40	0.46	0.03	0.08	0.05	0.9
Lot 1367 - Enriched 1.5 $\mu\text{mol/L}$ whole blood						
Derivatized - MS/MS non-kit	885	1.29	0.16	0.27	0.04	0.9
Non-derivatized - MS/MS non-kit	214	1.31	0.13	0.24	0.03	0.9
Derivatized - MS/MS PE NeoGram Kit	146	1.24	0.16	0.20	0.05	0.8
Non-derivatized - MS/MS PE NeoBase Kit	535	1.19	0.09	0.14	0.03	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	97	1.13	0.13	0.19	0.07	0.7
Non-derivatized - MS/MS Chromsystems MassChrom Kit	68	0.99	0.07	0.10	0.01	0.7
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	40	1.36	0.09	0.28	0.05	0.9
Lot 1368 - Enriched 3.0 $\mu\text{mol/L}$ whole blood						
Derivatized - MS/MS non-kit	877	2.67	0.30	0.50	0.04	0.9
Non-derivatized - MS/MS non-kit	215	2.69	0.23	0.46	0.03	0.9
Derivatized - MS/MS PE NeoGram Kit	148	2.51	0.27	0.34	0.05	0.8
Non-derivatized - MS/MS PE NeoBase Kit	528	2.38	0.18	0.29	0.03	0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	97	2.31	0.28	0.40	0.07	0.7
Non-derivatized - MS/MS Chromsystems MassChrom Kit	68	2.06	0.12	0.19	0.01	0.7
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	38	2.61	0.14	0.27	0.05	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.

MYRISTOYL Carnitine ($\mu\text{mol C14/L}$ whole blood)

- continued -

METHOD	N	Mean	Average Within		Y-Intercept*	Slope
			Lab SD	Total SD		
Lot 1461 - Nonenriched 0 $\mu\text{mol/L}$ whole blood						
Derivatized - MS/MS non-kit	781	0.08	0.02	0.03	0.07	1.0
Non-derivatized - MS/MS non-kit	200	0.06	0.01	0.02	0.06	1.0
Derivatized - MS/MS PE NeoGram Kit	128	0.08	0.03	0.03	0.08	0.9
Non-derivatized - MS/MS PE NeoBase Kit	550	0.06	0.01	0.01	0.05	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	126	0.10	0.04	0.05	0.10	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	60	0.04	0.00	0.00	0.04	0.8
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	39	0.07	0.01	0.01	0.07	1.1
Lot 1462 - Enriched 0.5 $\mu\text{mol/L}$ whole blood						
Derivatized - MS/MS non-kit	802	0.56	0.08	0.13	0.07	1.0
Non-derivatized - MS/MS non-kit	207	0.56	0.06	0.09	0.06	1.0
Derivatized - MS/MS PE NeoGram Kit	127	0.55	0.09	0.09	0.08	0.9
Non-derivatized - MS/MS PE NeoBase Kit	579	0.51	0.04	0.06	0.05	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	123	0.50	0.07	0.09	0.10	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	58	0.40	0.04	0.04	0.04	0.8
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	40	0.61	0.04	0.05	0.07	1.1
Lot 1463 - Enriched 1.5 $\mu\text{mol/L}$ whole blood						
Derivatized - MS/MS non-kit	785	1.49	0.17	0.28	0.07	1.0
Non-derivatized - MS/MS non-kit	206	1.57	0.14	0.25	0.06	1.0
Derivatized - MS/MS PE NeoGram Kit	122	1.45	0.18	0.19	0.08	0.9
Non-derivatized - MS/MS PE NeoBase Kit	566	1.42	0.11	0.16	0.05	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	125	1.27	0.16	0.23	0.10	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	58	1.18	0.10	0.11	0.04	0.8
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	40	1.71	0.14	0.18	0.07	1.1
Lot 1464 - Enriched 3.0 $\mu\text{mol/L}$ whole blood						
Derivatized - MS/MS non-kit	802	2.97	0.35	0.59	0.07	1.0
Non-derivatized - MS/MS non-kit	205	3.10	0.30	0.49	0.06	1.0
Derivatized - MS/MS PE NeoGram Kit	127	2.90	0.32	0.39	0.08	0.9
Non-derivatized - MS/MS PE NeoBase Kit	575	2.82	0.20	0.32	0.05	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	124	2.52	0.24	0.33	0.10	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	58	2.31	0.17	0.21	0.04	0.8
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	40	3.32	0.24	0.34	0.07	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 17ee. 2014 Quality Control Data
Summaries of Statistical Analyses

PALMITOYL Carnitine ($\mu\text{mol C16/L}$ whole blood)

METHOD	N	Average		Y- Intercept*	Slope
		Mean	Within Lab SD		
Lot 1365 - Nonenriched 0 $\mu\text{mol/L}$ whole blood					
Derivatized - MS/MS non-kit	894	0.82	0.10	0.15	0.42 0.9
Non-derivatized - MS/MS non-kit	222	0.82	0.08	0.13	0.41 0.9
Derivatized - MS/MS PE NeoGram Kit	146	0.76	0.09	0.10	0.41 0.8
Non-derivatized - MS/MS PE NeoBase Kit	550	0.71	0.06	0.09	0.34 0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	98	0.73	0.09	0.11	0.34 0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	69	0.70	0.06	0.07	0.27 0.8
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	39	0.80	0.05	0.08	0.46 0.9
Lot 1366 - Enriched 4.0 $\mu\text{mol/L}$ whole blood					
Derivatized - MS/MS non-kit	903	3.33	0.34	0.54	0.42 0.9
Non-derivatized - MS/MS non-kit	228	3.44	0.33	0.53	0.41 0.9
Derivatized - MS/MS PE NeoGram Kit	145	3.20	0.31	0.40	0.41 0.8
Non-derivatized - MS/MS PE NeoBase Kit	558	3.04	0.23	0.32	0.34 0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	97	3.01	0.30	0.40	0.34 0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	69	2.96	0.20	0.23	0.27 0.8
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	40	3.42	0.22	0.37	0.46 0.9
Lot 1367 - Enriched 8.0 $\mu\text{mol/L}$ whole blood					
Derivatized - MS/MS non-kit	919	7.47	0.70	1.18	0.42 0.9
Non-derivatized - MS/MS non-kit	228	7.67	0.69	1.34	0.41 0.9
Derivatized - MS/MS PE NeoGram Kit	146	7.17	0.75	0.92	0.41 0.8
Non-derivatized - MS/MS PE NeoBase Kit	560	7.06	0.52	0.78	0.34 0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	100	7.08	0.84	1.26	0.34 0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	67	6.91	0.42	0.59	0.27 0.8
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	40	8.06	0.51	1.30	0.46 0.9
Lot 1368 - Enriched 12.0 $\mu\text{mol/L}$ whole blood					
Derivatized - MS/MS non-kit	909	11.17	1.06	1.59	0.42 0.9
Non-derivatized - MS/MS non-kit	229	11.47	1.03	1.87	0.41 0.9
Derivatized - MS/MS PE NeoGram Kit	149	10.56	1.08	1.39	0.41 0.8
Non-derivatized - MS/MS PE NeoBase Kit	555	10.37	0.74	1.20	0.34 0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	97	10.43	1.05	1.47	0.34 0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	70	10.48	0.65	0.80	0.27 0.8
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	38	11.30	0.71	0.77	0.46 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.

PALMITOYL Carnitine ($\mu\text{mol C16/L}$ whole blood)

- continued -

METHOD	N	Average		Y-Intercept*	Slope
		Mean	Within Lab SD		
Lot 1461 - Nonenriched 0 $\mu\text{mol/L}$ whole blood					
Derivatized - MS/MS non-kit	815	1.01	0.12	0.17	0.62 0.9
Non-derivatized - MS/MS non-kit	225	0.98	0.08	0.12	0.62 0.9
Derivatized - MS/MS PE NeoGram Kit	124	0.92	0.11	0.12	0.60 0.8
Non-derivatized - MS/MS PE NeoBase Kit	585	0.92	0.08	0.11	0.54 0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	125	0.95	0.12	0.16	0.55 0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	57	0.87	0.05	0.06	0.50 0.8
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	50	1.06	0.07	0.13	0.73 1.0
Lot 1462 - Enriched 4.0 $\mu\text{mol/L}$ whole blood					
Derivatized - MS/MS non-kit	816	3.41	0.35	0.50	0.62 0.9
Non-derivatized - MS/MS non-kit	228	3.49	0.27	0.41	0.62 0.9
Derivatized - MS/MS PE NeoGram Kit	128	3.31	0.29	0.40	0.60 0.8
Non-derivatized - MS/MS PE NeoBase Kit	580	3.22	0.24	0.35	0.54 0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	125	3.26	0.41	0.48	0.55 0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	57	3.03	0.18	0.21	0.50 0.8
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	50	3.84	0.27	0.39	0.73 1.0
Lot 1463 - Enriched 8.0 $\mu\text{mol/L}$ whole blood					
Derivatized - MS/MS non-kit	811	7.76	0.77	1.23	0.62 0.9
Non-derivatized - MS/MS non-kit	228	7.94	0.62	1.01	0.62 0.9
Derivatized - MS/MS PE NeoGram Kit	124	7.37	0.76	0.91	0.60 0.8
Non-derivatized - MS/MS PE NeoBase Kit	582	7.54	0.59	0.80	0.54 0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	123	7.45	0.83	1.11	0.55 0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	58	7.18	0.46	0.51	0.50 0.8
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	50	8.69	0.59	0.93	0.73 1.0
Lot 1464 - Enriched 12.0 $\mu\text{mol/L}$ whole blood					
Derivatized - MS/MS non-kit	807	11.14	1.07	1.65	0.62 0.9
Non-derivatized - MS/MS non-kit	224	11.25	0.80	1.29	0.62 0.9
Derivatized - MS/MS PE NeoGram Kit	125	10.48	1.06	1.28	0.60 0.8
Non-derivatized - MS/MS PE NeoBase Kit	573	10.71	0.75	1.12	0.54 0.8
Derivatized - MS/MS Chromsystems MassChrom Kit	123	10.80	1.08	1.66	0.55 0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	57	10.17	0.54	0.62	0.50 0.8
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	48	12.09	0.78	1.23	0.73 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. 2014 Quality Control Data
Summaries of Statistical Analyses

HYDROXPALMITOYL CARNITINE ($\mu\text{mol C16OH/L}$ whole blood)

METHOD	N	Mean	Average		Y- Intercept*	Slope
			Within Lab SD	Total SD		
Lot 1365 - Nonenriched 0 $\mu\text{mol/L}$ whole blood						
Derivatized - MS/MS non-kit	885	0.01	0.01	0.01	0.01	0.6
Non-derivatized - MS/MS non-kit	243	0.01	0.00	0.01	0.01	0.6
Derivatized - MS/MS PE NeoGram Kit	136	0.01	0.01	0.01	0.02	0.6
Non-derivatized - MS/MS PE NeoBase Kit	555	0.01	0.00	0.01	0.01	0.5
Derivatized - MS/MS Chromsystems MassChrom Kit	75	0.02	0.01	0.01	0.01	0.6
Non-derivatized - MS/MS Chromsystems MassChrom Kit	69	0.01	0.00	0.00	0.00	0.5
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	50	0.01	0.00	0.00	0.01	0.6
Lot 1366 - Enriched 0.1 $\mu\text{mol/L}$ whole blood						
Derivatized - MS/MS non-kit	897	0.08	0.02	0.03	0.01	0.6
Non-derivatized - MS/MS non-kit	243	0.06	0.01	0.01	0.01	0.6
Derivatized - MS/MS PE NeoGram Kit	137	0.08	0.02	0.03	0.02	0.6
Non-derivatized - MS/MS PE NeoBase Kit	572	0.06	0.01	0.02	0.01	0.5
Derivatized - MS/MS Chromsystems MassChrom Kit	76	0.07	0.02	0.02	0.01	0.6
Non-derivatized - MS/MS Chromsystems MassChrom Kit	67	0.05	0.01	0.01	0.00	0.5
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	50	0.06	0.00	0.01	0.01	0.6
Lot 1367 - Enriched 0.5 $\mu\text{mol/L}$ whole blood						
Derivatized - MS/MS non-kit	909	0.33	0.05	0.09	0.01	0.6
Non-derivatized - MS/MS non-kit	250	0.30	0.04	0.06	0.01	0.6
Derivatized - MS/MS PE NeoGram Kit	140	0.33	0.06	0.08	0.02	0.6
Non-derivatized - MS/MS PE NeoBase Kit	541	0.27	0.02	0.04	0.01	0.5
Derivatized - MS/MS Chromsystems MassChrom Kit	75	0.33	0.05	0.05	0.01	0.6
Non-derivatized - MS/MS Chromsystems MassChrom Kit	70	0.23	0.02	0.03	0.00	0.5
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	50	0.31	0.02	0.08	0.01	0.6
Lot 1368 - Enriched 1.0 $\mu\text{mol/L}$ whole blood						
Derivatized - MS/MS non-kit	926	0.65	0.10	0.18	0.01	0.6
Non-derivatized - MS/MS non-kit	251	0.58	0.05	0.12	0.01	0.6
Derivatized - MS/MS PE NeoGram Kit	132	0.59	0.08	0.11	0.02	0.6
Non-derivatized - MS/MS PE NeoBase Kit	544	0.52	0.04	0.08	0.01	0.5
Derivatized - MS/MS Chromsystems MassChrom Kit	78	0.63	0.09	0.09	0.01	0.6
Non-derivatized - MS/MS Chromsystems MassChrom Kit	70	0.46	0.03	0.05	0.00	0.5
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	50	0.58	0.05	0.11	0.01	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.

HYDROXYPALMITOYL CARNITINE ($\mu\text{mol C16OH/L}$ whole blood)

- continued -

METHOD	N	Mean	Average Within		Y- Intercept*	Slope
			Lab SD	Total SD		
Lot 1461 - Nonenriched 0 $\mu\text{mol/L}$ whole blood						
Derivatized - MS/MS non-kit	791	0.01	0.01	0.01	0.01	0.7
Non-derivatized - MS/MS non-kit	231	0.01	0.00	0.01	0.01	0.7
Derivatized - MS/MS PE NeoGram Kit	123	0.01	0.01	0.01	0.02	0.7
Non-derivatized - MS/MS PE NeoBase Kit	565	0.01	0.00	0.01	0.01	0.6
Derivatized - MS/MS Chromsystems MassChrom Kit	111	0.02	0.01	0.02	0.02	0.7
Non-derivatized - MS/MS Chromsystems MassChrom Kit	55	0.01	0.00	0.01	0.00	0.6
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	57	0.01	0.00	0.00	0.01	0.6
Lot 1462 - Enriched 0.1 $\mu\text{mol/L}$ whole blood						
Derivatized - MS/MS non-kit	814	0.08	0.02	0.03	0.01	0.7
Non-derivatized - MS/MS non-kit	217	0.07	0.01	0.01	0.01	0.7
Derivatized - MS/MS PE NeoGram Kit	126	0.08	0.02	0.03	0.02	0.7
Non-derivatized - MS/MS PE NeoBase Kit	578	0.06	0.01	0.01	0.01	0.6
Derivatized - MS/MS Chromsystems MassChrom Kit	115	0.08	0.03	0.04	0.02	0.7
Non-derivatized - MS/MS Chromsystems MassChrom Kit	54	0.06	0.01	0.04	0.00	0.6
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	60	0.07	0.01	0.02	0.01	0.6
Lot 1463 - Enriched 0.5 $\mu\text{mol/L}$ whole blood						
Derivatized - MS/MS non-kit	804	0.35	0.05	0.09	0.01	0.7
Non-derivatized - MS/MS non-kit	225	0.34	0.03	0.06	0.01	0.7
Derivatized - MS/MS PE NeoGram Kit	127	0.34	0.06	0.07	0.02	0.7
Non-derivatized - MS/MS PE NeoBase Kit	578	0.30	0.03	0.04	0.01	0.6
Derivatized - MS/MS Chromsystems MassChrom Kit	117	0.34	0.06	0.08	0.02	0.7
Non-derivatized - MS/MS Chromsystems MassChrom Kit	55	0.29	0.04	0.20	0.00	0.6
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	60	0.33	0.03	0.08	0.01	0.6
Lot 1464 - Enriched 1.0 $\mu\text{mol/L}$ whole blood						
Derivatized - MS/MS non-kit	820	0.68	0.09	0.19	0.01	0.7
Non-derivatized - MS/MS non-kit	223	0.66	0.06	0.10	0.01	0.7
Derivatized - MS/MS PE NeoGram Kit	125	0.66	0.09	0.12	0.02	0.7
Non-derivatized - MS/MS PE NeoBase Kit	568	0.58	0.05	0.08	0.01	0.6
Derivatized - MS/MS Chromsystems MassChrom Kit	112	0.68	0.11	0.13	0.02	0.7
Non-derivatized - MS/MS Chromsystems MassChrom Kit	56	0.60	0.04	0.46	0.00	0.6
Non-derivatized - MS2 Screening Neo (MS-Neo) Siemens	60	0.64	0.05	0.15	0.01	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.

Table 17gg. 2014 Quality Control Data
Summaries of Statistical Analyses

STEAROYLCARNITINE ($\mu\text{mol C18/L}$ whole blood)

METHOD	N	Mean	Average Within		Y-Intercept*	Slope
			Lab SD	Total SD		
Lot 1365 - Nonenriched 0 $\mu\text{mol/L}$ whole blood						
Derivatized - MS/MS non-kit	854	0.68	0.10	0.15	0.66	0.8
Non-derivatized - MS/MS non-kit	180	0.69	0.07	0.10	0.66	0.9
Derivatized - MS/MS PE NeoGram Kit	135	0.69	0.09	0.10	0.66	0.9
Non-derivatized - MS/MS PE NeoBase Kit	546	0.66	0.06	0.08	0.63	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	99	0.66	0.10	0.18	0.63	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	70	0.58	0.04	0.06	0.53	0.8
Lot 1366 - Enriched 1.0 $\mu\text{mol/L}$ whole blood						
Derivatized - MS/MS non-kit	857	1.50	0.19	0.33	0.66	0.8
Non-derivatized - MS/MS non-kit	185	1.54	0.14	0.22	0.66	0.9
Derivatized - MS/MS PE NeoGram Kit	139	1.57	0.18	0.23	0.66	0.9
Non-derivatized - MS/MS PE NeoBase Kit	544	1.51	0.11	0.15	0.63	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	100	1.44	0.19	0.32	0.63	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	70	1.30	0.10	0.13	0.53	0.8
Lot 1367 - Enriched 2.0 $\mu\text{mol/L}$ whole blood						
Derivatized - MS/MS non-kit	863	2.27	0.27	0.45	0.66	0.8
Non-derivatized - MS/MS non-kit	185	2.37	0.23	0.39	0.66	0.9
Derivatized - MS/MS PE NeoGram Kit	140	2.39	0.27	0.36	0.66	0.9
Non-derivatized - MS/MS PE NeoBase Kit	549	2.40	0.18	0.24	0.63	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	98	2.27	0.29	0.49	0.63	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	68	2.07	0.15	0.21	0.53	0.8
Lot 1368 - Enriched 5.0 $\mu\text{mol/L}$ whole blood						
Derivatized - MS/MS non-kit	876	4.81	0.56	1.07	0.66	0.8
Non-derivatized - MS/MS non-kit	186	5.09	0.48	0.94	0.66	0.9
Derivatized - MS/MS PE NeoGram Kit	138	5.17	0.52	0.66	0.66	0.9
Non-derivatized - MS/MS PE NeoBase Kit	539	5.11	0.40	0.53	0.63	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	98	4.80	0.55	0.97	0.63	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	68	4.54	0.29	0.39	0.53	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.

STEAROYL CARNITINE ($\mu\text{mol C18/L}$ whole blood)

- continued -

METHOD	N	Mean	Average Within		Y-Intercept*	Slope
			Lab SD	Total SD		
Lot 1461 - Nonenriched 0 $\mu\text{mol/L}$ whole blood						
Derivatized - MS/MS non-kit	785	0.73	0.11	0.17	0.71	0.9
Non-derivatized - MS/MS non-kit	178	0.70	0.07	0.09	0.71	0.9
Derivatized - MS/MS PE NeoGram Kit	116	0.72	0.11	0.13	0.73	0.9
Non-derivatized - MS/MS PE NeoBase Kit	581	0.70	0.06	0.09	0.69	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	124	0.66	0.08	0.12	0.64	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	60	0.64	0.04	0.09	0.63	0.8
Lot 1462 - Enriched 1.0 $\mu\text{mol/L}$ whole blood						
Derivatized - MS/MS non-kit	769	1.54	0.19	0.31	0.71	0.9
Non-derivatized - MS/MS non-kit	185	1.59	0.15	0.22	0.71	0.9
Derivatized - MS/MS PE NeoGram Kit	119	1.61	0.19	0.24	0.73	0.9
Non-derivatized - MS/MS PE NeoBase Kit	574	1.57	0.12	0.18	0.69	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	124	1.40	0.19	0.27	0.64	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	58	1.44	0.10	0.16	0.63	0.8
Lot 1463 - Enriched 2.0 $\mu\text{mol/L}$ whole blood						
Derivatized - MS/MS non-kit	779	2.42	0.30	0.51	0.71	0.9
Non-derivatized - MS/MS non-kit	188	2.50	0.21	0.30	0.71	0.9
Derivatized - MS/MS PE NeoGram Kit	113	2.53	0.29	0.39	0.73	0.9
Non-derivatized - MS/MS PE NeoBase Kit	585	2.55	0.20	0.29	0.69	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	127	2.31	0.32	0.46	0.64	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	58	2.33	0.17	0.27	0.63	0.8
Lot 1464 - Enriched 5.0 $\mu\text{mol/L}$ whole blood						
Derivatized - MS/MS non-kit	763	5.00	0.53	0.91	0.71	0.9
Non-derivatized - MS/MS non-kit	184	5.12	0.37	0.62	0.71	0.9
Derivatized - MS/MS PE NeoGram Kit	117	5.14	0.50	0.66	0.73	0.9
Non-derivatized - MS/MS PE NeoBase Kit	581	5.26	0.42	0.67	0.69	0.9
Derivatized - MS/MS Chromsystems MassChrom Kit	125	4.73	0.53	0.84	0.64	0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	58	4.82	0.33	0.55	0.63	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 17hh. 2014 Quality Control Data
Summaries of Statistical Analyses

HYDROXYSTEAROYL Carnitine ($\mu\text{mol C18OH/L}$ whole blood)

METHOD	N	Average Within		Y- Intercept*	Slope
		Mean	Lab SD		
Lot 1365 - Nonenriched 0 $\mu\text{mol/L}$ whole blood					
Derivatized - MS/MS non-kit	580	0.01	0.01	0.01	0.12 0.8
Non-derivatized - MS/MS non-kit	90	0.01	0.01	0.01	0.10 0.7
Derivatized - MS/MS PE NeoGram Kit	127	0.02	0.01	0.01	0.12 0.8
Non-derivatized - MS/MS PE NeoBase Kit	430	0.00	0.00	0.01	0.10 0.7
Derivatized - MS/MS Chromsystems MassChrom Kit	64	0.01	0.00	0.01	0.12 0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	56	0.00	0.00	0.00	0.08 0.6
Lot 1366 - Enriched 0.1 $\mu\text{mol/L}$ whole blood					
Derivatized - MS/MS non-kit	595	0.29	0.05	0.13	0.12 0.8
Non-derivatized - MS/MS non-kit	90	0.25	0.04	0.12	0.10 0.7
Derivatized - MS/MS PE NeoGram Kit	122	0.30	0.05	0.07	0.12 0.8
Non-derivatized - MS/MS PE NeoBase Kit	419	0.26	0.02	0.04	0.10 0.7
Derivatized - MS/MS Chromsystems MassChrom Kit	67	0.28	0.06	0.07	0.12 0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	59	0.20	0.02	0.04	0.08 0.6
Lot 1367 - Enriched 0.5 $\mu\text{mol/L}$ whole blood					
Derivatized - MS/MS non-kit	603	0.55	0.09	0.24	0.12 0.8
Non-derivatized - MS/MS non-kit	90	0.48	0.07	0.24	0.10 0.7
Derivatized - MS/MS PE NeoGram Kit	123	0.56	0.08	0.13	0.12 0.8
Non-derivatized - MS/MS PE NeoBase Kit	426	0.52	0.05	0.07	0.10 0.7
Derivatized - MS/MS Chromsystems MassChrom Kit	70	0.57	0.14	0.16	0.12 0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	58	0.40	0.03	0.06	0.08 0.6
Lot 1368 - Enriched 1.0 $\mu\text{mol/L}$ whole blood					
Derivatized - MS/MS non-kit	604	0.86	0.13	0.37	0.12 0.8
Non-derivatized - MS/MS non-kit	90	0.72	0.09	0.36	0.10 0.7
Derivatized - MS/MS PE NeoGram Kit	122	0.88	0.12	0.20	0.12 0.8
Non-derivatized - MS/MS PE NeoBase Kit	427	0.79	0.06	0.11	0.10 0.7
Derivatized - MS/MS Chromsystems MassChrom Kit	67	0.84	0.14	0.20	0.12 0.8
Non-derivatized - MS/MS Chromsystems MassChrom Kit	58	0.63	0.04	0.10	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.

HYDROXYSTEAROYL Carnitine ($\mu\text{mol C18OH/L}$ whole blood)

- continued -

METHOD	N	Mean	Average		Y- Intercept*	Slope
			Within Lab SD	Total SD		
Lot 1461 - Nonenriched 0 $\mu\text{mol/L}$ whole blood						
Derivatized - MS/MS non-kit	571	0.01	0.01	0.01	0.01	0.6
Non-derivatized - MS/MS non-kit	113	0.00	0.00	0.01	0.00	0.6
Derivatized - MS/MS PE NeoGram Kit	116	0.01	0.01	0.01	0.02	0.6
Non-derivatized - MS/MS PE NeoBase Kit	478	0.00	0.00	0.01	0.00	0.6
Derivatized - MS/MS Chromsystems MassChrom Kit	94	0.01	0.01	0.01	0.00	0.6
Non-derivatized - MS/MS Chromsystems MassChrom Kit	59	0.00	0.00	0.00	0.00	0.5
Lot 1462 - Enriched 0.5 $\mu\text{mol/L}$ whole blood						
Derivatized - MS/MS non-kit	589	0.31	0.05	0.12	0.01	0.6
Non-derivatized - MS/MS non-kit	110	0.28	0.04	0.13	0.00	0.6
Derivatized - MS/MS PE NeoGram Kit	116	0.33	0.05	0.07	0.02	0.6
Non-derivatized - MS/MS PE NeoBase Kit	473	0.29	0.03	0.05	0.00	0.6
Derivatized - MS/MS Chromsystems MassChrom Kit	99	0.28	0.06	0.14	0.00	0.6
Non-derivatized - MS/MS Chromsystems MassChrom Kit	55	0.23	0.02	0.03	0.00	0.5
Lot 1463 - Enriched 1.0 $\mu\text{mol/L}$ whole blood						
Derivatized - MS/MS non-kit	566	0.61	0.09	0.20	0.01	0.6
Non-derivatized - MS/MS non-kit	110	0.56	0.08	0.28	0.00	0.6
Derivatized - MS/MS PE NeoGram Kit	119	0.65	0.11	0.15	0.02	0.6
Non-derivatized - MS/MS PE NeoBase Kit	488	0.59	0.05	0.08	0.00	0.6
Derivatized - MS/MS Chromsystems MassChrom Kit	99	0.57	0.09	0.25	0.00	0.6
Non-derivatized - MS/MS Chromsystems MassChrom Kit	58	0.51	0.05	0.11	0.00	0.5
Lot 1464 - Enriched 1.5 $\mu\text{mol/L}$ whole blood						
Derivatized - MS/MS non-kit	576	0.93	0.13	0.31	0.01	0.6
Non-derivatized - MS/MS non-kit	109	0.83	0.12	0.38	0.00	0.6
Derivatized - MS/MS PE NeoGram Kit	120	0.95	0.12	0.20	0.02	0.6
Non-derivatized - MS/MS PE NeoBase Kit	485	0.90	0.08	0.14	0.00	0.6
Derivatized - MS/MS Chromsystems MassChrom Kit	99	0.88	0.13	0.38	0.00	0.6
Non-derivatized - MS/MS Chromsystems MassChrom Kit	60	0.76	0.08	0.16	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.

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